

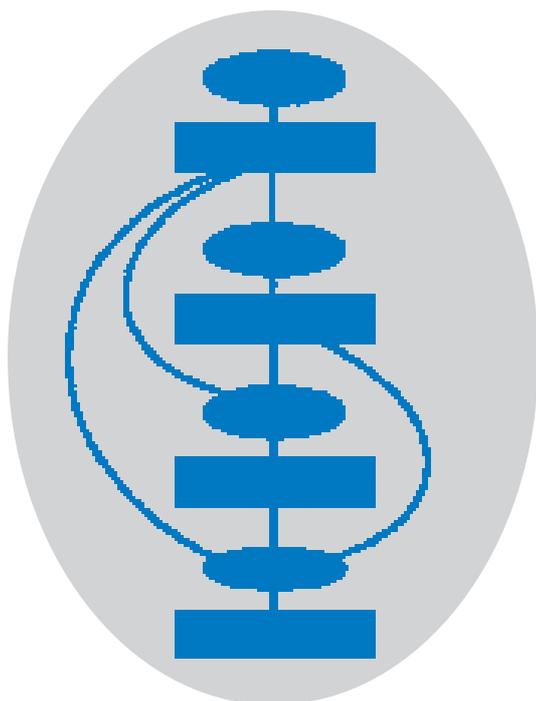




Guidance on Cancer Services

# Improving Outcomes in Colorectal Cancers

Manual Update



## Improving Outcomes in Colorectal Cancers

Cancer service guidance supports the implementation of *The NHS Cancer Plan* for England,<sup>1</sup> and the NHS Plan for Wales *Improving Health in Wales*.<sup>2</sup> The service guidance programme was initiated in 1995 to follow on from the Calman-Hine Report, *A Policy Framework for Commissioning Cancer Services*.<sup>3</sup> The focus of the cancer service guidance is to guide the commissioning of services and is therefore different from clinical practice guidelines. Health services in England and Wales have organisational arrangements in place for securing improvements in cancer services and those responsible for their operation should take this guidance into account when planning, commissioning and organising services for cancer patients. The recommendations in the guidance concentrate on aspects of services that are likely to have significant impact on health outcomes. Both the objectives and resource implications of implementing the recommendations are considered. This guidance can be used to identify gaps in local provision and to check the appropriateness of existing services.

## References

1. Department of Health (2001) *The NHS Cancer Plan*. Available from: [www.dh.gov.uk](http://www.dh.gov.uk)
2. National Assembly for Wales (2001) *Improving Health in Wales: A Plan for the NHS and its Partners*. Available from: [www.wales.gov.uk/healthplanonline/health\\_plan/content/nhsplan-e.pdf](http://www.wales.gov.uk/healthplanonline/health_plan/content/nhsplan-e.pdf)
3. *A Policy Framework for Commissioning Cancer Services: A Report by the Expert Advisory Group on Cancer to the Chief Medical Officers of England and Wales* (1995). Available from: [www.dh.gov.uk](http://www.dh.gov.uk)

### This guidance is written in the following context:

This guidance is a part of the Institute's inherited work programme. It was commissioned by the Department of Health before the Institute was formed in April 1999. The developers have worked with the Institute to ensure that the guidance has been subjected to validation and consultation with stakeholders. The recommendations are based on the research evidence that addresses clinical effectiveness and service delivery. While cost impact has been calculated for the main recommendations, formal cost-effectiveness studies have not been performed.

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Guidance on Cancer Services

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# Foreword

**Professor R A Haward,  
Chairman, National Cancer Guidance Steering Group**

When the editorial group responsible for this update first met, there was discussion about the durability of the recommendations made in the original Clinical Outcomes Group (COG) guidance, published in November 1997. How well did they stand up to scrutiny six years later? The view within the editorial group was that much of the content remains valid, although updating was needed in a few important areas where new evidence had become available.

A great deal has been done to take forward the agenda set out in 1997. Nevertheless, there was concern about the unevenness of implementation of those recommendations. The first national peer review of cancer services in 2001/2, together with the results of similar exercises around the country, suggested that progress in improving services for patients with colorectal cancer was not as far advanced in some places as it was in breast cancer services. It was therefore felt to be important to use the opportunity provided by this update to give fresh impetus to the task.

The updating process has therefore concentrated on three main tasks. The first was to breathe new life into dialogue about services for managing bowel cancer by highlighting key issues and enhancing and clarifying the original text. In refocusing attention on this topic, it was felt to be important to emphasise that implementing the colorectal guidance was not a 'done deal'. Whilst much has been achieved, much remains to be done. The expansion of the role of Cancer Networks over recent years provides an opportunity to re-examine these issues.

The second aim was to examine developments in research evidence and refine the text accordingly. The most exciting area has been the management of rectal cancer. Advances have occurred on all fronts: diagnosis, staging, surgery, evaluation of surgery, and radiotherapy. Despite the difficulties of mounting large-scale surgical trials, this has been achieved in rectal cancer, and results were available in time for this update.

The third change was expansion of the scope of the guidance, with the inclusion in this edition of anal cancer. The coverage of rarer cancers has become our usual practice in recent reports. This makes sense because the rarer cancers do not usually present as separate entities, but tend to fall within the conventional structure of clinical services for more common conditions.

The implementation of population screening for colorectal cancer in older people has not been included within this guidance, as responsibility for this lies with other national bodies. However, implementation of screening will inevitably impact on services required for symptomatic patients, which are covered by this update. We welcome national moves to co-ordinate initiatives for this disease group. All share the aim of improving outcomes for people with bowel cancer. The recommendations in this guidance are consistent with such an approach.

I am particularly grateful to Professor Bob Steele from Ninewells Hospital and Medical School at Dundee for his chairmanship of the editorial board for this update. He also played an important role in the production of the 1997 guidance when he worked in Nottingham, supporting the evidence review team at the Centre for Reviews and Dissemination.

# Note on the update format

This edition of *Improving Outcomes in Colorectal Cancers* is an updated version of the manual published by the Department of Health in 1997. This manual update covers cancers of the colon and rectum (bowel) as before, plus an additional section on anal cancer. The *Background* section is intended as a general introduction to colorectal cancer, for people who are not experts in the area; it is not based on a formal systematic review.

Material in the *Evidence* section of each topic area is derived from two different types of source: systematic reviews of research evidence carried out by the Centre for Reviews and Dissemination, and information from audit and other sources which describe the current situation in the NHS.

The reviews of research evidence are designed to provide and evaluate information on the effectiveness of specific interventions. The summaries in this document do not include references; these are given in the full review of research evidence which is published with this update, or in the review of research evidence published with the previous edition of this guidance, which is available from the Department of Health.<sup>1</sup> Evidence from the reviews is graded A (derived from randomised controlled trials - RCTs), B (observational studies) and C (professional consensus). These are broad categories and the quality of evidence within each category varies widely. Thus it should not be assumed that RCT evidence (grade A) is always more reliable than evidence from observational studies (grade B). More detailed information on the reliability of evidence is given in the review of research evidence. Information from sources which are not included in either review of research evidence is referenced in this document.

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<sup>1</sup> *Improving Outcomes in Colorectal Cancer: the Research Evidence* (1997). Available from the Department of Health publication order line on 08701 555 455, reference No. 23573.

# Key recommendations

- Action should be taken to improve recognition of potential symptoms of colorectal cancer in primary care and in the community. Efficient systems should be set up to ensure that patients who may have colorectal cancer are rapidly referred for endoscopy.
- There is an urgent need for substantial expansion of lower gastrointestinal (GI) endoscopy services. Access to both flexible sigmoidoscopy and colonoscopy should be improved and the focus of diagnostic effort should move from barium enema to endoscopy. (Note - This will be crucial for screening services when they are introduced.)
- Cancer Networks and Trusts should review the composition and function of colorectal cancer multi-disciplinary teams (MDTs) and make sure that each MDT has a co-ordinator. They should:
  - Establish systems within Trusts to ensure that *all* patients with suspected or newly diagnosed colorectal cancer are promptly referred to, and managed by, a colorectal cancer MDT.
  - Review operational links with hepatobiliary (HPB) services and the relevant clinical teams to ensure that patients with potentially resectable liver metastases are referred to specialist MDTs for assessment.
  - Identify specialist MDTs which will manage patients with anal cancer.
- Emergency patients (particularly those with intestinal obstruction) should be managed by colorectal cancer MDTs. This may require the development of emergency teams and transfers of patients between neighbouring hospitals.
- Patients with rectal cancer should be managed by teams trained in all aspects of total mesorectal excision (TME), including pre- and post-operative assessment, surgical technique, and the role of clinical oncology.

- All aspects of patient-centred care should be re-assessed in the light of recommendations in this manual update. In particular, Trusts should:
  - Improve the provision of appropriately trained staff and resources;
  - Ensure that patients receive all the information they want at all times;
  - Arrange ongoing support for patients and carers from a clinical nurse specialist who is encouraged to play an active part in MDT discussions.

# Background

## The size of the problem: incidence, mortality and survival rates

Colorectal (large bowel) cancer is the second most common cancer after lung cancer, in terms of both incidence and mortality, in England and Wales. Although prostate cancer is more common in men and breast cancer more common in women, colorectal cancer affects both sexes.<sup>2</sup> Each year, over 30,000 new cases of colorectal cancer are diagnosed, and colorectal cancer is registered as the underlying cause of death in about half this number (Table 1).

**Table 1a. Incidence and mortality rates, colorectal cancers, England<sup>3</sup>**

Cancer site	ICD 10 code	No of registrations 1999		Incidence: crude rate per 100,000 1999		No of deaths 2000		Mortality: crude rate per 100,000 2000	
		Men	Women	Men	Women	Men	Women	Men	Women
Colon	C18	8,822	9,013	35.9	35.8	4,814	4,740	19.5	18.7
Rectum	C19 & C20	6,009	3,970	24.5	16.8	2,605	1,895	10.5	7.5
Anus	C21	255	382	1.0	1.5	78	104	0.3	0.4

**Table 1b. Incidence and mortality rates, colorectal cancers, Wales<sup>4</sup>**

Cancer site	ICD 10 code	No of registrations 2000		Incidence: crude rate per 100,000 2000		No of deaths 2000		Mortality: crude rate per 100,000 2000	
		Men	Women	Men	Women	Men	Women	Men	Women
Colon	C18	652	597	45.1	39.8	378	327	26.2	21.8
Rectum	C19 & C20	449	273	32.0	18.2	155	116	10.7	7.7
Anus	C21	14	27	1.0	1.8	7	7	0.5	0.5

<sup>2</sup> Quinn M, Babb P, Brock A, Kirby L, Jones J. *Cancer trends in England and Wales 1950-1999*. London: The Stationery Office, 2001.

<sup>3</sup> Source: data on Office for National Statistics website <[www.statistics.gov.uk](http://www.statistics.gov.uk)>.

<sup>4</sup> Source: Welsh Cancer Intelligence & Surveillance Unit, data provided on request, November 2002.

The incidence of colorectal cancer is gradually increasing. One reason for this is the ageing of the population: as with most forms of cancer, the probability of developing colorectal cancer rises sharply with age. In young people, the risk is very low (except in a small minority with hereditary forms of the disease); between the ages of 45 and 55, the incidence is about 25 per 100,000. Among those aged 75 and above, however, the rate is more than 10 times this: over 300 per 100,000 per year. The median age of patients at diagnosis is over 70 years.<sup>5</sup> But population ageing is not the only reason for the overall rise. There has been a gradual increase in age-specific incidence, particularly among men between 65 and 84; and age-specific incidence rates vary across Britain; both of which suggest that lifestyle or environmental factors also contribute. These issues are discussed later in this section.

Survival rates (relative to age-matched groups without colorectal cancer) are now around 45% at five years after diagnosis; beyond five years, relative survival rates decline only slightly: most of those who live this long are cured. Survival rates in the UK have been rising steadily over the past three decades, but substantial international differences (Table 2a) suggest that in the early 1990s (the most recent period for which comparative data are available) there was considerable scope for improvement. For anal cancer, Eurocare figures are not available and meaningful comparisons between survival rates in different countries cannot be made.

The accuracy of Eurocare figures has been questioned, particularly in relation to survival rates among patients with colorectal cancer in Wales. Data from the Welsh Cancer Intelligence & Surveillance Unit show higher survival rates during this period than Eurocare suggests, and there is evidence of a marked improvement in outcomes during the 1990s (Table 2b). Nevertheless, these figures remain below the European average.

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<sup>5</sup> Incidence figures in Quinn 2001 (see footnote 2) show that the median age at diagnosis is 70-74 years.

**Table 2a. Survival rates after diagnosis of colorectal cancer (ICD-9 153-154)<sup>6</sup>**

Country	Age-standardised relative survival (%), one year after 1990-1994 diagnosis (95% confidence interval)			
	Colon		Rectum	
	Men	Women	Men	Women
England	64.9 (64.3 – 65.6)	64.2 (63.6 – 64.8)	70.5 (69.8 – 71.2)	71.8 (71.1 – 72.6)
Scotland	65.7 (64.1 – 67.2)	65.7 (64.4 – 67.1)	71.3 (69.3 – 72.3)	71.3 (69.3 – 73.4)
Wales	53.5 (51.5 – 55.7)	52.5 (50.6 – 54.5)	64.5 (62.3 – 66.9)	63.9 (61.3 – 66.6)
Europe	69.2 (68.4 – 69.9)	69.8 (69.2 – 70.5)	73.7 (72.8 – 74.5)	75.2 (74.4 – 76.1)

**Table 2b. One year relative survival for colorectal cancer in Wales, 1989-1993 and 1994-1998<sup>7</sup>**

Time-period	Age-standardised relative survival (%), one year after diagnosis (95% confidence interval)					
	Colon			Rectum		
	Men	Women	Persons	Men	Women	Persons
<b>1989-93</b>	60.6 (58.3-62.9)	59.8 (57.5-62.0)	60.2 (58.6-61.8)	68.0 (65.7-70.3)	66.8 (64.0-69.5)	67.5 (65.8-69.3)
<b>1994-98</b>	67.1 (65.1-69.1)	62.4 (60.3-64.4)	64.8 (63.3-66.2)	72.8 (70.6-74.9)	72.6 (69.8-75.2)	72.7 (71.0-74.4)

It appears that survival rates were poorer in the UK than in Europe as a whole. Scandinavia, the Netherlands, France, Germany, Italy and Switzerland all reported significantly better outcomes for colon or rectal cancer, and generally both; these differences between countries were similar to those found in previous studies (Eurocare and Eurocare-2) of survival rates among patients diagnosed in the

<sup>6</sup> Figures from the International Agency for Research on Cancer. *Survival of cancer patients in Europe: the Eurocare Study: Eurocare-3* (unpublished).

<sup>7</sup> Figures from Welsh Cancer Intelligence & Surveillance Unit, *Cancer Survival in Wales 1989-1998*.

1980s.<sup>8,9</sup> In Europe generally, the poorest outcomes were found in countries such as Poland, Estonia, Slovakia and Slovenia, which were part of the former Soviet bloc.

The contrast between Eurocare figures for other Western European countries and those for Britain was greater for colon cancer than for rectal cancer. People with colon cancer tend to develop non-specific symptoms and may present, eventually, as emergency cases with advanced disease. Most colorectal cancer emergencies (about 85%) are due to colon, not rectal, cancer; the prognosis for these patients is often very poor.

European evidence supports the view that the problem in the UK has mainly been due to late diagnosis of colon cancer, leading to high emergency rates. A detailed study of survival variations, using data on samples of patients with colorectal cancer from 11 European cancer registries, was carried out after Eurocare-2.<sup>10</sup> Most of the differences in long-term survival between countries were shown to result from differences in death-rates in the first six months after diagnosis. Death-rates were highest in places where patients were most likely to be treated as emergencies.

Further investigation revealed that in countries where patients survived longer, a higher proportion had early-stage tumours and patients were more likely to undergo elective surgery. It is clear that the major determinant of survival is disease stage, and that it is possible to achieve earlier diagnosis of colorectal cancer (and thus higher survival rates) across whole populations. High case-survival rates in European countries other than Britain are believed by some to be associated with greater use of opportunistic screening, but no research assessing the veracity of this belief has been identified.<sup>11</sup>

Socio-economic and cultural differences between countries could also play a part. There is an obvious association between patterns of affluence and survival, which can be seen both between European countries and within Britain. The reasons for this are not clear.

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<sup>8</sup> Berrino F, Sant M, Verdecchia A, *et al* (eds). *Survival of Cancer Patients in Europe: the Eurocare Study*. IARC Scientific Publications No. 132. Lyon: International Agency for Research on Cancer, 1995.

<sup>9</sup> Berrino F, Capocaccia R, Esteve J, *et al* (eds). *Survival of Cancer Patients in Europe: the Eurocare-2 Study*. IARC Scientific Publication No. 151. Lyon: International Agency for Research on Cancer, 1999.

<sup>10</sup> Gatta G, Capocaccia R, Sant M, Bell CMJ, *et al*. Understanding variations in survival for colorectal cancer in Europe: a EURO CARE high resolution study. *Gut* 2000;**47**:533-538.

<sup>11</sup> This suggestion is based on the following strands of indirect evidence:

- Fewer colonoscopies are carried out in relation to population in the UK than in the US and northern Europe. Since symptoms are likely to be similar, higher examination rates suggest opportunistic screening.
- In some European countries, e.g. Germany, screening programmes are available to the public.
- Higher endoscopy rates seem to be associated with lower mortality associated with colorectal cancer.

Within England, colorectal cancer survival rates vary significantly between health authorities.<sup>12</sup> An analysis of outcomes among patients with colon cancer diagnosed between 1993 and 1995 showed that the national five-year survival rate was 43%, but there was a marked north-south gradient. In northern areas, relative survival rates were 40% or below, whereas in the south, health authority mean rates were around 46%. There were large variations within the conurbations of London and the West Midlands, but overall survival rates in these areas were close to the national average. Outcomes were worst in north-east England (Tyneside, Northumberland and Tees), with five-year survival rates of 30% or lower, and in East London and the City, where only 25% survived for five years. By contrast, Surrey, Hampshire, Dorset and Brent achieved 51% survival rates.

For anal cancer, Eurocare figures are not available and meaningful comparisons between different countries cannot be made. Five-year survival data from the Northern and Yorkshire Cancer Registry for cases diagnosed between 1990 and 1999 showed an overall relative survival of 52.8% (CI: 48.2 to 57.2). The male rate was 44.5% (CI: 37.7 to 51.2), significantly lower than the female rate of 58.8% (CI: 52.6 to 64.5). There was evidence of improvement over time with the overall rate for 1995-9 being 55.7% (CI: 49.7 to 61.2). Clinical trials data from a British centre show that, with modern management, five-year overall survival for HIV-negative patients with localised disease and good performance status is of the order of 75%.<sup>13</sup>

## Characteristics of colorectal cancer

The large intestine, or bowel, has two main sections, the colon and the rectum. About two thirds of tumours develop in the colon and the remainder in the rectum (Figure 1). Colon cancer is equally common in men and women, but rectal cancer is more common in men.

Most tumours are adenocarcinomas which evolve from polyps – small outgrowths in the bowel wall – which may be present for 10 years or more before malignancy develops. The disease usually progresses quite slowly. Nevertheless, a substantial proportion of patients – between a third and half in most Trusts – are admitted as emergencies; overall, about 20% arrive through Accident and Emergency departments. Most of these patients have had symptoms for some weeks, and often months, before admission.

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<sup>12</sup> Office for National Statistics. Cancer survival in the health authorities of England, 1993-2000. *Health Statistics Quarterly* 2002;**13**:95-104.

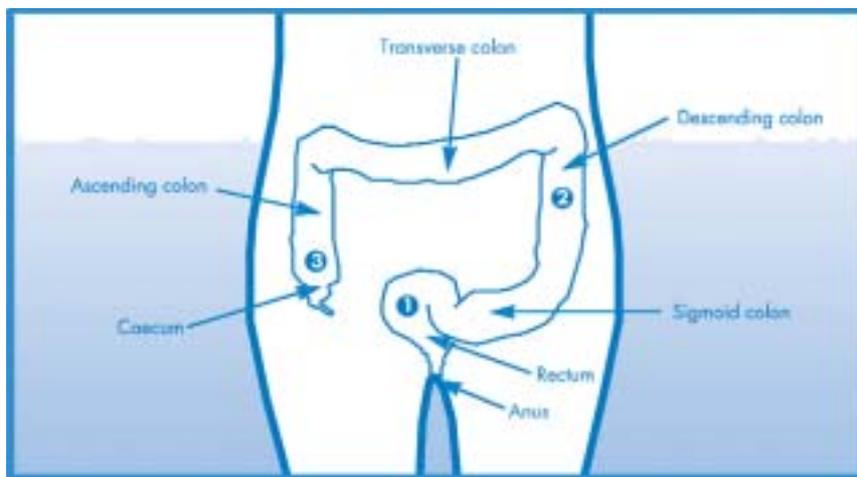
<sup>13</sup> Melcher AA, Sebag-Montefiore D. Concurrent chemoradiotherapy for squamous cell carcinoma of the anus using a shrinking field radiotherapy technique without a boost. *Br J Cancer* 2003;**88**:1352-1357.

## Diagnosis

Colorectal tumours can usually be seen directly, through an endoscope (colonoscope or sigmoidoscope). A colonoscope allows the inner surface of the whole large bowel to be seen, whilst a flexible sigmoidoscope can reach deep enough into the bowel to detect about 60% of tumours (Figure 1). These instruments can also be used to remove polyps or take samples of tissue for biopsy. Colorectal cancer can also be detected by imaging, using virtual colonoscopy or barium enema.

Diagnosis is therefore fairly straightforward – at least, in theory. The main problems are in deciding whether a particular individual should undergo investigation in the first place, and then, getting rapid access to appropriate investigations. Deficiencies both in appropriate referral and in access to diagnostic facilities in some NHS hospitals, are reflected in delays in diagnosis. In 1999/2000, over a third of patients with colorectal cancer waited more than three months after consulting their GPs with symptoms before getting their first hospital appointment.<sup>14</sup>

**Figure 1. The large intestine or bowel, and limits of endoscopic access.**



- 1 Limit of visual field of rigid sigmoidoscope
- 2 Limit of flexible sigmoidoscope
- 3 Limit of colonoscope.

<sup>14</sup> Airey C, Becher H, Erens B, Fuller E. *National Surveys of NHS Patients: Cancer - National Overview 1999/2000*. London: Department of Health, 2002.

The most common presenting symptoms and signs of cancer or large polyps are rectal bleeding, persisting change in bowel habit, and anaemia; more advanced tumours are likely to cause weight loss, nausea and anorexia, and abdominal pain. The early symptoms may not be severe and are often not clear-cut, they are common in the general population and can have a variety of other causes. In some patients, symptoms do not become apparent until the cancer is far advanced.

Although the diagnosis is most easily and reliably established by flexible sigmoidoscopy or colonoscopy, barium enema (alone or in association with rigid sigmoidoscopy) has been used in many NHS hospitals. A new form of imaging, virtual colonoscopy, is now being adopted in an increasing number of units. Computed tomography (CT) or magnetic resonance (MR) imaging is necessary to assess the extent of the tumour.

Patients survive, on average, for three years after diagnosis, but survival times vary widely. The prognosis and type and effectiveness of treatment depend largely on the degree to which the cancer has spread. Spread is often described in terms of Dukes' stage (Table 3), although the more precise TNM classification, based on the depth of tumour invasion (T), lymph node involvement (N) and metastatic spread (M), is slowly superseding Dukes' system.

Approximately 55% of patients present with advanced colorectal cancer (Dukes' stage C or D) – that is, cancer which has spread to the lymph nodes, metastasised to other organs, or is so locally invasive that surgery to remove the primary tumour alone is unlikely to be sufficient for cure (see Table 3 below).

**Table 3. Colorectal cancer staging<sup>15</sup>**

Dukes' stage (modified)	Definition	Approximate frequency at diagnosis	5-year survival
A	Cancer localised within the bowel wall	11%	83%
B	Cancer penetrating the bowel wall	35%	64%
C	Cancer in lymph nodes	26%	38%
D	Distant metastases (most often in the liver)	29%	3%

<sup>15</sup> Frequency and survival statistics based on data from 777 patients derived from St Vincent's Hospital colorectal cancer database, Dublin. (Mulcahy, 1997, personal communication.) Note that stage frequency and survival figures vary widely between published series from different centres.

# Treatment

## Colorectal cancer

Surgery to remove the primary tumour is the principal first-line treatment for approximately 80% of patients, after which about 40% will remain disease-free in the long term. In 20-30% of cases, the disease is too far advanced at initial presentation for any attempt at curative intervention; many of these patients die within a few months.

Surgical skill is crucial to outcomes, and there is evidence of wide variation between the survival rates of patients operated on by individual surgeons. Evidence showing large differences between surgeons in the outcomes they achieve was reviewed for the earlier edition of this guidance. More recent studies suggest that variations between both surgeons and institutions persist.<sup>16</sup>

Metastatic disease usually develops first in the liver. 20-25% of patients have clinically detectable liver metastases at the time of the initial diagnosis and a further 40-50% of patients develop liver metastases within three years of primary surgery.<sup>17</sup> When the metastatic deposits are confined to a limited area of the liver, expert surgery offers the possibility of long-term cancer-free survival. About 8% of patients are potential candidates for liver resection, which can be life-saving in about 35% of these cases.<sup>18</sup>

Chemotherapy is given as an adjuvant to surgery to a minority of patients, usually those whose tumour has spread to lymph nodes (Dukes' stage C), for whom the benefit of chemotherapy has been most clearly demonstrated. Adjuvant radiotherapy can be used to treat rectal cancer; again, a minority of patients receive it. Surgery, chemotherapy, or radiotherapy may also be used as part of palliative treatment for patients with advanced disease. In the Northern and Yorkshire region in 1999, 27% of patients who underwent surgery for colorectal cancer also received chemotherapy. 12% received radiotherapy in addition to surgery; almost all of these patients had rectal cancer.<sup>19</sup>

## Anal cancer

Anal cancer is a relatively rare disease (Table 1). The most common form of anal cancer, squamous cell carcinoma, is fundamentally different from other cancers of the colon or rectum. It can usually be successfully treated with concurrent radiotherapy and chemotherapy. Surgery may be used if medical treatment fails.

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<sup>16</sup> See Review of Research Evidence for Topics 3 and 5.

<sup>17</sup> Scheele J, Stangl R, Altendorf-Hofmann A. Hepatic metastases from colorectal carcinoma: impact of surgical resection on the natural history. *Br J Surg* 1990;**77**:1241-1246.

<sup>18</sup> McArdle C. ABC of colorectal cancer: Effectiveness of follow up. *BMJ* 2000;**321**:1332-1335.

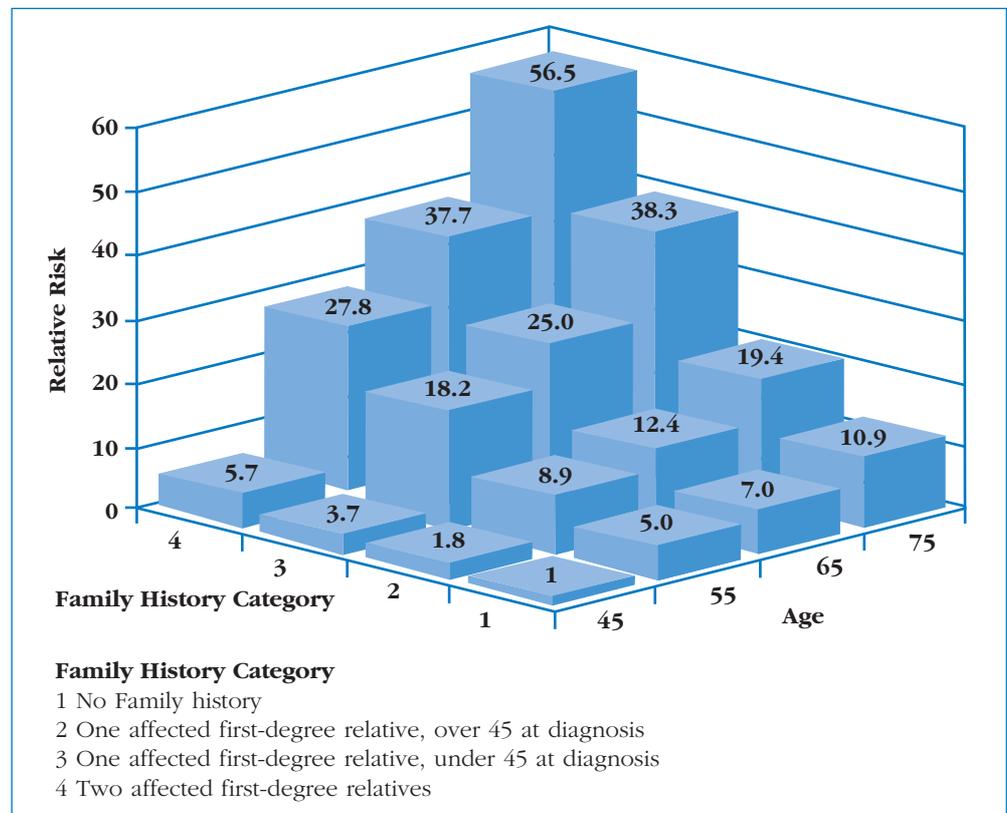
<sup>19</sup> Northern and Yorkshire Cancer Registry and Information Service. *Northern and Yorkshire Cancer Networks: A report on incidence and management for the main sites of cancer, 1999*. Leeds: NYCRIS, 2002.

## Populations at increased risk of colorectal cancer

Colorectal cancer is more common in close relatives of those who have been diagnosed with the disease (a family history) than in the general population. There are two specific genetic syndromes which cause colorectal cancer, FAP (familial adenomatous polyposis) and HNPCC (hereditary non-polyposis colorectal cancer), but clusters of cases also occur in families without either of these.

Meta-analysis of data from 27 studies shows that, for people with at least one affected first-degree relative (parent, child or sibling), the risk of having a diagnosis of colorectal cancer is more than double that for the general population (relative risk 2.25, 95% CI: 2.00 to 2.53).<sup>20</sup> When more than one first-degree relative is affected, the risk is substantially higher – especially when there is a family history of colon, rather than rectal, cancer; and the younger the age at diagnosis, the greater the risk for relatives. A similar pattern of increased risk among family members is found with adenomas. Figure 2, below, shows how an individual's family history and age jointly affect the risk of colorectal cancer.

**Figure 2.<sup>21</sup> Risk of colorectal cancer by age and family history (relative to risk in 45 year olds with no family history)**



<sup>20</sup> Johns LE, Houlston RS. A systematic review and meta-analysis of familial colorectal cancer risk. *American Journal of Gastroenterology* 2001;**96**:2992-3003.

<sup>21</sup> Diagram constructed by Tim Bishop and Arabella Melville for the 1997 edition of this guidance, using figures calculated by Bishop from unpublished data from St John; see research evidence for 1997 edition for further details.

Around 5% of patients with colorectal cancer have identified genetic syndromes known to confer very high risk. People with FAP develop hundreds of polyps in the colon; by the age of 40, most will have cancer unless they have surgery to remove the colon. People with HNPCC also develop colorectal cancer at an early age, but it is less often preceded by the growth of multiple polyps. Genetic testing can identify gene carriers in members of affected families.

Colitis due to inflammatory bowel disease is also associated with increased risk of colorectal cancer and the risk rises with the duration of the condition. Patients who have had ulcerative colitis for 10 years or more face two to eight times the usual level of risk for their age. Such patients account for fewer than 1% of cases of colorectal cancer.<sup>22</sup> However, around 75% of patients have neither a clear family history nor any condition known to predispose them to developing colorectal cancer.

## Prevention, surveillance and screening (cancers of the colon or rectum)

There are reasons to believe that many deaths from colorectal cancer could be prevented. The various strands of the argument are given below; each suggests a different form of intervention, but all are complementary.

- Associations between a range of aspects of lifestyle and colorectal cancer are strong and age-standardised incidence rates vary widely between populations, from fewer than two per 100,000 in parts of India and Africa to 55 per 100,000 among men in New Zealand. Overall, colorectal cancer rates are four times as high in more affluent (developed) countries than in less developed countries.<sup>23</sup> This suggests that lifestyle and socio-economic circumstances have a major effect on risk. Although the effectiveness of lifestyle interventions for the reduction of colorectal cancer has not yet been demonstrated in randomised trials, the type of lifestyle that is associated with relatively low rates of colorectal cancer (see below) is known to be generally beneficial for health.
- Polyps can be seen and removed by endoscopy before they become malignant. This means that screening really can prevent this form of cancer.

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<sup>22</sup> Hardy RG, Meltzer SJ, Jankowski JA. Molecular basis for risk factors. In: Kerr DJ, Young AM, Hobbs FDR (eds). *ABC of colorectal cancer*. London: BMJ Books, 2001.

<sup>23</sup> Ferlay J, Bray F, Pisani P, Parkin DM. *GLOBOCAN 2000: Cancer Incidence, Mortality and Prevalence Worldwide, Version 1.0*. IARC CancerBase No. 5. Lyon: International Agency for Research on Cancer Press, 2001.

- Some polyps and early tumours bleed, so their presence can be detected by alert patients, by testing the faeces for blood, or by adequate investigation of iron-deficiency anaemia.
- The disease tends to develop slowly. Resection of early disease usually eliminates it completely, so appropriate action in response to early symptoms can prevent further spread.

These features of colorectal cancer suggest that educational and screening initiatives, designed both to reduce the incidence of the disease and to increase the probability of early diagnosis, could prevent a substantial proportion of deaths.

## **Lifestyle**

It has been suggested that about three quarters of cases of colorectal cancer may be associated with lifestyle and are therefore theoretically avoidable.<sup>24</sup> It is not always clear whether the lifestyle factors identified below act independently on risk, since some are associated with each other (e.g. high consumption of processed meat, low consumption of vegetables, and smoking) and with obesity, which is also linked with higher rates of colorectal cancer.

Lower risk has been convincingly linked with the following aspects of lifestyle:

- Infrequent consumption of meat. A meta-analysis of prospective observational studies found that an increase of 100g of meat eaten each day was associated with a significant 12-17% increase in risk of colorectal cancer. Processed meat (including sausage, ham, bacon and burgers) was linked with substantially greater risk: each 25g consumed per day increased risk by 49%.<sup>25</sup>
- Matching calorie consumption to need. It has been widely believed that dietary fat increases risk, because fat accounts for a much higher proportion of overall calorie intake in Western countries with higher incidence levels than in low-risk populations. However, detailed analysis of epidemiological evidence shows that the overall proportion of fat in the diet is not significant; what matters is total calorie intake and body mass index. Leaner people are less likely to develop colorectal cancer. There is a consistent – albeit weak – association between dietary cholesterol and colorectal cancer, which may be a marker for specific foods such as red meat and eggs.<sup>26</sup>

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<sup>24</sup> Boyle P, Langman JS. Epidemiology. In: Kerr DJ, Young AM, Hobbs FDR (eds). *ABC of colorectal cancer*. London: BMJ Books, 2001.

<sup>25</sup> Sandhu MS, White IR, McPherson K. Systematic review of the prospective cohort studies on meat consumption and colorectal cancer risk: a meta-analytical approach. *Cancer Epidemiology, Biomarkers and Prevention* 2001;**10**:439-446.

<sup>26</sup> Howe GR, Aronson KJ, Benito E, Castelletto R, *et al.* The relationship between dietary fat intake and risk of colorectal cancer: evidence from the combined analysis of 13 case-control studies. *Cancer Causes and Control* 1997;**8**:215-228.

- An active lifestyle. Most studies show an inverse relationship between risk of colon cancer and physical activity; moderately demanding exercise, such as regular brisk walking, can reduce risk by 40 to 50%.<sup>27</sup> Active people are also less likely to become obese or to have high waist-to-hip ratios, both of which are associated with higher rates of colorectal cancer.<sup>28,29</sup>
- Not smoking. Long-term heavy smokers have two to three times the risk of developing colorectal adenoma, but it may be three or four decades before clinical colorectal cancer becomes apparent. It has been estimated that up to 20% of colorectal cancers in the US could be due to smoking.<sup>30</sup> The weak association that has been observed between alcohol consumption and colorectal cancer could be due to confounding with smoking, since studies that demonstrated this did not control for smoking, which was not believed to be relevant to colorectal cancer.<sup>31</sup>
- Frequent consumption of vegetables and possibly fruit.<sup>32</sup> The evidence on this seems somewhat inconsistent; most studies show significantly higher risk in people who rarely eat vegetables but others do not.<sup>33</sup> However, if energy-dense foods are replaced with low-calorie vegetable dishes, this will tend to reduce total energy intake, thus reducing risk.

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<sup>27</sup> Boyle P, Leon ME. Epidemiology of colorectal cancer. *Brit Med Bull* 2002;**64**:1-25.

<sup>28</sup> Thune I, Lund E. Physical activity and risk of colorectal cancer in men and women. *Br J Cancer* 1996;**73**:1134-1140.

<sup>29</sup> Martinez ME, Giovannucci E, Spiegelman D, Hunter DJ, *et al.* Leisure-time physical activity, body size, and colon cancer in women. *J Nat Cancer Inst* 1997;**89**:948-955.

<sup>30</sup> Giovannucci E. An updated review of the epidemiological evidence that cigarette smoking increases risk of colorectal cancer. *Cancer Epidemiology, Biomarkers and Prevention* 2001;**10**:725-731.

<sup>31</sup> Longnecker MP, Orza MJ, Adams ME, Vioque J, *et al.* A meta-analysis of alcoholic beverage consumption in relation to risk of colorectal cancer. *Cancer Causes Control* 1990;**1**:59-68.

<sup>32</sup> World Cancer Research Fund. *Food, nutrition and the prevention of cancer: a global perspective*. Washington, DC: WCRF, 1997.

<sup>33</sup> Steinmetz KA, Potter JD. Vegetables, fruit and cancer. I. Epidemiology. *Cancer Causes Control* 1991;**2**:325-357.

- A high-fibre diet. A well-controlled prospective multi-centre European study (EPIC) which followed 519,978 people over 1,939,011 person-years, found that the quantity of fibre in the diet was inversely related to the incidence of colorectal cancer. Incidence rates in the 20% of participants who consumed the most fibre (32g per day) were about 40% lower than in the 20% who consumed the least (13g per day) (adjusted relative risk, 0.58).<sup>34</sup> A second recent study, of 45,000 older women in the US, found no such protective effect; however, over 80% of these women would have fallen into the lowest fibre intake group of the EPIC study, so this cannot be regarded as evidence against the possible protective effects of a high fibre diet.<sup>35</sup> One study of patients with histories of adenomas and high dietary calcium intake, reported increased adenoma formation in those who took supplements of fibre (ispaghula husk).<sup>36</sup>

### **Nutritional supplements and medication**

Long-term use of particular nutritional supplements and specific types of drugs has been linked with reduced incidence of colorectal cancer. These include:

- Vitamin supplements containing folic acid. The Nurses' Health Study found that folic acid in green vegetables was associated with a modest reduction in risk of colon cancer, but the effect of supplementation was much greater and increased over time. After 15 years, the incidence of colon cancer in those who regularly took folic acid was *less than one quarter* of that among those who did not (15 versus 68 new cases per 10,000 women, 55 to 69 years old). Other studies have also shown inverse associations between folate intake and colon cancer.<sup>37</sup>
- Selenium. Low selenium intake (reflected in low serum selenium levels) is associated with higher rates of colon cancer.<sup>38</sup> A randomised controlled trial (RCT) assessing the effectiveness of 200µg selenium daily in patients with a history of skin cancer found that the total number of cancer deaths was halved by just 4.5 years of selenium supplementation (29 cancer deaths in the

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<sup>34</sup> Bingham SA, Day NE, Luben R, Ferrari P, *et al.* Dietary fibre in food and protection against colorectal cancer in the European Prospective Investigation into Cancer and Nutrition (EPIC): an observational study. *Lancet* 2003;**361**:1496-1501.

<sup>35</sup> Mai V, Flood A, Peters U, Lacey JV, *et al.* Dietary fibre and risk of colorectal cancer in the Breast Cancer Detection Demonstration Project (BCDDP) follow-up cohort. *Int J Epidemiol* 2003;**32**:234-239.

<sup>36</sup> Bonithon-Kopp C, Kronberg O, Giacosa A, Rath U, *et al.* Calcium and fibre supplementation in prevention of colorectal adenoma recurrence: a randomised intervention trial. *Lancet* 2000;**356**:1300-1306.

<sup>37</sup> Giovannucci E, Stampfer MJ, Colditz GA, Hunter D, *et al.* Multivitamin use, folate and colon cancer in women in the Nurses' Health Study. *Annals of Internal Medicine* 1998;**129**:517-524.

<sup>38</sup> Virtamo J, Valkeila E, Alfthan G, Punsä S, *et al.* Serum selenium and risk of cancer: a prospective follow-up of nine years. *Cancer* 1987;**60**:145-148.

treatment group, compared with 57 in controls; relative risk 0.50, 95% CI: 0.31 to 0.80); the incidence rates for colorectal, lung and prostate cancers all fell.<sup>39</sup>

- Calcium. Epidemiological data and three published RCTs suggest that calcium supplementation can reduce the risk of adenoma formation in patients with histories of polyps. The benefit (over a period of three years) seems to be fairly small but calcium supplements do not produce any significant adverse effects.<sup>40</sup>
- Regular use of non-steroidal anti-inflammatory drugs (NSAIDs), notably aspirin, seems to reduce the risk of colorectal cancer. Three recent prospective randomised trials have shown that aspirin reduces the frequency of new colorectal polyps in high-risk groups.<sup>41</sup> Epidemiological studies have found about 30% fewer cases of colorectal cancer among regular users of aspirin, and the NSAID sulindac has been shown to reduce the size and number of polyps in people with familial polyposis.<sup>42</sup>
- Hormone replacement therapy appears to offer protection to women, particularly from colon cancer; five to 10 years' use halves the risk.<sup>43</sup> However, this benefit is balanced by an increased risk of breast cancer and coronary heart disease.

## Screening and polyp removal

Most colorectal cancers result from malignant changes in polyps (adenomas) that developed at least a decade earlier. Polyps can be seen and removed during endoscopic examination of the bowel; 90% of adenomas can be seen and removed during colonoscopy and about 70% during flexible sigmoidoscopy, which is a quicker and generally less difficult procedure and therefore more appropriate for people who are not at especially high risk of colorectal cancer. Sigmoidoscopy has been shown to be an effective method of reducing cancers of the rectum and proximal (descending and sigmoid) colon. Initial results have now been published from a multi-centre Medical Research Council (MRC) trial of screening with flexible

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<sup>39</sup> Clark LC, Combs GF, Turnbull BW, Slate EH, Chalker DK, *et al.* Effects of selenium supplementation for cancer prevention in patients with carcinoma of the skin. *JAMA* 1996;**276**:1957-1963.

<sup>40</sup> Baron JA, Beach M, Mandel JS, van Stolk, *et al.* Calcium supplements and colorectal adenomas. *Ann NY Acad Sci* 1999;**889**:138-145; Hofstad B, Almeddingen K, Vatn M, Andersen SN, *et al.* Growth and recurrence of colorectal polyps: a double-blind 3 year intervention with calcium and antioxidants. *Digestion* 1998;**59**:148-156; Bonithon-Kopp C, Kronberg O, Giacosa A, Rath U, *et al.* Calcium and fibre supplementation in prevention of colorectal adenoma recurrence: a randomised intervention trial. *Lancet* 2000;**356**:1300-1306.

<sup>41</sup> Dyer O. Aspirin could be used to prevent cancer (News). *BMJ* 2003;**326**:565.

<sup>42</sup> Information from the US National Cancer Institute website <[www.cancer.gov/cancerinfo/pdq/prevention/colorectal/healthprofessional/](http://www.cancer.gov/cancerinfo/pdq/prevention/colorectal/healthprofessional/)>.

<sup>43</sup> Boyle P, Leon ME. Epidemiology of colorectal cancer. *Brit Med Bull* 2002;**64**:1-25.

sigmoidoscopy of people aged 55-65, followed by colonoscopy in those considered to be at high risk. Cancers were found in 0.3% of those screened, 74% of which were Dukes' stage A or B, and adenomas were detected in 12%. The authors conclude that this screening regimen is acceptable, feasible and safe.<sup>44</sup>

Both cancers and large polyps (adenomas) may bleed; the quantity may be too small to be visible in the stools but it can often be detected by more sensitive tests for faecal occult blood (FOB). This is the rationale for screening by faecal occult blood testing, followed by endoscopy (flexible sigmoidoscopy or colonoscopy) if the result is positive. Meta-analysis of four randomised controlled trials has shown that screening by FOB testing reduced the risk of death from colorectal cancer by 16% overall, and by 23% (RR 0.77, 95% CI: 0.57 to 0.89) in those who were actually screened.<sup>45</sup>

Although population screening in older age-groups is now known to be effective, screening is not thought generally appropriate for people in younger age-groups (under 50 years), among whom the risk of colorectal cancer is low. It is anticipated that some form of screening will be introduced in the NHS.

### **Anal cancer: causes and risk factors**

The most common cause of anal cancer appears to be sexually transmitted infection with the human papillomavirus (HPV) – the virus which is also thought to be responsible for cervical cancer.<sup>46</sup> Known risk factors include immunosuppression, usually due to HIV infection or immunosuppressive drugs; taking the receptive role in unprotected anal intercourse; and longstanding problems in the anal area, such as fistulas (abnormal openings). Smoking also increases risk, with a particularly strong relationship between the number of cigarettes smoked and the risk of anal cancer among pre-menopausal women.<sup>47</sup>

For most people, the risk of anal cancer is low (Table 1). Members of groups in which the prevalence is greater, such as gay men, can reduce their risk by not smoking and not engaging in unprotected anal intercourse.

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<sup>44</sup> UK Flexible Sigmoidoscopy Screening Trial Investigators. Single flexible sigmoidoscopy screening to prevent colorectal cancer: baseline findings of a UK multicentre randomised trial. *Lancet* 2002;**359**:1291-1300.

<sup>45</sup> Towler B, Irwig L, Glasziou P, *et al.* A systematic review of the effects of screening for colorectal cancer using the faecal occult blood test, Haemoccult. *BMJ* 1998;**317**:559-565.

<sup>46</sup> Frisch M, Glimelius B, van den Brule AJC, Fenger C, *et al.* Sexually transmitted infection as a cause of anal cancer. *New Engl J Med* 1997;**337**:1350-1358.

<sup>47</sup> Frisch M, Glimelius B, Wohlfahrt J, Adami HO, *et al.* Tobacco smoking as a risk factor in anal carcinoma: an antiestrogenic mechanism? *J Natl Cancer Inst* 1999;**91**:708-715.

## The NHS Bowel Cancer Programme

The NHS Bowel Cancer Programme was launched in February 2003 to reduce deaths from colorectal cancer. This programme has three main strands: the development of a national screening programme, streamlining care for symptomatic patients, and improving treatment. This will be underpinned by expansion and modernisation of endoscopy services and a communications strategy for patients and professionals.

# Patient-centred care

## 1

Supportive and palliative care guidance is due to be published by the National Institute for Clinical Excellence (NICE) in mid 2004. This is intended to complement site-specific guidance, giving detailed and specific recommendations on many of the issues introduced in this section as they apply to cancer care generally. It deals with the following topic areas:

1. Co-ordination of care
2. User involvement in planning, delivering and evaluating services
3. Face-to-face communication
4. Information
5. Psychological support services
6. Social support services
7. Spiritual support services
8. General palliative care services, incorporating care of dying patients
9. Specialist palliative care services
10. Rehabilitation services
11. Complementary therapy services
12. Services for families and carers, incorporating bereavement care
13. Research in supportive and palliative care: current evidence and recommendations for direction and design of future research.

## A. Recommendations

### **Clear information**

Clear, accurate and accessible information is important, for people at high risk of colorectal cancer and patients with cancer, and to their carers. Cancer Networks and Trusts should provide information in appropriate formats for patients and carers about diagnostic tests and about the nature and treatment of their colorectal cancer. This should include details of further sources of information and support. Relevant information should be offered to patients at the time when it is likely to be most helpful: before the first hospital appointment for initial diagnostic procedures; when the diagnosis is discussed with the patient; when decisions are being made about further investigation or treatment; and before any particular form of treatment begins.

There should be systems for rapid and efficient communication between primary and secondary care, to ensure that GPs receive crucial information as quickly as possible.

Clinicians should give patients all the information they want and encourage them to become involved in decision-making to the degree that they wish; and they should specifically ask each patient if there is anything else he or she wants to know. Information offered should include information about the disease, diagnostic procedures, treatment options and their effects (including potential adverse effects) and as far as possible, a realistic assessment of predicted outcome. After primary treatment, patients should be offered a candid assessment of the success of the treatment. Copies of letters to GPs should be given to patients.

Those who give this information should be sensitive to the patient's concerns, preconceptions, preferences and reactions. They should be aware that patients may need time to absorb all the relevant information and that they are likely to have additional questions after the consultation. They should ensure that patients know where they can find information and support between hospital appointments. Clinical staff should ask patients how much they want to know about specific aspects of their disease and management at any particular time, and always give patients' views precedence over those of their relatives or carers.

Patients should have access to individual support and guidance from a member of the specialist colorectal cancer team when required. They should also be given information about sources of social support and practical help, such as local support groups and disability and benefits helplines; again, this should be provided both orally and in writing.

All members of the team whose roles involve face-to-face interaction with patients share responsibility for ensuring that their patients understand what is happening to them and about any forms of intervention that are being considered. Clinical nurse specialists (CNSs) have particularly important roles in checking that patients do receive all the information that they want, that they understand the information they have been given, and that they receive answers to any additional questions they may have.

Members of the colorectal cancer team - including senior clinicians who break the news to patients that they have cancer - should have training in communication skills. They need to be aware that patients often find it difficult to take in information given during the “bad news” consultation. Patients should be given adequate time to reflect and get answers to their questions before decisions are made about treatment. Consideration should be given to tape-recording consultations (with the patient’s consent) and offering the tape to patients to take home.

### **Psychosocial support and continuity of care**

Every patient should have access to psychosocial support from a CNS who has had specific training in counselling patients with colorectal cancer and who can offer continuity of care. Patients and their carers should be given a contact telephone number for this nurse so that they can talk to her or him if they have problems or concerns after discharge from hospital.

The condition may be embarrassing and distressing for patients, with taboos about body function and anxiety about continence and odour compounding fears about cancer. Around one fifth of patients are aged over 80 and this group, in particular, are likely to need practical help (particularly from CNSs, other allied health professionals, and community care services) with coping with the consequences of their disease.

Psychosocial support is also important for carers looking after patients with advanced colorectal cancer at home. The primary and palliative care teams have important roles in ensuring that the needs of both patients and carers are identified and met.

### **Patients with stomas**

Patients who may require stomas - whether temporary or permanent - should be counselled before surgery by a CNS (either a colorectal cancer CNS who has expertise in stoma care, or a stoma specialist) on the position and implications of a stoma. After surgery, the same nurse should be available to assist patients in managing the stoma and to advise for as long as required on physical, social, sexual and emotional problems associated with the stoma. Patients with stomas should have access to specialist dietary support and advice. If they wish, patients who are expected to require, or have received, stomas,

should be introduced to others who have stomas and given contact details for local support groups and national patient associations.

## B. Anticipated benefits

Information and support are highly valued. Most people with cancer want to understand what is happening to them and want to know about their prognosis; and there is considerable research evidence showing that better informed patients tend to suffer less anxiety and look after themselves better. Patients particularly value sensitive communication of the cancer diagnosis, which, for most, has an intense emotional impact.

## C. Evidence

Note: the reliability and quality of evidence supporting the recommendations is graded as A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

### **Patient-centred care in the NHS**

A national survey of patients' experience, which included 15,891 patients with colorectal cancer, revealed considerable scope for improvement in services.<sup>48</sup> Although almost all patients were told of their diagnosis in person by a hospital doctor, only 27% were then given written information about their condition or the treatment they might receive.

Most patients (83%) said they understood the diagnosis but 28% did not understand the purpose of tests and 35% did not understand explanations about different types of treatment. This level of information provision and understanding is lower than that reported by patients with breast cancer. At the time of first treatment, however, 95% of patients found the doctors' explanations very or fairly easy to understand; just 2% reported that no explanation was given.

Explanations given by nurses at some Trusts were not so clear. 35% of nurses' answers to patients' questions at the worst Trusts were not understood all or most of the time. This suggests deficiencies in nurses' training in communication at these Trusts, which could reflect a lack of suitably trained CNSs (see below); 42% of patients did not know the name of the nurse in overall charge of their care. There were also problems with information about possible side effects of treatment: 40% of patients reported that these had not been adequately explained.

<sup>48</sup> Airey C, Becher H, Erens B, Fuller E. *National Surveys of NHS Patients: Cancer - National Overview 1999/2000*. London: Department of Health, 2002.

There was wide variability between Trusts in patients' sense that they were treated with respect and dignity. At the best performing Trust, 6% reported deficiencies in this aspect of care, compared with 38% of patients at the worst. 38% of patients at the worst performing Trust reported that staff talked about them as though they were not there. A similar proportion (34%) felt that hospital staff did not do all they could to help with their pain; at the best, this figure was 7%.

After their first treatment, 19% of patients overall reported that hospital staff had not spent enough time talking to them about what would happen to them after they left hospital. Only 56% said they had been given written information and 51% were told of support or self-help groups.

A study by the Commission for Health Improvement/Audit Commission provides further information on patient-centred care in NHS hospitals in 2000/1. This reports that 28% of Trusts visited did not have a CNS for colorectal cancer and that 40% of CNSs felt that they were not able to give sufficient time to patients with colorectal cancer. Less than 40% of Trusts had assessed patients' views of the services they provided, and 90% of lead consultants had had no specific training in breaking bad news to patients.

### **Psychosocial support**

Colorectal surgery can adversely affect several aspects of well-being in the period after treatment. After discharge from hospital, patients report problems with mobility, bowel function, fatigue, pain, nutrition, anxiety and the wound.(B: see evidence review for 1997 edition of this document.)

### **Patients with stomas**

A review of cross-sectional studies comparing patients with stomas and those without suggested that stomas are associated with impaired social and sexual functioning. Emotional problems including depression and loneliness were found to be significantly more prevalent among patients with stomas, affecting as many as half in some studies. Body image problems were found in two-thirds of patients with stomas, again significantly more often than in patients without. Patients with stomas were also more likely to report worsening relationships with partners, decreased ability to work and greater limitations on social activities.(B: see evidence review for 1997 edition of this document.)

## D. Measurement

### Structure

- Providers should be able to demonstrate that appropriate and adequate oral and written information about colorectal cancer in general and the patient's own situation and options is given to every patient.
- Providers should be able to demonstrate that services designed to meet the psychosocial needs of patients are available.

### Process

- There should be evidence that patients receive oral and written information and support from suitably trained staff, and are informed about other reliable sources of information and support.
- Training for consultants in communication, breaking bad news, discussing prognosis and end of life issues.

### Outcome

- Surveys of patients should be carried out by providers to assess the adequacy of each component of patient-centred care.

## E. Resource implications

Resources may be required to allow sufficient staff time for provision of psychosocial, practical and educational support for patients, and for training in communication skills for medical and surgical staff.

Additional resources are required to fund training and employment of adequate numbers of CNSs for colorectal cancer.

# Access to appropriate services

## A. Recommendations

Improving access to appropriate services is crucial to reducing colorectal cancer mortality, and should be given priority by all levels of the service – primary care, hospital Trusts, and Cancer Networks. Delays in diagnosis can be reduced by streamlining referral systems and improving access to endoscopy. The introduction of a national colorectal cancer screening programme, to which the Department of Health is now committed, will require that improvements have been achieved in these aspects of the service. A specific strategy for the expansion and modernisation of endoscopy services is being developed.

Cancer Networks should review referral systems and ensure that all those who are likely to refer patients with colorectal cancer, particularly GPs, geriatricians and haematologists, are aware of local referral guidelines. A referral proforma for suspected colorectal cancer should be developed by the Network and distributed to GPs and Trusts throughout the Network. Each Trust should have a central system (either a computer link or a fax/telephone number) specifically for rapid and efficient referral of patients with possible or suspected colorectal cancer to a designated diagnostic service managed by the colorectal cancer multi-disciplinary team (MDT). Such patients should not be referred initially either to individual clinicians or to radiology services for barium enema.

### **Urgent referral guidelines**

The Department of Health has published the following criteria for referral within two weeks.<sup>49</sup> These are currently being revised and new guidelines are scheduled for publication in 2005.

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<sup>49</sup> Available on the Department of Health website <[www.dh.gov.uk](http://www.dh.gov.uk)>.

**Table 4. Criteria for urgent referral**

Sign, symptom or combination	Age threshold
<ul style="list-style-type: none"> <li>Rectal bleeding WITH a change in bowel habit to looser stools and/or increased frequency of defecation, persistent for six weeks.</li> </ul>	All ages
<ul style="list-style-type: none"> <li>A definite palpable right-sided abdominal mass.</li> </ul>	All ages
<ul style="list-style-type: none"> <li>A definite palpable rectal (not pelvic) mass.</li> </ul>	All ages
<ul style="list-style-type: none"> <li>Rectal bleeding persistently WITHOUT anal symptoms*.</li> </ul>	Over 60 years <sup>†</sup>
<ul style="list-style-type: none"> <li>Change of bowel habit to looser stools and/or increased frequency of defecation, WITHOUT rectal bleeding and persistent for six weeks.</li> </ul>	Over 60 years <sup>†</sup>
<ul style="list-style-type: none"> <li>Iron deficiency anaemia without an obvious cause (Hb &lt; 11g/dl in men or &lt; 10g/dl in postmenopausal women).</li> </ul>	<i>no age criterion</i>

\* Anal symptoms include soreness, discomfort, itching, lumps, prolapse and pain.

<sup>†</sup> 60 years is considered to be a maximum age threshold. Local Cancer Networks may elect to set a lower age threshold (e.g. 55 years or 50 years).

80-85% of patients with bowel cancer have these symptoms at the time of diagnosis, but only about one third of patients come through the fast-track route. When these symptom and sign combinations occur *for the first time* in any patient, he or she should be referred to a colorectal cancer diagnostic service as an urgent case under the two week standard.

Patients with the following symptoms and no abdominal or rectal mass are at low risk of cancer:

- Rectal bleeding with anal symptoms.
- Change in bowel habit to decreased frequency of defecation and harder stools.
- Abdominal pain without clear evidence of intestinal obstruction.

### **Prompt recognition of warning signs and symptoms, and appropriate action**

GPs should carefully establish whether the patient's signs or symptoms fulfil the criteria for urgent referral for suspected colorectal cancer, and act accordingly. Because colorectal cancer is both relatively common and curable if treated early, it is important that the possibility of cancer should be considered early in the diagnostic process, particularly by GPs, but also by elderly medicine physicians, haematologists, and others who may see these patients.

Symptoms other than those in the list above, which should also prompt referral for endoscopy, include faecal incontinence and passing mucus via the rectum. Colonoscopy (or flexible sigmoidoscopy plus barium enema, if patients find colonoscopy unacceptable) should be used when symptoms suggest possible cancer of the right or transverse colon.

Patients with iron-deficiency anaemia (apart from menstruating women) should be referred for colonoscopy (see Topic 4, *Diagnosis*). People over the age of 50 with rectal bleeding of recent onset or other suspicious symptoms should have rectal examination and flexible sigmoidoscopy or colonoscopy; their symptoms should not be attributed to haemorrhoids until the possibility of colorectal cancer or adenomatous polyps has been excluded. GPs should be alert to the possibility that colorectal cancer can co-exist with haemorrhoids. It is important that investigations for bowel symptoms or anaemia should continue until the cause is found. The threshold for referral for investigation should be reduced if other members of the patient's family have had a diagnosis of colorectal cancer.

GPs and practice nurses should take opportunities to discuss bowel problems with patients who, because of their age, lifestyle or family history might be at risk of developing colorectal cancer, and should explain to such patients how they might reduce their level of risk. They should describe the symptoms of colorectal cancer and emphasise its curability when treated early. Primary care staff should routinely offer lifestyle guidance, encouraging and assisting patients to give up smoking, take regular exercise, minimise their consumption of processed meat, eat more vegetables and lose weight; this will tend to reduce the risk of a wide range of diseases including colorectal cancer (see *Background: Prevention, surveillance and screening (cancers of the colon or rectum)*).

GPs should not refer patients with suspected colorectal cancer to a specific clinician (as opposed to a diagnostic clinic) who is not a core member of a colorectal cancer multi-disciplinary team (see Topic 3, *Multi-disciplinary teams*).

### **Access to endoscopy**<sup>50</sup>

Endoscopy services throughout England and Wales need to be expanded and improved; this should be recognised as an urgent priority by all Networks and Trusts. The NHS Modernisation Agency's endoscopy programme has demonstrated scope for service improvement through streamlining care. This approach should be extended to all endoscopy services in England and Wales. It is also clear that greater endoscopy capacity is required for diagnosis and

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<sup>50</sup> In this document, endoscopy refers to any method used to examine the inside of the bowel. Colonoscopy and sigmoidoscopy are forms of endoscopy which allow examination of the whole bowel and the lower part of it, respectively (Figure 1, p.13).

management of symptomatic disease, and will be essential when screening programmes are implemented. High quality training programmes need to be established to meet this demand.

All patients with symptoms that could be due to colorectal cancer, particularly rectal bleeding or a recently-established change to looser and/or more frequent motions, should have rapid access to colonoscopy or flexible sigmoidoscopy and any further procedures that may be necessary to reach a diagnosis (see Topic 4, *Diagnosis*). Networks will need to monitor waiting time to endoscopy, to achieve the target of two months from urgent referral by a GP to treatment, which will become national policy in 2005. It is unlikely that this target will be achieved unless colonoscopy waiting times are less than four weeks.

Trusts should consider establishing open-access (possibly qualified by criteria such as the patient's age) endoscopy clinics;<sup>51</sup> these may be led by any appropriately trained individuals, including specialist nurses and GPs. All those who carry out endoscopy should be able to demonstrate that they have adequate training and should audit their results. Endoscopy staff should use check-lists to ensure that each patient's history and endoscopy findings are accurately recorded.

### **Patients with non-specific symptoms**

The most common non-specific symptoms of colorectal cancer - for example, tiredness - are due to iron-deficiency anaemia caused by undetected blood loss, particularly in older men or post-menopausal women; patients with bowel polyps or cancer may have no other symptoms. Trusts should agree specific local guidelines which ensure that such patients are referred promptly to the endoscopy service.

### **Emergency admissions**

Patients who present as emergencies with large bowel obstruction or other symptoms likely to be caused by colorectal cancer should be assessed and managed by members of a colorectal cancer MDT. If no such MDT is available at the hospital to which patients are initially admitted, transfer to a neighbouring hospital which has emergency access to an appropriate MDT, should be considered. This applies to patients admitted at night or during weekends, as well as those who are admitted during normal working hours.

Inevitably, colorectal cancer MDT members will not be available to provide initial care for a small proportion of patients who present as emergencies, particularly those with peritonitis. The management of such patients should be passed to the appropriate MDT following diagnosis. A policy should be agreed by each Trust which links the colorectal cancer MDT with this form of triage system.

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<sup>51</sup> Open access should be taken to mean direct referral by GPs, rather than through consultants or other indirect routes.

GPs and others who may deal with such patients should be informed about which local hospitals offer emergency treatment for colorectal cancer, so that they can make the initial referral to the appropriate hospital.

### **High risk groups**

Cancer Networks should develop guidelines on the nature and frequency of surveillance for people at high risk of developing colorectal cancer. This should be based on guidance published by the British Society of Gastroenterology and the Association of Coloproctology of Great Britain and Ireland (BSG/ACPGBI), which can be found on the BSG website ([www.bsg.org.uk](http://www.bsg.org.uk)). The recommendations below are derived mainly from this guidance.

Several disease groups are associated with increased risk, of which the largest are patients who have had colorectal cancer, those found to have multiple or large ( $\geq 1\text{cm}$ ) adenomatous polyps, and patients with longstanding colitis. Regular colonoscopy is recommended for people in all these groups, but the frequency with which this should be carried out depends on the particular condition.

About 10% of patients have an inherited predisposition to develop colorectal cancer. Specific identifiable gene mutations (notably familial adenomatous polyposis (FAP) and hereditary non-polyposis colorectal cancer (HNPCC)) confer exceptionally high risk – probably about a 60% lifetime risk of developing colorectal cancer.<sup>52</sup>

A family history should be taken for all patients in whom colorectal cancer is diagnosed. If the family history suggests genetic susceptibility, the patient should be referred to a clinical geneticist. Members of families known to carry such mutations, and people with more than two first degree relatives with colorectal cancer, should also be invited to discuss their situation with a clinical geneticist. All those with high-risk genetic syndromes require frequent surveillance from a younger age; those who have familial polyposis (associated with a 1 in 2.5 risk of death from colorectal cancer) are likely to require surgery to remove the colon and lifetime surveillance of the remaining bowel.

People with two first degree relatives with colorectal cancer, or one first degree relative whose colorectal cancer is diagnosed before the age of 45, have a lifetime risk of death from colorectal cancer of 1 in 6 or 1 in 10 respectively. The BSG/ACPGBI guidelines suggest that people who meet these criteria should be referred for colonoscopy at 35-40 years of age, or as soon thereafter as the risk is recognised.

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<sup>52</sup> Priority Areas Cancer Team/Genetics Sub-Committee of the Scottish Cancer Co-ordinating and Advisory Committee. *Cancer Genetics Services in Scotland*. The Scottish Office, 1998.

Appropriate systems should be established for locating individuals in high risk groups and inviting them for surveillance. Clinicians who carry out these tests should have appropriate training and should be able to refer patients to genetic counselling services.

Colonoscopy, flexible sigmoidoscopy and barium enema can be uncomfortable and embarrassing to the patient and involve some risk (see Topic 4, *Diagnosis*). Patients should be informed about these disadvantages, which must be balanced against potential benefits of surveillance.

## B. Anticipated benefits

Reducing the threshold for action on symptoms of colorectal cancer, reducing diagnostic delay by improving referral systems and enhancing access to appropriate investigations, and developing systems for tracing and screening high-risk individuals, would all increase the probability of early diagnosis and thus, of successful treatment. These changes could also reduce the number of patients who present as emergencies, since most have symptoms for weeks or months before admission.

Late diagnosis appears to be the main reason for relatively poor survival rates among patients with colorectal cancer in England and Wales.<sup>53</sup> Improving awareness of symptoms and the importance of adequate investigation, and expanding access to appropriate forms of diagnostic technologies must, therefore, be crucial components of any strategy to improve outcomes.

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<sup>53</sup> Gatta G, Capocaccia R, Sant M, Bell CMJ, *et al.* Understanding variations in survival for colorectal cancer in Europe: a EURO CARE high resolution study. *Gut* 2000;**47**:533-538.

## C. Evidence

Note: the reliability and quality of evidence supporting the recommendations is graded as A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

### **Urgent referrals and the two-week guidelines**

Some GPs seem to be over-cautious about classifying referrals as urgent, and some do not follow national guidelines correctly. This could have serious consequences since diagnosis and treatment is delayed when patients with cancer are not referred as urgent cases. The Commission for Health Improvement/Audit Commission investigation of cancer services in 2000/1 reported that 18% of patients found to have colorectal cancer were referred as “not urgent”, when adherence to national guidelines should have led to urgent referral. This study also found that at least half of those who are referred as urgent cases do not fit national guideline criteria.(B)

Studies of the impact of the two-week referral guidelines show wide variations between different hospitals. In three out of four studies, the experience appears to have been positive. In some hospitals, the establishment of services to deal with patients referred under the two-week guidelines have meant that all patients – including those who are not referred as urgent – are now being seen more quickly. One report describes a service run by two district general hospitals (DGHs), where the time from referral to diagnosis was 11 days for fast-track referrals and 35 days for non-emergency referrals. The average wait for all elective patients dropped from 38 days in the run-up to the introduction of the two-week service to 17 days thereafter.(B)

However, a Welsh university hospital found that the majority of patients with colorectal cancer were not referred through the fast-track service. Whilst those who were classed as urgent were seen quickly, waiting times for other patients increased from nine to 16 weeks.(B) This type of problem is not unique to this particular hospital.(C)

Between 1.7% and 14% of patients referred through fast-track services described in the evidence review were found to have cancer. It is not clear whether these clinics accept referrals under all the criteria in the two-week guidelines; some hospitals have a different referral pathway for patients with anaemia.

## Delays in diagnosis

There is considerable evidence in the research literature of delays, often lasting a year or more, between the onset of symptoms of colorectal cancer and diagnosis. This is principally due to patient delay in reporting symptoms, and to a lesser extent, GP and hospital delay. There is no clear relationship between length of delay and stage of cancer or outcome, but the situation is confounded by the fact that more advanced tumours (for which the outcome of treatment is poor) produce more obvious and alarming symptoms, so tend to be investigated relatively quickly. (B) Some GP and hospital delay is due to inadequate investigation of symptoms, misdiagnosis, and false negative results of diagnostic tests. (B: see evidence review for 1997 edition of this document.)<sup>54</sup>

## Waiting times in the NHS

A national survey of NHS patients carried out in 1999/2000 (just before the publication of two-week referral guidelines for colorectal cancer) found that 34% of patients with colorectal cancer had had an appointment with a hospital doctor within two weeks of visiting their GP with symptoms.<sup>55</sup> However, a substantial proportion – 37% – had to wait over three months for their first hospital appointment. 13% waited seven or more months. 39% of women and 35% of men reported that their condition deteriorated while they were waiting for a hospital appointment.

Delays associated with inadequate assessment of iron-deficiency anaemia can be particularly long. This is an issue of concern because anaemia may be the only symptom of colon cancer, but the majority of patients with anaemia of unknown cause are not referred for investigations that would reliably reveal the presence of colon cancer. The potential importance of this is illustrated by a study of post-menopausal women or men with documented iron-deficiency anaemia, which found that 25% of those in which the cause was identified within one year, had bowel cancer. A quarter of cases were not diagnosed for over a year; two of these patients had had negative barium enemas.<sup>56</sup> Only 35% of the study group of 431 patients had any investigation of the lower gastro-intestinal (GI) tract; 56% of those with histories of GI complaints were offered no GI investigation at all.<sup>57</sup>

<sup>54</sup> *Improving Outcomes in Colorectal Cancer: the Research Evidence* (1997). Available from the Department of Health publication order line on 08701 555 455, reference No. 23573.

<sup>55</sup> Airey C, Becher H, Erens B, Fuller E. *National Surveys of NHS Patients: Cancer - National Overview 1999/2000*. London: Department of Health, 2002.

<sup>56</sup> Logan ECM, Yates JM, Stewart RM, *et al.* The investigation and management of iron deficiency anaemia in general practice: a cluster randomised controlled trial of a simple management prompt. *Postgrad Med J* 2002;**78**:533-537.

<sup>57</sup> Logan E, personal communication, 2003.

## Open-access and one-stop lower GI endoscopy services

Most open-access clinics for patients with bowel symptoms offer flexible sigmoidoscopy. The yield of cancers and polyps detected varies widely between clinics, according to the particular patient population investigated.

One report described an evening clinic which picked up an unusually high proportion of cases: 25 cancers in 179 self-referred patients and 91 cancers in 648 patients referred by GPs – a 14% cancer rate in both groups. Another evening clinic reported highly positive feedback from patients and GPs but a much lower cancer incidence rate (2.4%). A potentially crucial difference between these is that the former was advertised in the context of a public awareness campaign conducted by a cancer charity, and patients had direct access to the clinic via a telephone help-line provided by the charity. This seems to have been particularly effective for getting men to get their symptoms investigated.(B)

The largest study identified (2,701 cases) was of an open-access colonoscopy service established in 1996. Waiting time averaged 44 days in the last four months of the audit. Overall, 4% of patients had cancer and 10% had polyps. Change in bowel habit (particularly development of diarrhoea) in patients over the age of 45 was especially likely to signify cancer or polyps: of 348 patients with unexplained diarrhoea, 10% had cancer and 10% polyps. Among 69 patients referred to the same hospital for investigation of anaemia, 28% had a malignant condition, of whom six (8.7%) had bowel cancer.<sup>58</sup>

Despite the availability of the open-access colonoscopy service, fewer than half of all referrals for suspected colorectal cancer came by that route – probably because of GPs' misapprehension that direct referral to a consultant leads to faster diagnosis.

Another direct-access colonoscopy service reported an 8% incidence of colorectal cancer among 100 patients. Few details were given in this report.

Another large study (2,181 patients) describes the experience of a one-stop clinic run by a specialist multi-disciplinary colorectal cancer team. Flexible sigmoidoscopy was used for patients over the age of 45. This service achieved a median waiting time of nine days and median time to treatment of 24 days. Over three-quarters of patients with cancer were referred via this clinic; 8% of the patients seen in the clinic had cancer. In 62% of cases, the tumour stage was Dukes' A or B; by contrast, only 22% of patients referred by other routes had Dukes' stage A or B tumours: most of these were stage C.(B)

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<sup>58</sup> Greenaway JA. *The utilisation of endoscopy services: strategies for patient management at the primary/secondary care interface*. MD Thesis, Newcastle upon Tyne, 2001.

Two services were described in one Trust, one led by doctors, the other by nurses. The doctor-led service saw patients with rectal bleeding, weight loss, altered bowel habit or a family history of colorectal cancer. The cancer rate was 13.2% and there was a trend towards identification of cancer at an earlier stage (25% stage A in 1997-8, compared with 10% in 1993). Fewer cancers (1.6%) were detected among patients referred to the nurse-led flexible sigmoidoscopy clinic for investigation of rectal bleeding.

Similarly low cancer rates (1.7% and 2%) were reported in other nurse-led sigmoidoscopy clinics. However, establishment of these services produced other benefits: one report noted that the waiting time for routine out-patient clinics fell from 16 weeks to eight, whilst the other noted improvements in the stage of cancers diagnosed.<sup>(B)</sup> Levels of satisfaction among patients using nurse-led endoscopy clinics are consistently high, and where accuracy of diagnosis is reported, nurses perform as well as doctors.

### **Improving access to hospital-based services: information based on experience in the Cancer Services Collaborative**

Improvements in the referral process between GPs and bowel clinics have been described by several Trusts. In East Berkshire, referral criteria were agreed by relevant clinical leads/consultants. Establishment of a standard referral proforma and a central fax point to deal with initial referrals led to a steady rise in the number of referrals received in this way.<sup>59</sup>

Referral systems in Aintree, Liverpool, were re-designed with the help of the NHS Cancer Services Collaborative.<sup>60</sup> Now, all referrals go to a co-ordinator who agrees a clinic appointment time with the patient, sends information about the test and an appropriate bowel preparation product to the patient, and liaises with the GP. The co-ordinator ensures that patients are sent to the right clinic and that feedback is given to those who require it. One in nine patients referred through this system were found to have cancer.

### **Emergency admission**

About a fifth of patients who undergo surgery for colorectal cancer are admitted as emergencies; the average GP is likely to encounter one such patient every three years. The Trent/Wales audit found that the mortality rate in this group was four times higher than among those who underwent elective surgery (21.7% for emergency/urgent

<sup>59</sup> Cancer Services Collaborative, case study BwC 2.2, available at: <[www.nelh.nhs.uk/nsf/cancer/bowel\\_sig/referral/bowel\\_2\\_2.htm](http://www.nelh.nhs.uk/nsf/cancer/bowel_sig/referral/bowel_2_2.htm)>.

<sup>60</sup> This case-study was reported at the Colorectal Cancer Conference of the Cancer Services Collaborative, March 2002; information derived from the NHS Modernisation Agency website <[www.modernnhs.nhs.uk](http://www.modernnhs.nhs.uk)>. The project managers, Julie Cunningham and Kathy Collins, can be contacted on 0151 529 3899.

surgery, versus 5.5% for scheduled/elective procedures; see also Topic 5, *Surgery and histopathology*).<sup>61</sup> Patients who present as emergencies are likely to have experienced symptoms (most often change in bowel habit, abdominal pain and vomiting) for about three weeks; in up to a quarter of cases, symptoms may have been present for three months before admission.(B)

Although there is no reliable research evidence to indicate how emergency rates could be reduced, comparisons between parts of Europe show that higher emergency admission rates and poorer survival rates are both typical of places where colon cancer is diagnosed at a later stage.<sup>62</sup>

**High risk groups** (See evidence review for 1997 edition of this document.)

About 15-20% of colorectal cancers occur in people with one or more first degree relatives who have also had colorectal cancer. These people are more than twice as likely to develop colorectal cancer as the general population in the same age-group.<sup>63</sup> Individuals with a family history are more likely to develop the disease at an early age, especially if cancer was diagnosed in their relative(s) before the age of 55. The degree of risk, relative to individuals with no family history of the disease, varies with the age of the individual (Figure 2, *Background*).

The genetic syndromes FAP and HNPCC account for about 5% of colorectal cancers. People with FAP develop hundreds of polyps; by the age of 40, most will have colon cancer unless they have had surgery to remove the colon. People with HNPCC also develop colorectal cancer at an early age but it is less often preceded by the growth of multiple polyps. Genetic testing can identify those who have these mutations, but people with a strong family history of colorectal cancer are at increased risk even if they do not have a genetic mutation known to be associated with the disease.(B)

Surveillance of members of families carrying the mutation for HNPCC produces significant reductions in both colorectal cancer and overall death-rates. In a 15-year controlled trial, cancer rates and deaths were monitored in 133 individuals considered to be at risk because of family history and who had colonoscopic screening at three-yearly intervals, and compared with rates in 119 other family members who declined screening or could not be traced when the study began. Colorectal cancer developed in 6% of those who were screened and 16% of those who were not. In mutation-positive individuals,

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<sup>61</sup> Mella J, Biffin A, Radcliffe AG, Stamatakis JD, Steele RJ. Population-based audit of colorectal cancer management in two UK health regions. Colorectal Cancer Working Group, Royal College of Surgeons of England Clinical Epidemiology and Audit Unit. *Br J Surg* 1997;**84**:1731-1736.

<sup>62</sup> Gatta G, Capocaccia R, Sant M, Bell CMJ, *et al*. Understanding variations in survival for colorectal cancer in Europe: a EURO CARE high resolution study. *Gut* 2000;**47**:533-538.

<sup>63</sup> Johns LE, Houlston RS. A systematic review and meta-analysis of familial colorectal cancer risk. *American Journal of Gastroenterology* 2001;**96**:2992-3003.

colorectal cancer rates in the screened and unscreened groups were 18% and 41% respectively ( $p=0.02$ ). There were no deaths due to colorectal cancer in the screened group, compared with nine in those who were not screened; the overall death rates were 8% and 22%, respectively, over 15 years ( $p<0.01$ ).<sup>64</sup>

People with inflammatory bowel disease, including Crohn's disease and ulcerative colitis, are at higher than average risk of developing colorectal cancer, but such individuals account for fewer than 1% of new cases. The risk increases with the duration of the disease.

## D. Measurement

### Structure

- Referral guidelines and referral pro-formas for patients with signs or symptoms suggestive of colorectal cancer.
- Availability of adequate rapid-access endoscopy services.
- Systems for stabilisation of patients with intestinal obstruction and rapid transfer of emergency patients, when necessary, to hospitals where they can be assessed by a specialist colorectal cancer MDT.
- Access to testing for early detection of colorectal cancer for those at high risk, with reminder systems and quality control programmes.
- A genetic assessment and surveillance service.
- Protocols for screening high risk individuals.

### Process

- Audit of use by GPs of access routes to diagnosis of colorectal cancer, and audit of timescales from initial referral to first treatment.
- Audit of proportion of non-menstruating adult patients with iron-deficiency anaemia of unknown cause, as defined in two-week referral guidelines, who are referred for investigation.
- Audit of time-lag between GP consultation with bowel symptoms that could be due to colorectal cancer, and appropriate endoscopy.

<sup>64</sup> Jarvinen HI, Aarnio M, Mustonen H, Aktan-Collan K, *et al.* Controlled 15-year trial on screening for colorectal cancer in families with hereditary nonpolyposis colorectal cancer. *Gastroenterology* 2000;**118**:829-834.

- Audit of time from first hospital appointment to definitive diagnosis.
- Audit of effects of GP referral guidelines.
- Provider compliance with surveillance protocols.
- Proportion of patients invited for surveillance who take up the offer.
- Proportion of patients with colorectal cancer presenting as emergencies.
- Evidence that all patients found to have colorectal cancer are referred to the colorectal cancer MDT.

### **Outcome**

- Stage of cancer at diagnosis.

## **E. Resource implications**

Surveillance of members of high-risk groups, as proposed in BSG/ACPGBI guidelines, is not likely to change dramatically the number of colonoscopies performed annually, but rather ensure that colonoscopy is offered to the correct groups of patients and that resources are not wasted.

Resources will be required for the establishment of colorectal assessment and genetic counselling and surveillance services.

# Multi-disciplinary teams

## A. Recommendations

The management of all patients with colorectal cancer should be the responsibility of colorectal cancer multi-disciplinary teams (MDTs). Any patient under the care of a clinician who is not a core member of such an MDT should be promptly referred to an appropriate team when colorectal cancer is suspected. Cancer Networks should make specific arrangements to ensure rapid access to a member of a specialist colorectal cancer MDT for all patients admitted as emergencies to any hospital, at any time. (See Topic 5, *Surgery and histopathology*, for discussion of emergency cases.) Guidelines should be agreed by all Trusts within each Cancer Network to ensure prompt and efficient referral of every patient suspected or found to have colorectal cancer to a colorectal cancer MDT, and the implementation of these guidelines should be audited.

Colorectal cancer MDTs in general hospitals should take responsibility for all patients with cancer of the colon or rectum. Cancer Networks should agree specialisation criteria for members of these teams (see Topic 5, *Surgery and histopathology*).

Where Trusts already have colorectal cancer MDTs, their composition, mode of operation and functions should be reviewed and refined in line with the recommendations in this section. If more than one colorectal cancer MDT works in a single Trust, all should work to a single protocol. Teams should be merged if they deal with small numbers of patients (fewer than 60 new cases per year) or if core members such as radiologists or oncologists cannot attend meetings regularly. Small hospitals within a single Trust should consider merging their teams.

Colorectal cancer MDTs should refer patients with anal cancer to designated teams with expertise in the management of this condition; these teams will work in a limited number of Cancer Centres (see *Anal cancer MDTs*, below). Patients who might benefit from resection of liver metastases should also be referred to specialised MDTs, which may in practice be those which have been previously established to provide surgery for patients with pancreatic cancer,<sup>65</sup> except where separate specialist liver resection teams have been established.

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<sup>65</sup> This type of team is defined in *Improving Outcomes in Upper Gastro-intestinal Cancers, The Manual*, available on the Department of Health website at: <[www.dh.gov.uk](http://www.dh.gov.uk)>.

Colorectal cancer MDTs should consist of a core team of members who have a particular interest and expertise in this area and who will make a commitment to attend a majority of MDT meetings, and associates who are members of an extended team. The extended team should consist of designated individuals who should be available to work with core MDT members when their expertise is required. Where shortage of staff time creates problems with regular MDT attendance, Trusts should examine individual members' commitments and seek to streamline administrative processes to increase efficiency, using methods developed by the Cancer Services Collaborative.<sup>66</sup>

At any one time, a named member of the team should be the principal clinician to whom the patient relates, e.g. the surgeon in the early stages of the disease, the oncologist during adjuvant treatment, and oncologist or palliative care physician at later stages. It is important that such arrangements should be explicit and properly understood by patients and their GPs, who should be given information about the members of the team involved in their management.

The core team should be responsible for planning care in a seamless way so that each patient receives prompt and appropriate care throughout the process of diagnosis and treatment, including the period when palliation may be needed, until the patient is released from follow-up or dies. One member of this team (either a clinical nurse specialist or the team co-ordinator) must have a system for tracking all patients throughout their illness, including those who are referred to linked MDTs (for example for liver resection) and bringing them back to the core team.

### **The colorectal cancer MDT**

A colorectal cancer MDT in a relatively small district general hospital (DGH), serving a population of 200,000, could expect to deal with about 120 new patients per year, and would include two or three surgeons. Larger Centres may be able to form teams with more specialised members, such as hepatobiliary surgeons.

The core team should include the following members:

- At least two specialist surgeons who have been trained in, and maintain a special interest in, techniques relevant to colorectal cancer, and who can demonstrate a high level of skill in this area. Each surgeon in the MDT should carry out a minimum of 20 colorectal resections with curative intent per annum. Sub-specialisation should be specifically encouraged among surgeons who treat patients with rectal cancer.

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<sup>66</sup> [www.nhs.uk/npat](http://www.nhs.uk/npat)

- Oncologist. Whenever elective surgery is considered for patients with rectal cancer, a clinical oncologist should be involved in discussion about each patient before surgery is scheduled. In view of the current shortage of clinical oncologists in the NHS, teleconferencing may be appropriate to enable this discussion to be held. A medical oncologist may also be included in the MDT if available.
- Diagnostic radiologist with gastro-intestinal expertise.
- Histopathologist.
- Skilled colonoscopist of any discipline (surgeon, physician, or specialist nurse). See Topic 4, *Diagnosis*, for criteria for assessing skill in colonoscopy and recommendations on training.
- Clinical nurse specialists (CNSs). In many respects, the role of CNSs for colorectal cancer is similar to that of breast care nurses. A CNS should be available to provide support, assistance, information and advice to every patient. She/he should have specific expertise in colorectal cancer and in addition, should be trained in communication skills and counselling. These nurses should ensure that patients' non-clinical needs – for example, for information and support – are met (see Topic 1, *Patient-centred care*).
- Palliative care specialist (doctor or nurse), who should work with palliative care services in the community.
- Meeting co-ordinator, who should take responsibility for organising MDT meetings (see below). The co-ordinator should have the authority to ensure that extended team members such as social workers and psychologists are available when required. The co-ordinator should also be responsible for feedback about patients referred to more specialised teams, and the return of such patients to the local colorectal cancer MDT.
- Team secretary who will provide clerical support for the MDT, recording all decisions made by the team and communicating appropriate information promptly to all those (such as GPs) who may require it. In smaller teams, the co-ordinator may take the role of team secretary.

MDTs should maintain close contact with other professionals who are actively involved in supporting the patient or carrying out the treatment strategy decided by the core team (the extended team). Extended teams should include the following members:

- Gastroenterologist.
- Liver surgeon who is a member of a liver resection MDT and can advise the colorectal cancer MDT.
- Thoracic surgeon with expertise in lung resection.
- Interventional radiologist with expertise in insertion of lower intestinal stents.
- GPs/primary care teams.
- Dietitian.
- Liaison psychiatrist/clinical psychologist.
- Social worker.
- Clinical geneticist/genetics counsellor.
- Clinical trials co-ordinator or research nurse.

Selected individuals from the extended team may be included in the core team.

Each Network should ensure that nominated individuals are available to fill each role in every extended team and should carry out regular audits to check that they do, in fact, fulfil the function of that role when required. Trusts may pool resources so that individuals with specific expertise work with more than one colorectal cancer team. Teams based in Cancer Units must work closely with colleagues in the associated Cancer Centre.

### **Anal cancer MDTs**

Particular colorectal cancer MDTs, based in Cancer Centres with radiotherapy facilities, should be designated as specialist anal cancer MDTs which will provide treatment for patients with anal cancer (see Topic 8, *Anal cancer*). These teams will be called “anal cancer MDTs” in the text below. It is not envisaged that these would be teams which deal only with anal cancer, nor are they expected to hold meetings separately from their parent colorectal cancer MDTs; rather, this term is intended to describe the *function* of designated MDTs which have the range of expertise necessary for the management of anal cancer.

Cancer Networks and radiotherapy Centres should work together to determine where patients with anal cancer should be treated. Clear referral systems should be established within each Network to ensure that responsibility for the management of every patient with anal cancer is passed to the appropriate MDT when the initial diagnosis is made.

Anal cancer MDTs should include the same range of disciplines as other colorectal cancer MDTs (see above), but the members should also have specific expertise in the management of anal cancer. In addition, each anal cancer MDT requires access to plastic surgery and should have links with a gynaecological oncologist with expertise in vulval cancer. At least one, and preferably two, members of the anal cancer MDT should specialise in surgery for anal cancer.

Within each designated radiotherapy facility, responsibility for the treatment of patients with anal cancer should be taken by no more than two clinical oncologists, who should have specialist knowledge of chemoradiotherapy and be core members of the anal cancer MDT.

### **Liver resection MDTs**

Each Network should identify or establish a specialised MDT which has the expertise and facilities to provide surgery for patients with liver metastases in a Centre which serves a population of at least two million. Where two or three smaller Networks co-operate to create a joint team, there should be explicit arrangements for referral between Networks.

Referral to a specialist liver resection MDT, for an opinion about the feasibility of resection, should be considered for patients in relatively good general health who have undergone curative resection for a primary colorectal tumour or who have a resectable primary tumour and who are believed, on the basis of imaging, to have resectable liver metastases; decisions about liver resection should be made by the specialist team. Cancer Networks should agree criteria specifying which patients should be referred to the specialist liver resection MDT and produce formal referral protocols for them; other patients should not normally be referred to this team.

The membership of the liver resection MDT should normally be the same as the hepatobiliary and pancreatic cancer MDT which is responsible for pancreatic resection,<sup>67</sup> except where a specialist liver resection team with expertise in cancer treatment is available.

<sup>67</sup> This type of team is defined in *Improving Outcomes in Upper Gastro-intestinal Cancers, The Manual*, available on the Department of Health website at: <[www.dh.gov.uk](http://www.dh.gov.uk)>.

## Organisation of MDT meetings

Meetings should be arranged weekly in sessional time by the team co-ordinator. The co-ordinator should work with other members of the MDT to ensure that all the following patients are identified for discussion at the meeting, and that copies of their case notes, along with diagnostic, staging, and pathology information, are available for consideration at the meeting:

- Every new patient with a diagnosis of colorectal cancer. The MDT co-ordinator should work with pathologists, radiologists and endoscopists to ensure that all new cases are identified.
- All patients who have undergone resection with curative intent and histopathological information is available.
- All patients with newly identified recurrent or metastatic disease.
- Patients who have been referred back for management by their local colorectal cancer MDT after referral to a specialist MDT.
- Any other patients whose management is thought by any member of the MDT to require discussion.

All information necessary for effective team functioning and clinical decision-making should be available at each meeting. Team members should be adequately prepared for the meeting, so that they can discuss each case without delay; such preparation and attendance at meetings should be recognised as important clinical commitments and time should be allocated accordingly.

Each MDT should have adequate systems for recording decisions made at meetings and ensuring that appropriate action is taken to carry out these decisions. Information and decisions about individual patients should be recorded on an appropriate pro-forma; ideally, this should be available on a laptop computer so that it can be used during MDT meetings. The meeting co-ordinator should keep a record of attendance by individual MDT members.

The MDT should discuss the histopathological features of each excised specimen after surgery, in order both to monitor the quality of surgery and to decide whether the patient might benefit from further treatment. Photographs of the margin of the specimen can be helpful to inform this debate. Patients with rectal cancer for whom elective surgery is planned should be discussed by the MDT before surgery; a clinical oncologist should be involved in this discussion.

The lead clinician, working with the meeting support staff, should take responsibility for ensuring that treatment plans and other decisions relevant to specific patients are sent to their GPs as quickly as possible.

Audit, clinical trials, and other issues of relevance to the Trust or Cancer Network should also be discussed at MDT meetings. Networks and Trusts should ensure that adequate resources and support – in terms of investment, expertise and time – are provided for audit, and MDT lead clinicians should provide feedback about such requirements to those who have responsibility for managing clinical audit.

There should be an operational policy meeting at least once a year at which the colorectal cancer team discusses and reviews its policies. This meeting should be organised around an open agenda to which all members of the team may contribute.

### **Achieving consistency within Cancer Networks**

Network-wide guidelines should be agreed, with joint protocols for clinical management, referral and audit. There should be adequately supported Network-wide audit, not only of clinical issues and outcomes, but also of the activity of individual surgeons and of patients' and carers' experience of the service. Cancer Networks should organise meetings between colorectal cancer MDTs at least biannually, at which information derived from audit is used to identify and reduce variations within the Network.

### **How the team functions**

Each MDT should have an administrative head, usually the lead clinician, who should work closely with the co-ordinator. Teams should, however, seek to achieve pluralistic or distributed leadership for decision-making, and a democratic ethos should be encouraged. It is important that all clinical members of the MDT, including specialist nurses, should play active parts in discussing treatment plans, since each can offer a distinctive and valuable perspective. The participation of clinical nurse specialists should be regarded as essential to effective team function. MDTs should consider taking specific training in effective team-work.

## **B. Anticipated benefits**

The most important benefits of team working are improved co-ordination of care and the opportunity to consider each case from a variety of perspectives. Patients managed by a team are more likely to be offered a range of types of treatment at appropriate times and to receive seamless care through all stages of the disease. When MDTs function well, they offer a supportive environment where individual members can share their concerns. MDT meetings also provide opportunities for surgeons to receive feedback from histopathologists and other team members on the results of their work. This can lead to marked improvements in surgical technique.

Treatment by MDTs which treat relatively large numbers of patients, rather than by individual surgeons who may only deal with a few, can be expected to produce substantial benefits for patients. There is accumulating evidence that hospitals that treat more than 20 new patients with rectal cancer per annum – the minimum number that would be treated by MDTs working in accordance with the recommendations in this section – achieve better outcomes. Their patients are less likely to receive permanent colostomies, suffer fewer post-operative complications, have lower local recurrence rates and are more likely to become long-term survivors. Concentration of surgery in the hands of fewer, more specialised surgeons, working in the context of MDTs, can be expected to produce similar benefits.

## C. Evidence

Note: the reliability and quality of evidence supporting the recommendations is graded as A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

A recent report, based on site visits carried out by the Commission for Health Improvement and the Audit Commission in winter 2000/1,<sup>68</sup> shows that multi-disciplinary team working is less well developed in colorectal cancer care than in breast cancer care. Of 12 Trusts which reported that they had colorectal cancer MDTs, half held weekly patient-planning meetings and a third held meetings fortnightly; the other two met monthly or less. It seems that the other six Trusts did not hold regular colorectal cancer MDT meetings at which patient management was planned.

In Trusts that did have colorectal cancer MDTs, surgeons who were not members nevertheless carried out operations. A third of lead consultants reported problems dissuading colleagues from occasional practice. In one Trust, for example, four out of eight surgeons who carried out operations for colorectal cancer attended MDT meetings; in a second, only one of the two main colorectal cancer surgeons attended MDT meetings and the patients treated by the second surgeon (about a quarter of the total) were not discussed by the MDT. 40% of lead consultants, working in 21 Trusts, said there were surgeons in their Trust who regularly carried out operations for colorectal cancer but did not attend MDT meetings.

Patients who underwent emergency surgery by anyone other than a designated specialist working in an MDT were unlikely to be referred on to a specialist for subsequent management.

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<sup>68</sup> Commission for Health Improvement, Audit Commission. *NHS cancer care in England and Wales*. National Service Framework assessments No. 1. London: The Stationery Office, 2001.

Fewer than 20% of MDTs had administrative support for meetings, and in those Trusts where regular MDT meetings were held, only 56% kept minutes. Most MDT meetings were held outside normal working hours, often during lunch time.

Research evidence on MDT function in cancer care is mainly based on experience with breast care MDTs. This is summarised in *Improving Outcomes in Breast Cancer - Manual Update* (2002), which can be found on the National Institute for Clinical Excellence (NICE) website.<sup>69</sup>

The NHS Cancer Services Collaborative offers information based on practical experience of improving the effectiveness of colorectal cancer MDTs. The following reforms have emerged as helpful:

- Improve organisation of MDT meetings (the role of the co-ordinator is crucial to this – see below).
- Review the timing of meetings by discussion with all members, including visiting oncologists and radiologists, to allow all members to attend.
- Streamline referral systems. For example, the MDT registration form can be designed to double as an oncology referral letter.
- Develop a clear and efficient structure for the meeting and work to a defined agenda.

Better organisation of meetings leads to more efficient use of time and allows more patients to be discussed. It also results in more patients being managed in accordance with guidelines. Audit data from a Cancer Centre in Wales show that the proportion of patients referred to specialist oncologists increased from below 60% to 100% with the institution of regular MDT meetings.(B)

The NHS Modernisation website<sup>70</sup> includes a description of the role of the co-ordinator of the colorectal cancer MDT at the Royal Hants County Hospital. The co-ordinator maximises the efficiency and effectiveness of the MDT by ensuring that it has the information it needs to make decisions efficiently at meetings, and that its decisions are recorded and acted upon. She is in touch with all members of the MDT, acting as the focal point for information, collecting information from a variety of sources and making sure it is available when and where it will be required. She identifies patients who should be discussed at each MDT meeting and ensures that their notes and films are available; she prepares the minutes, records

<sup>69</sup> [www.nice.org.uk](http://www.nice.org.uk)

<sup>70</sup> [www.nhs.uk/npat](http://www.nhs.uk/npat)

decisions in patients' notes, checks that appropriate action is taken, writes referral letters, and passes information to patients and GPs. She maintains the Cancer Outcomes Database, tracks requests for endoscopy and imaging and their results, and acts as the contact point for audit.

### **Surgical specialisation and patient throughput**

There is now a substantial body of research assessing the effects on outcomes in colorectal cancer of surgical specialisation and patient throughput (both the number of cases treated per surgeon and per hospital). The evidence review carried out to support this guidance includes six systematic reviews and 33 primary studies, none of which had been published at the time of the first edition of this guidance (1997).

As a general rule, the more complex the operation, the greater the surgical skill required; such skill is acquired and developed through specialised training and experience and maintained by regular practice. It is not, therefore, surprising that in surgical oncology as a whole, the benefits of higher volume practice and greater specialisation would be particularly apparent in outcomes for types of cancer for which surgery is more challenging; and this is indeed the pattern with colorectal cancer. Surgery for rectal cancer, which is more difficult to do well, shows volume and specialisation effects much more clearly than surgery for colon cancer.

None of the reviews which contribute to the evidence on this issue included more than five primary studies of colorectal cancer. Nevertheless, they are consistent in finding evidence that for rectal cancer at least, higher patient volumes and greater specialisation among surgeons were associated with better outcomes: lower surgical complication rates, decreased local recurrence, lower colostomy rates, and improved survival. One review concluded that outcomes in rectal cancer were related more to the surgeon's technique than to the number of patients treated; another commented that later studies found greater differences between specialist surgeons than earlier.

Most of the primary studies report more recent data, and as such, are likely to be more relevant to current practice.

In rectal cancer, 11 of 13 studies assessing surgical specialisation reported that more specialised surgeons achieved better outcomes. Greater specialisation tends to be associated with higher patient throughput, so it is difficult to separate these issues. Six out of eight good quality studies of specialisation in rectal cancer showed significant effects on one or more of the following measures of outcome: survival rates (up to five years); quality of surgery (assessed by complication rates or tumour-free excision margins); and local recurrence rates. Greater specialisation is also associated with shorter in-patient stay and less frequent use of stomas.(B)

There is less evidence for colon cancer: only two studies looked at colon cancer alone. Eight publications reported on patients with colorectal cancer, the majority of whom would have had cancer of the colon. These show little evidence of any effect of patient throughput. However, two studies found that surgery by specialists was reflected in higher survival rates.(B)

One study examined liver resection for metastatic colorectal cancer. This found a highly significant association between higher hospital throughput and 30-day survival rates.(B)

## D. Measurement

### Structure

- A system for identification of all patients with newly-diagnosed or recurrent colorectal cancer and assembly of all information relevant to these patients which may be required to inform discussion by the MDT.
- Appropriate pro-forma for recording information and MDT decisions about individual patients.
- Arrangements for MDT meetings in normal working hours.
- Meeting co-ordinator and secretarial resources to support MDT meetings.
- Systems to ensure that all patients with colorectal cancer who receive initial treatment by anyone other than an MDT member are promptly referred to the MDT.
- Presence of specialist team members with adequate training and dedicated sessions.
- Systems to ensure that patients are promptly referred to an anal cancer MDT.
- Designation of members of colorectal cancer MDTs to form anal cancer MDTs in specified Cancer Centres.
- Designated liver resection MDTs.

## Process

- Minutes and attendance records of formal MDT meetings.
- Evidence in minutes of meetings that the management of every patient with newly diagnosed or newly recurrent colorectal cancer is discussed at an MDT meeting.
- Use of pro-forma to record decisions about individual patients.
- Evidence of discussion of all patients found to have liver or lung metastases, and referral of such patients for further management by appropriate specialists.
- Evidence in minutes that resection margins of all excised specimens are discussed at MDT meetings.
- Evidence that clinical nurse specialists contribute to discussion at MDT meetings.
- Details of patients who undergo resection by any surgeon who is not an MDT member, and reasons for this.
- Delay between surgery and initiation of chemotherapy.
- Number of new patients treated annually by each MDT.
- Number of resections carried out annually by each surgeon in the MDT.

## Outcome

- 30-day, three- and five-year relative survival rates, adjusted by age and stage at diagnosis, for each surgeon and for the MDT.
- Audit of variations in outcomes and use of adjuvant therapy within the Network.

## E. Resource implications

Where recommendations made in the previous edition of this guidance have not been fully implemented, additional investment will be required to support the activities of colorectal cancer MDTs and liver resection MDTs, which are likely to deal with larger numbers of patients. Increasing both the proportion of patients managed by specialists and the range of activities carried out by specialists will produce pressure for increasing the number of key members of staff. These changes and their resource consequences will have to be assessed locally.

Adequate funding is essential for audit, data collection, and employment of data managers.

# Diagnosis

## A. Recommendations

### **Responsibilities of Cancer Networks**

Improving diagnostic services for patients who could have colorectal cancer should be a recognised priority for Cancer Networks and Trusts. The Department of Health has made a specific commitment to expansion and modernisation of lower gastro-intestinal (GI) endoscopy services. In order that this may be implemented in the most effective manner, an urgent review of the availability and pattern of use of endoscopy services should be carried out by each Network.

Increased use of endoscopy will lead to removal of more polyps and suspicious lesions from the lower GI tract, which will generate increased demand for histopathological assessment of tissue samples. Networks and Trusts should take steps to ensure that this expansion in histopathology workload is adequately supported.

Multi-disciplinary teams (MDTs) within each Network should agree local clinical guidelines for diagnostic investigations to detect colorectal cancer in all potential patient groups, the use of which should be audited throughout the Network. These should deal with establishing the initial diagnosis, pre-operative assessment, assessment of emergency cases, follow-up procedures, and surveillance of patients at high risk (particularly those with known genetic susceptibility to colorectal cancer, discussed in Topic 2, *Access to appropriate services*).

### **Initial investigations**

Two main types of investigation should be available: endoscopy (flexible sigmoidoscopy or colonoscopy) and imaging (barium enema and computed tomography (CT), including CT colonography<sup>71</sup>). Patients require bowel preparation for any of these methods to produce accurate results.

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<sup>71</sup> CT colonography is also popularly known as “virtual colonoscopy”. The term CT colonography is used in this document because it is more precise.

Each method has specific advantages and disadvantages which make it more or less appropriate for particular patients. Decisions about which form of investigation should be used at any point in the diagnostic process should depend on the patient's symptoms, age and general condition. These factors should be taken into account in locally-agreed guidelines, which should be used to aid decisions about which forms of investigation are used and their sequence in individual patients.

The local availability of facilities, equipment, and skilled staff will inevitably influence the choice of investigation used. As diagnostic services are upgraded, the impact of these service variables should diminish.

### **Endoscopic investigation: flexible sigmoidoscopy and colonoscopy**

Endoscopic investigation has an important advantage over any form of imaging: it permits biopsy and histopathological assessment of any suspicious lesion. This means that endoscopy (flexible sigmoidoscopy or colonoscopy) is generally the most useful method for diagnosis of colorectal cancer. In addition, polyps can be removed during the procedure.

Flexible sigmoidoscopy is relatively quick and virtually risk-free, and is therefore the most appropriate initial investigation for the majority of patients with symptoms – notably rectal bleeding and/or change in bowel habit – that suggest possible lesions in the left (descending or distal) colon, sigmoid or rectum.

The reach of the flexible sigmoidoscope is limited to 60 cm, but when neither cancer nor significant polyps are found in patients with these symptoms, and none of the symptoms or signs of right-sided disease, described below, are present, the probability of cancer is very low. A watch-and-wait strategy to see if symptoms resolve is therefore likely to be appropriate for low-risk patients. Decisions on whether, or when, to carry out further investigations should be made by discussion between hospital specialists and patients. Colorectal cancer MDTs in each Cancer Network should agree protocols to define the actions that should be taken when a diagnosis cannot be established by flexible sigmoidoscopy alone.

If the patient is considered to be at risk of colon cancer because of older age, an abdominal mass, iron deficiency anaemia or symptoms such as abdominal pain with loss of appetite and weight, or if significant clinical doubt remains after flexible sigmoidoscopy, it is necessary to visualise the whole colon. Diagnostic colonoscopy is usually appropriate for patients with right-sided symptoms, except for those with palpable masses, for whom imaging (barium enema or CT) is likely to be more suitable. If a complete colonoscopy is not achieved and clinical doubt remains, imaging is necessary. When patients present with iron deficiency anaemia, investigation should continue until the cause is found.

Although colonoscopy involves little risk when carried out by experienced operators, it causes more adverse effects than flexible sigmoidoscopy or barium enema. Polyps should be removed during the procedure; this may prevent the development of cancer but it can lead to bleeding and occasionally, perforation. Rapid access to colonoscopy should be facilitated by increased provision of services and streamlined referral systems (see Topic 2, *Access to appropriate services*).

Those who carry out colonoscopy need a high level of skill which can only be achieved by appropriate training, extensive experience and regular practice. Colonoscopy services should be concentrated so that those who carry out this procedure do a minimum of one lower GI endoscopy session (including at least three full colonoscopies) per week or 100 per annum. Trusts should consider allocating this work to colonoscopy specialists with much higher colonoscopy workloads.

The performance of all those who carry out colonoscopy should be audited, and those with completion<sup>72</sup> rates below 90% (excluding patients with obstruction or failed bowel preparation) should have further training. Completion should be confirmed by imaging, photography, or an adequate report of the appearance of the caecum. Routine biopsy of the terminal ileum is not necessary as other clinical markers of completion are usually sufficiently clear.

## **Imaging**

### ***Barium enema***

Barium enema is well established in the NHS and staff are experienced in its use. It has the advantages of safety and availability, and there is no need for sedation, which means that patients can travel home alone after the procedure. However, because barium enema on its own is a less sensitive diagnostic method than colonoscopy, a negative result cannot always be relied upon to demonstrate that the patient's symptoms are not due to colorectal cancer or polyps. Also, barium enema does not permit tissue diagnosis or polyp removal. For these reasons, the use of barium enema is declining as the availability of colonoscopy and CT colonography increase. Trusts should manage the reduction in use of barium enema with care, to ensure that all patients with possible colon cancer are adequately investigated and that waiting times for diagnostic investigations do not increase.

Symptomatic patients with equivocal or normal barium enemas may need further investigation by colonoscopy.

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<sup>72</sup> To inspect the whole colon, the operator must get the tip of the colonoscope all the way to the caecum, where the large bowel starts; this is known as completion.

### ***CT Colonography (virtual colonoscopy)***

CT colonography is increasing in the NHS; at the time of writing, it is believed that a third of Units have some experience of using it.<sup>73</sup> Where a radiologist experienced in this technology is available, CT colonography can be used instead of barium enema. There is some evidence suggesting that CT colonography in skilled hands may offer greater accuracy than barium enema, and it appears to be as accurate as optical colonoscopy for diagnosis of larger polyps. However, patients with abnormal findings may require colonoscopy to biopsy or remove suspicious lesions. As with other forms of diagnostic technology, accuracy depends on adequate training and experience. This is a new technology and training issues are currently being addressed by relevant professional bodies. Audit of outcomes is essential.

CT colonography is currently being assessed in a randomised Health Technology Assessment trial which compares it with both barium enema and colonoscopy, but results are not expected to be available before 2006.

### ***Emergency patients and patients with palpable abdominal masses***

CT scanning or colonography should be used to assess patients with suspected intestinal obstruction or palpable masses, unless the patient has a condition such as peritonitis which would make post-operative CT more appropriate.

### **Further assessment of suspected rectal cancer**

Patients with invasive rectal cancers for whom surgery is being considered should have magnetic resonance imaging (MRI) scans before treatment begins, to determine the precise location and extent of the tumour and clarify who might benefit from adjuvant therapy and who is likely to be adequately treated by surgery alone.

Particular MDTs should be identified which have, and can further develop, expertise in the management of early rectal cancer. Patients with T<sub>1</sub> tumours, who might benefit from local excision, should be referred to these teams. Rectal endosonography should be available to assess such tumours.

### **Further assessment and identification of metastatic colorectal cancer**

Patients should undergo pre-operative abdomino-pelvic CT scanning to assess cancer stage and metastatic spread, unless this information would have no influence on management – for example, if the patient is receiving palliative treatment only. CT scanning may be done after emergency surgery if it is not possible beforehand.

<sup>73</sup> Burling D, Halligan S, Taylor SA, Usiskin S, Bartram CI. CT colonography practice in the United Kingdom: a national survey. *Clinical Radiology* 2004;**59**:39-43.

Ultrasound (US) imaging of the liver may be used to check for metastatic disease, but it should be recognised that negative findings may not be reliable. If the patient is in good general health and external US reveals either no evidence of metastatic disease or only limited metastatic deposits, either CT imaging, MRI where the requisite experience and access is available, or intra-operative US, may be necessary to determine what further treatment might be appropriate. CT or MR imaging of the liver is especially important for patients who appear to have Dukes' stage B or C cancers and are fit enough for local treatment of liver metastases; when a patient appears to have limited liver metastases, his or her management should be discussed with the liver resection MDT.

Positron emission tomography (PET) scanning is an emerging technology, capable of identifying local recurrence, liver metastases and distant metastases in colorectal cancer. In conjunction with other imaging modalities it may be helpful in assessing the extent of metastatic disease, and hence influencing decisions on patient management. The optimum role of PET scanning in relation to more established imaging methods is not yet clear. PET imaging facilities are currently only available in a few Centres in the UK, although this situation is expected to change substantially over the next few years.

### **Co-ordination of patient journeys and support for patients**

Trusts should establish pre-booking systems so that dates for further diagnostic investigations and initial treatment can be agreed with patients when they are informed of the diagnosis. Diagnostic tests should be scheduled so as to minimise the number of hospital appointments required for each patient. Patients should be given clear information about each test before it is carried out.

Patients should be given information about their disease and potential treatment options as soon as the diagnosis is confirmed. They should have the support of a clinical nurse specialist at this time and should be given his or her telephone number so they can call if they have any questions or other problems. (See Topic 1, *Patient-centred care*.)

## **B. Anticipated benefits**

Streamlining, expanding and modernising services for the provision of flexible sigmoidoscopy, colonoscopy and imaging should improve the speed and accuracy of diagnosis of colorectal cancer. Concentration of colonoscopy services, so that highly-skilled operators carry out more procedures and low-volume activity is avoided, can be expected to improve both the efficiency of the service and the accuracy of diagnosis.

Patients will benefit from the continued trend to substitute colonoscopy and CT colonography for barium enema, both because these techniques offer greater diagnostic accuracy, and because they will avoid a form of examination which many find particularly unpleasant. This can be expected both to increase the probability that cancer or other pathology will be correctly identified, and to reduce the risk of inappropriate surgery.

Accurate assessment of tumour spread enables the MDT to select the most appropriate treatment for each patient and allows more accurate case-mix data to be collected. Precise imaging is crucial to appropriate selection of patients who might benefit from further treatment of liver metastases.

## C. Evidence

Note: the reliability and quality of evidence supporting the recommendations is graded as A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

### **Diagnosis of colorectal cancer in NHS hospitals**

The 1999/2000 survey of NHS cancer patients<sup>74</sup> found that just over half of those with colorectal cancer were given the diagnosis during their first hospital appointment but 22% had to wait for another two weeks or more; 4% waited for over three months. For almost a third of patients (32%), the delay between first hospital appointment and first treatment was over three months. Those referred under the two-week urgent referral guidelines may wait up to six weeks for diagnostic colonoscopy. The diagnostic test reported by the largest proportion of patients was some form of scan (41%). 60% of patients did not recall having any form of endoscopy. 23% had barium enemas. This report does not say what proportion of patients had more than one form of diagnostic investigation.

A case study reported by the Cancer Services Collaborative describes how the co-ordination of patients' journeys from referral to treatment was improved at the Leicester Royal Infirmary.<sup>75</sup>

<sup>74</sup> Airey C, Becher H, Erens B, Fuller E. *National Surveys of NHS Patients: Cancer - National Overview 1999/2000*. London: Department of Health, 2002.

<sup>75</sup> Cancer Service Collaborative *Service Improvement Guide*, Case study BwC 4.1. Contact Kim Brett, Radiology Department, 0116 258 5155.

## Lower GI endoscopy services in the NHS

Hospital episode statistics show that the use of both colonoscopy and flexible sigmoidoscopy has been rising each year since 1995/6. In 2000/1, the last year for which data are available, there were 154,000 colonoscopies in England and 134,000 day-case flexible sigmoidoscopies. A typical Trust carried out between 500 and 1,000 colonoscopies and 400-800 flexible sigmoidoscopies per annum.<sup>76</sup>

## Research evidence on endoscopy

A survey of 164 endoscopy units in the UK (published in 1999) revealed that the median population size served was 250,000, and that the median number of colonoscopies performed was 150 per 100,000 people (375 per 250,000) per year. 70% of units reported that they could not create an additional weekly endoscopy session, usually because of lack of nursing support (81% of units), shortage of endoscopists (72%) and the lack of theatre time (51%). (See research evidence for Topic 2, *Access to appropriate services*.)(B)

Traditionally, endoscopy has been carried out by hospital doctors. However, there is accumulating evidence that both flexible sigmoidoscopy and diagnostic colonoscopy can be carried out safely by appropriately trained nurses or GPs. Complication rates for both diagnostic methods can be found in the evidence review for the 1997 edition of this document.<sup>77</sup>

A survey of prevalence of, and attitudes to, endoscopy carried out by nurses in the UK, found that nurses carried out endoscopy in 43% of the 176 units from which responses were obtained. Respondents – medical directors of endoscopy units – generally appeared unhappy about nurses conducting colonoscopy, particularly therapeutic colonoscopy. (See research evidence for Topic 2, *Access to appropriate services*.)(B)

A randomised controlled trial (RCT) comparing flexible sigmoidoscopy results achieved by doctors and nurses showed equally good outcomes for both groups.(A) Similar outcomes were also demonstrated in a non-randomised controlled trial in which either nurses or doctors carried out diagnostic colonoscopy. Uncontrolled studies of lower GI endoscopy also report that nurses are able to achieve excellent results: a completion rate of 94% (documented by video) in one study of colonoscopy, and a 93% success rate for flexible sigmoidoscopy in another. No complications were reported in any of these studies.(B)

<sup>76</sup> Figures quoted in *The NHS Colorectal Cancer Programme*. Department of Health, 2003.

<sup>77</sup> *Improving Outcomes in Colorectal Cancer: the Research Evidence* (1997). Available from the Department of Health publication order line on 08701 555 455, reference No. 23573.

A survey of 27 NHS primary care endoscopy providers, of which 21 provided lower GI endoscopy, found that GPs could perform both flexible sigmoidoscopy and colonoscopy safely. Results were reported for 12,260 lower GI investigations, including 1,386 colonoscopies; six of these procedures led to hospital admission and there was one death. Average waiting times were 1.2 weeks for urgent cases and 3.4 weeks for routine referrals. 98% of patients said the service was very good or excellent.(B)

Case-control studies from the US, comparing colonoscopy carried out by family practitioners with colonoscopy by gastroenterology or general surgery services, found that the only significant difference between these groups was a higher rate of cancer diagnosis in the family practice group.(B) Two uncontrolled, retrospective studies of diagnostic/therapeutic colonoscopy undertaken by a rural family physician showed completion rates of over 90% in sedated patients but only 35% of patients who had not received sedation. One of these studies reported one major complication in 751 examinations.(B) Complication rates found in prospective studies of colonoscopy performed by hospital-based doctors and surgeons are given in the summary of evidence on *Achieving competence in colonoscopy*, below.

### **Choice of initial diagnostic method**

#### ***Flexible sigmoidoscopy or examination of the whole colon?***

Over a 15 year period, cancer was diagnosed in 5.6% of 16,487 patients who underwent flexible sigmoidoscopy for lower gastrointestinal symptoms in a district general hospital (DGH) out-patient clinic. Among patients with bowel symptoms (usually rectal bleeding, changed bowel habit or pain), no other reason (for example, iron deficiency anaemia) to suspect cancer, and negative findings on flexible sigmoidoscopy, 0.2% had cancer beyond the reach of the sigmoidoscope. Some patients in this group also had severe abdominal pain or profound weight loss, so investigation would have continued for these reasons when sigmoidoscopy proved negative.<sup>78</sup>(B)

The proportion of patients with colorectal cancer, whose diagnosis might be delayed if a policy of watch-and-wait were adopted after negative sigmoidoscopy for those with bowel symptoms other than severe pain, is therefore less than 0.2%. The potential benefit of further colonic imaging for such patients is very limited.

<sup>78</sup> Unpublished data from MR Thompson, Queen Alexandra Hospital, Portsmouth. Early results from this study have been described in conference presentations, for example Anwar R, Flashman K, O'Leary D, Senapati A, Thompson MR. Probability of proximal cancers of the rectum and left colon to 60cm in patients presenting with rectal bleeding to a surgical outpatient clinic. *Colorectal Disease* 2002;4(Suppl.1):47.

### ***Examination of the whole colon: effectiveness and acceptability of diagnostic methods***

A systematic review of studies of the accuracy of double contrast barium enema and colonoscopy found that colonoscopy is significantly more sensitive than barium enema for the detection of both colorectal cancer and polyps, but barium enema is associated with a much lower risk of complications. A large retrospective study from a UK teaching hospital came to similar conclusions.(B) A Swedish study has demonstrated that the use of barium enema decreases with increased use of colonoscopy.<sup>79</sup>

The review reported that there have been few studies of patients' views. Two studies in which patients were sedated during colonoscopy found that they preferred this method, whilst two in which no sedation was used found no difference in patient satisfaction between colonoscopy and barium enema. A recent UK study, however, has found that patients with bowel symptoms (mainly rectal bleeding or change in bowel habit) and patients at higher than normal risk of colorectal cancer, particularly dislike barium enema, preferring all other diagnostic options, including colonoscopy.<sup>80</sup> Patients reported more pain during colonoscopy or flexible sigmoidoscopy than during CT colonography, and tended to choose CT colonography as the preferred follow-up investigation.

### ***CT colonography***

A systematic review of studies comparing CT colonography with colonoscopy for detection of colorectal polyps found that CT colonography was capable of identifying most polyps over 10 mm in size correctly. The pooled sensitivity for detection of polyps  $\geq 10$  mm was 0.81 (95% CI: 0.76 to 0.85), but sensitivity fell to 0.43 for small polyps ( $\leq 5$  mm). Specificity figures were not reported. Although a diagnostic method that can detect polyps might also be expected to pick up cancers, this review was not concerned with detection or diagnosis of colorectal cancer.(B)

### ***Achieving competence in colonoscopy***

Colonoscopy permits removal of polyps (polypectomy) and biopsy, and is therefore particularly useful for investigating symptoms that could be due to polyps or cancer in the transverse or ascending (right) colon. However, the skill of the operator is crucial to the effectiveness of any diagnostic method used; and reliable diagnosis of colon cancer by colonoscopy requires a high completion rate, which can only be achieved by a skilled colonoscopist.

<sup>79</sup> Dafnis G, Blomqvist P, Pahlman L, Ekblom A. The introduction and development of colonoscopy within a defined population in Sweden. *Scand J Gastroenterol* 2000;**7**:765-771.

<sup>80</sup> Taylor S, Halligan S, Saunders B, Bassett P, *et al.* Acceptance by patients of multidetector CT colonography compared with barium enema examinations, flexible sigmoidoscopy, and colonoscopy. *AJR* 2003;**181**:913-921.

A large retrospective study from Sweden found that endoscopists who carried out colonoscopy more often were significantly more likely to achieve a complete examination. There was a clear correlation between completion rates and the number of examinations performed in a 90 day period among endoscopists who carried out fewer than 29 procedures (about two per week), but there was no improvement above this level. The total number of colonoscopies carried out by the endoscopist was also important, with continued improvement over the first 200 cases.(B)

A prospective study of 3,504 colonoscopies carried out by surgeons in the US found that, whilst colonoscopy volume did not affect complication rates, it was associated with both completion rates and time to completion. Surgeons who carried out 100-200 colonoscopies per annum had completion rates of 92.3%; among those who did fewer than 10 per annum, completion rates were 72.8%. Complication rates for diagnostic colonoscopy were very low: just 0.02% of procedures caused perforation. Therapeutic colonoscopy (polypectomy) caused bleeding in 0.19% of cases and perforation in 0.15%. One death was reported, in a man with multiple co-morbidities who was hospitalised for a “massive” gastro-intestinal haemorrhage.(B)

An audit in a UK hospital focused on colonoscopy completion rates for individual endoscopists over a 17 month period. Two consultants achieved rates of 96% and 98%, but completion rates for two assistants, who carried out 143 and 65 colonoscopies, were poorer: 77% and 80%, respectively. The authors suggested that this was due to pressure of work in the first case, and inadequate numbers carried out in the second; the assistants' workloads were adjusted and at re-audit, their completion rates had risen to 93%.(B)

Another UK audit, carried out in a combined DGH and specialist endoscopy unit, reported on colonoscopy completion rates by specialist endoscopists, gastroenterology consultants, colorectal surgeons, specialist registrars, and a nurse practitioner. Patients with very inadequate bowel preparation or impassable tumours were excluded. The overall completion rate was 93%, with little difference between disciplines: the range was from 89% (surgeons) to 98% (specialist endoscopists). This was a prospective study which lasted for two months; health care professionals knew their performance was being audited.(B)

### **Liver imaging**

Studies of the diagnostic accuracy of pre-operative liver imaging suggest that overall, CT is slightly better than US. But there have been few direct comparisons between US and CT in this situation, and the studies that were identified have serious methodological flaws. Other studies give figures for sensitivity and specificity but the research methods and patient populations differ; consequently, figures derived from these studies vary widely.

In general, abdominal US offers high levels of specificity but relatively poor sensitivity (42-75% in different studies; accuracy around 90%) in other words, when lesions are identified as metastases, they are likely to be malignant. However, a substantial proportion of patients with negative US scans – possibly more than half of those who appear to be free of metastatic disease – do in fact have cancer in the liver. Two studies report sensitivity figures for contrast-enhanced CT of 93-94%, but a small study (n=44) (the focus of which was the potential role of PET scanning) reported a much lower figure for the sensitivity of CT: just 37.5%.(B)

One study reported that both laparoscopic and intra-operative ultrasound were more accurate than CT. Intra-operative ultrasound appears to be particularly accurate for detecting liver metastases.(B)

Evidence on the accuracy of MR imaging for detection of liver metastases was not reviewed.

## **Imaging for local staging of rectal cancer**

### **CT versus MRI**

The evidence reviewed suggests that MRI is better than CT for locally staging primary rectal cancer, but it is not entirely consistent. There is wide variability between results reported in different studies and considerable overlap between the results obtained with each form of imaging.

The findings were most consistent on identification of cancer-positive lymph nodes; both primary studies and a systematic review concluded that MRI was more effective than CT in this respect, although it appears that a substantial proportion of involved lymph nodes are likely to be missed with either method. The primary studies reviewed showed that MRI, using a body coil or endorectal coil, was superior to CT for correctly staging rectal cancer. For the assessment of lymph nodes, MRI with the body phased coil was superior.(B) Preliminary results are now available from a multi-centre study (MERCURY, n=712) designed to discover whether MRI, with a phased-array body coil, allows reliable determination of the stage of rectal cancer before surgery. For patients treated by surgery alone (approximately half of the total) the correlation between MRI and pathological staging was 0.92, with an observed agreement of 84% (kappa 0.49, 95% CI: 0.35 to 0.61) between the MERCURY assessment of prognosis and pathology findings after primary surgery. Further studies are planned to assess the impact on long-term outcomes for patients.

### **Rectal endosonography**

Rectal endosonography is used to distinguish between lesions confined to superficial layers of the rectum (which may be benign) and those that invade the muscle wall. This information is important for decision-making about the extent of surgery. Primary studies reported varying levels of accuracy for this discrimination, from 76% to 100%. There were some variations according to the type of equipment used, but it is not clear whether any of these is superior to the others: the apparent differences could reflect differences between studies in patient populations and methods used.(B)

A systematic review compared rectal endosonography with CT and MRI. The authors concluded that endosonography was the most accurate way of assessing tumour penetration into the muscle of the bowel wall, with pooled sensitivity, specificity and accuracy figures of 78%, 93% and 87%, respectively.(B)

## **D. Measurement**

### **Structure**

- Dissemination of clear, locally-agreed protocols for investigation of colorectal cancer to all units which offer diagnostic services for symptoms which could be due to cancer.
- Availability of colonoscopy service with fully trained staff and sufficient capacity to provide prompt diagnostic services for patients with suspected colon cancer.
- Availability of rapid-access flexible sigmoidoscopy.
- Rapid access to CT imaging.
- Availability of MRI for patients with rectal cancer.
- Access to rectal endosonography.

### **Process**

- Audit of delay between initial referral and appropriate endoscopy.
- Audit of the number of colonoscopies carried out per year by each individual who carries out this procedure, and their completion rate.
- Proportion of patients who undergo CT scanning.
- Audit of delay between initial diagnosis and CT scan of patients with operable disease.

- Audit of delay between initial diagnosis and MRI scan of patients with locally advanced rectal cancer.
- Use of appropriate imaging procedures for detection of early metastatic disease.
- A system for auditing the quality of diagnostic procedures which links outcomes with training.

### **Outcome**

- Complications of diagnostic procedures such as perforations.
- Accuracy of diagnoses.

## **E. Resource implications**

The number of endoscopies (flexible sigmoidoscopy and/or colonoscopy) has been increasing over recent years, and this trend is expected to continue. A cost impact analysis has been carried out to assess the effects of moving from the current position to a situation in which, on average, 85% of all referrals in England and Wales would receive flexible sigmoidoscopy as the initial investigation and 15% would receive a full bowel investigation, assumed to be a colonoscopy. The analysis also assumes that 30% of those who receive flexible sigmoidoscopy would go on to require colonoscopy, and that colonoscopy will be incomplete in 10% of patients, who will then have barium enemas.

Such a shift in practice would result in an increase of 180% over current levels of flexible sigmoidoscopy and 11% more colonoscopies each year. Based on costs of £57 for flexible sigmoidoscopy and £208 for colonoscopy, the total cost of these additional procedures is estimated to be around £19.3 million, an increase of 42% over current levels.

These cost estimates are subject to considerable uncertainty. Sensitivity analyses show a range from £2 million, if it is assumed that only 10% of patients will receive colonoscopy after flexible sigmoidoscopy and the cost of each investigation is as given above, to £44.6 million if it is assumed that flexible sigmoidoscopy costs £154 and colonoscopy £180. In addition, there is much local variability in current practice, such that implementation of the guidance will have a large cost impact in some hospitals and little or none in others.

In view of the large investment in equipment, staff, training and facilities that will be necessary to deal with increased demand for endoscopy services, it is likely that the full cost will not accrue for several years.

Better access to imaging (both CT and MRI) is also required; an initiative designed to improve access to CT scanning is now underway.

# Surgery and histopathology

Surgery with curative intent aims to remove the whole tumour; if it succeeds, the patient may be rendered free from cancer. When curative surgery is not possible, patients may benefit from stenting to relieve obstruction, or from palliative surgery.

## A. Recommendations

High quality surgery can be crucial to patients' survival. Surgery should be undertaken by specialist colorectal cancer surgeons who are members of colorectal cancer multi-disciplinary teams (MDTs) and who can demonstrate low tumour involvement at the margins of the excised specimens, low rates of surgical complications, and high survival rates among their patients.

Surgeons should assess the liver during surgery. If primary surgery is potentially curative but metastases are suspected or discovered in a limited area of the liver, imaging should be used to judge whether these might also be resectable. Further action based on these findings, such as offering chemotherapy or referral to a specialist liver resection team, should be discussed by the MDT.

Every MDT which treats patients with rectal cancer should undergo training in total mesorectal excision (TME); all members of the core team should be involved. Since TME is the technique most likely to achieve clear surgical margins of cancers of the middle and lower third of the rectum, it should be available for all patients with rectal cancer for whom it is appropriate.

Surgeons should aim to preserve the nerves and plexuses on which sexual potency and bladder function depend, as far as this can be achieved without compromising tumour excision.

Each Cancer Network should agree evidence-based guidelines dealing with antibiotic use, prophylaxis for deep vein thrombosis and bowel preparation before surgery. Adherence to these guidelines should be audited.

Surgical performance should be discussed in MDT meetings, using histopathology reports and audit of short- and long-term outcomes of surgery. The margins of excised tissue should be checked by a histopathologist to ascertain whether they contain cancer. Avoidable adverse effects of surgery such as leaking anastomoses and local recurrence should be audited and should be used to identify surgeons who require further training.

Time and facilities must be made available for continuing training for MDT members in techniques such as TME, which lead to better outcomes for patients.

National Institute for Clinical Excellence (NICE) guidance, published in 2000, recommends that open resection should be used in preference to laparoscopic surgery. This guidance is under review.<sup>81</sup>

### **Management of emergencies**

Appropriate management of patients admitted as emergencies demands a high level of expertise and facilities. If these are not available, the mortality rate in this group can be very high. Cancer Networks should therefore develop and agree specific guidelines for the management of these patients, including those who present out of normal working hours. These should state that any patient admitted as an emergency with intra-luminal obstruction or other signs or symptoms of colorectal cancer should, like patients coming through standard routes, be managed by a colorectal cancer MDT. The guidelines should specify holding procedures to stabilise patients without surgery until they can be seen by MDT members, except where the patient's condition is such that delaying surgery would increase the risk of death.

It may be necessary to extend colorectal cancer teams across organisational boundaries to allow emergency patients to be managed in this way. Procedures should be developed for transferring patients to neighbouring hospitals when the admitting hospital does not have a colorectal cancer MDT to deal with emergencies. (See Topic 2, *Access to appropriate services*.)

Facilities and services should be established to provide stenting for patients with intestinal obstruction, particularly those with serious co-morbidity, so that emergency surgery may be avoided. Cancer Networks should assemble teams with appropriate expertise and sufficient capacity to stent about 15 people per million population per annum. Decision-making on use of stents should be the responsibility of colorectal cancer MDTs. Stents should be inserted

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<sup>81</sup> National Institute for Clinical Excellence. *Guidance on the use of laparoscopic surgery for colorectal cancer*. Technology Appraisal Guidance No. 17. London: NICE, 2000 <[www.nice.org.uk](http://www.nice.org.uk)>.

within 48 hours of admission, by appropriately trained individuals (usually interventional radiologists, ideally working with endoscopists).

Patients with rectal cancer rarely are less likely to present as emergencies, but should be treated in the same way.

### **Histopathology**

Histopathologists should report on every resection specimen examined at the earliest possible MDT meeting after surgery carried out with curative intent. Circumferential margin involvement of excised rectal tumours should be specifically discussed, and the team should audit each surgeon's performance in terms of this measure.

The histopathologist should search for as many lymph nodes as possible in the excised specimen (particularly when the tumour appears to be Dukes' stage B), and the number found should be audited. In patients with colon cancer who are treated with curative intent, 12 or more nodes should normally be examined; if the median number is consistently below 12, the surgeon and the histopathologist should discuss their techniques. Time and facilities should be available for additional training for histopathologists in the assessment of colorectal cancer specimens.

Pathologists should complete the Royal College of Pathologists' minimum dataset for colorectal cancer and bring this to be discussed at the first available colorectal cancer team meeting. Photographs of the surgical specimen can be helpful in this discussion. The dataset should include information on the size, stage, type, grade and appearance of the tumour, depth of invasion, number of lymph nodes excised and number affected, and tumour involvement at surgical margins, including circumferential plane involvement or clearance in rectal cancer. These data should also be communicated to the local cancer registry.

### **Stoma**

Surgeons should aim, wherever possible and desirable, to conserve the anal sphincter. If any patient is likely to be given a stoma, whether temporary or permanent, its nature and implications should be carefully explained to the patient and his/her carers and its position discussed before surgery. Patients should be invited to contribute to decision-making about the siting of the stoma and the system to be used. Any patient who receives a temporary stoma should be given a pre-booked date for closure prior to discharge after initial surgery. Closure should be carried out as soon as practicable but may be scheduled to follow chemotherapy and/or radiotherapy.

## B. Anticipated benefits

Audit has revealed that over 20% of patients with colorectal cancer who undergo emergency surgery for intestinal obstruction die within a month.<sup>82</sup> Improved systems for managing these patients is likely to reduce peri-operative death-rates. Stents may be used to relieve intestinal obstruction so that emergency surgery can be avoided, and may prevent peri-operative death in patients with high levels of co-morbidity. The cost of intestinal stenting is likely to be balanced by reduced intensive care costs.

Good surgery – in particular, TME for patients with rectal cancer – is associated with reduced local recurrence, reduced permanent stoma rates and improved long-term survival. Where a stoma is unavoidable, expert surgery by a specialist in the field should minimise problems with poor stoma construction. A reduced rate of stoma formation is likely to improve quality of life for individual patients and reduce long-term costs to the NHS.

Accurate and detailed histopathology reporting can lead to improvements in the quality of surgery through feedback to surgeons on the results they achieve, and provides better information on which decisions on adjuvant therapy may be based. Increasing the number of lymph nodes examined in the surgical specimen will improve the accuracy of staging and will tend to increase long-term survival rates, particularly in patients with colon cancer; there is no consensus on the precise number of nodes that need to be examined, but the research evidence suggests that it should be in double figures.

## C. Evidence

Note: the reliability and quality of evidence supporting the recommendations is graded as A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

### **Surgical skill, technique and quality of surgery**

There is evidence of wide variability in outcomes achieved by individual surgeons, with large differences in both peri-operative and long-term survival rates.(B) For example, rates of anastomotic dehiscence (breakdown of the surgical re-connection of the bowel) have been found to vary from 0% to 43% between surgeons.(B)

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<sup>82</sup> Mella J, Biffin A, Radcliffe AG, Stamatakis JD, Steele RJ. Population-based audit of colorectal cancer management in two UK health regions. Colorectal Cancer Working Group, Royal College of Surgeons of England Clinical Epidemiology and Audit Unit. *Br J Surg* 1997;**84**:1731-1736.

## Lymph nodes

The removal and identification of lymph nodes containing tumour can be crucial to survival for two reasons. First, tumour left behind in lymph nodes after surgery can precipitate local recurrence. Second, decision-making on the need for adjuvant therapy depends on the stage of the cancer. Chemotherapy is not normally appropriate for patients with Dukes' stage B (node-negative) tumours (see Topic 7, *Adjuvant chemotherapy*), but offers proven benefits for those with stage C tumours – that is, those whose cancer has spread to neighbouring lymph nodes. It is not clear, however, how many lymph nodes need to be removed and checked before surgeons and histopathologists can be confident that all that contain tumour have been identified, and there is no consensus on the optimum number that should be examined.

Three variables contribute to the yield of lymph nodes: the aggressiveness of surgery; the diligence of the pathologist in searching the specimen; and the anatomy of the patient and the tumour. There are costs to be balanced against potential benefits of a higher node harvest. More precise surgery and pathological techniques demand more time and effort. In theory, more aggressive surgery to remove more lymph nodes might have adverse effects, but the evidence reviewed did not show this.

The research evidence shows that when more nodes are examined, tumours are significantly more likely to be classified as node-positive (Dukes' stage C). Conversely, when few nodes are examined, there is a substantial risk of under-staging.<sup>(B)</sup>

The survival rate among patients whose tumours are classified as node-negative (Dukes' stage B) on the basis of the examination of a relatively small number of lymph nodes (the criterion varies between studies, from six to 16, with a mode of 14) is consistently poorer than that of comparable patients whose tumour was staged on the basis of more nodes. In studies which compared outcomes in these groups, patients in the former group fared as badly as those classified as Dukes' stage C. In studies which reported recurrence and survival rates, both outcomes were significantly poorer among patients classified as node-negative when fewer lymph nodes were examined. In one such study, 43% of patients staged as T3 N0 (Dukes' stage B) after examination of nine or fewer nodes had local recurrences and 30% survived, compared with 10% local recurrence and 71% survival rates in similarly staged patients when 10 or more nodes had been assessed.

A study carried out using cancer registry data from 1988-91 reports that 14% of patients treated in the UK had 12 or more nodes examined: 10% in the Thames region, 15% in the Mersey region.<sup>83</sup>

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<sup>83</sup> Gatta G, Capocaccia R, Sant M, Bell CMJ, *et al.* Understanding variations in survival for colorectal cancer in Europe: a EURO CARE high resolution study. *Gut* 2000;**47**:533-538.

### **Local recurrence after surgery for rectal cancer**

Local recurrence is a serious problem after surgery for rectal cancer, with reported rates varying from less than 10% to over 40%.

Recurrence usually leads to death after a prolonged period of severe pain and distressing symptoms. Complete excision of the tumour, with surgical margins free from cancer cells, is associated in observational studies with one-tenth of the recurrence rate and one-third of the death-rate found when there is involvement of the margin.(B: see evidence review for 1997 edition of this document.)

The technique of TME involves meticulous mobilisation, followed by either coloanal anastomosis or completion as an abdominoperineal anorectal excision, and is the standard of surgery for cancers of the middle and distal thirds of the rectum. Similarly meticulous dissection should be used in mobilising and resecting upper third cancers, followed by colorectal anastomosis. TME is associated with about half the rate of local recurrence, compared with the generality of much previous surgery for cancer in the lower two thirds of the rectum. Surgical communities internationally (including Norway, Sweden and the Netherlands), who have jointly learned the technique known as TME have reported dramatic improvements in their local recurrence rates in rectal cancer surgery. Long-term survival rates are significantly higher after TME.(B) TME is also less likely to damage sexual function in men.(B) Outcomes - particularly the incidence of surgical complications - improve with increasing experience of the technique.

In some regions of England, colorectal cancer MDTs have now been trained in TME; this training is believed to pay for itself by reducing morbidity after surgery.(C) The majority of surgeons who carry out operations for rectal cancer in the NHS have not yet had such training, although there is a national programme in England to roll out this training. TME is now standard practice among specialist rectal surgeons.

### **Laparoscopic surgery**

The evidence on laparoscopic surgery has been reviewed for NICE.<sup>84</sup> This shows that laparoscopic surgery leads to consistently better short-term outcomes than open surgery, but effects on long-term survival rates are not yet known and there is concern that this technique has important drawbacks, such as limited opportunity for tumour staging. Randomised controlled trials (RCTs) currently in progress, in particular the Medical Research Council (MRC) CLASICC trial, are expected to clarify the situation.

<sup>84</sup> National Institute for Clinical Excellence. *Guidance on the use of laparoscopic surgery for colorectal cancer*. Technology Appraisal Guidance No. 17. London: NICE, 2000 <[www.nice.org.uk](http://www.nice.org.uk)>.

### **Emergency surgery**

About a third of colon cancer patients and a tenth of rectal cancer patients are admitted as emergencies. The peri-operative mortality rate of emergency surgery is many times higher than that of elective surgery (see Topic 2, *Access to appropriate services*). This appears to be due mainly to the poor physical status of patients at admission. After taking into account 30-day mortality, emergency admission does not appear to be an independent predictor of longer term survival.(B: see evidence review for 1997 edition of this document.)

### **Colorectal stents**

A systematic review of published data on the efficacy and safety of stenting in colorectal obstruction identified 29 case series describing 598 attempted stent insertions. 97% of the patients had cancer. The review reported clinical success in 88% of cases and effective palliation in 90%. Adverse effects included a 1% mortality rate, 10% stent migration rate and 10% stent re-obstruction rate. 56% of stent insertions were palliative, 44% pre-operative. The authors concluded that colorectal stents offer good palliation and are safe and effective as a “bridge to surgery”. Use of a stent can avoid the need for a stoma.

18 additional published case-series, each reporting at least 20 procedures, confirm these conclusions. These show that expanding metal stents usually remain effective for more than a year, and in many cases, provide palliation until death. Stenting can also provide temporary relief of acute obstruction in patients for whom resection might be appropriate, so that elective colorectal surgery, with tumour staging and adequate surgical preparation, can be planned.(B)

About 30 hospitals in the UK use colorectal stents regularly. Most of these offer stenting only for palliation of intestinal obstruction; very few currently provide stenting before surgery. It is believed that the reasons for this are lack of experience with the technique and difficulty in obtaining funding.

### **Histopathology**

Local recurrence of rectal cancer is associated with tumour involvement in the surgical margins, and accurate staging requires information on lymph node status.(B: see evidence review for 1997 edition of this document.)

### Preparation for surgery

Antibiotic prophylaxis, usually given at the time of anaesthesia for colorectal surgery, significantly reduces the risk of wound and other infections.(A: see evidence review for 1997 edition of this document.) CEPOD data indicates that routine procedures for appropriate management may be neglected in emergency cases. For example, 28% of these patients received no antibiotic prophylaxis before or during surgery. There is reliable evidence for the effectiveness of thromboprophylaxis with anti-platelet therapy.(B: see evidence review for 1997 edition of this document.)

### Stoma

The type of operation surgeons choose to carry out is an important determinant of stoma rates. Data from the Trent/Wales Audit (carried out in the early 1990s) shows that 47% of patients with rectal cancer were given a stoma after surgery.<sup>85</sup> By contrast, some specialist units report stoma rates as low as 10%. Stomas reduce the patient's quality of life and are costly to maintain. There is no evidence that removal of bowel wall tissue more than 2cm below (distal to) a tumour in the lower third of the rectum confers any survival advantage, but it may affect the need for permanent stoma formation.(B: see evidence review for 1997 edition of this document.)

## D. Measurement

### Structure

- An efficient system of data collection, audit and feedback for individual surgeons and teams.
- Availability of stenting for patients with acute intestinal obstruction.

### Process

- Audit of circumferential margin involvement of rectal tumours excised by each surgeon.
- Proportion of resections of rectal cancers carried out with curative intent, where tumour is found in surgical margins.
- Use of suitably detailed proforma for histopathology data; this should be based on the Association of Coloproctology of Great Britain and Ireland (ACPGBI) national colorectal cancer dataset, to which all teams should contribute.

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<sup>85</sup> Mella J, Biffin A, Radcliffe AG, Stamatakis JD, Steele RJ. Population-based audit of colorectal cancer management in two UK health regions. Colorectal Cancer Working Group, Royal College of Surgeons of England Clinical Epidemiology and Audit Unit. *Br J Surg* 1997;**84**:1731-1736.

- The proportion of histopathology reports which give the degree of involvement of surgical margins, including circumferential margins, the number of lymph nodes examined and the number involved.
- Positive circumferential margin rate for each surgeon; this should be audited and should be consistently below 20% for the MDT (except where patients have had a long course of pre-operative radiotherapy).
- Number of lymph nodes examined in surgical specimens from patients treated with curative intent. The median number should not fall below 12 in patients with Dukes' stage B or C colon cancer.
- Regular reviews of histopathology at team meetings to ensure that standards are met both for histopathology reports and for surgery.
- Presence and use of evidence-based protocols for bowel preparation, antibiotic prophylaxis and thromboprophylaxis.

### **Outcome**

- Case-mix adjusted peri-operative mortality; infection, anastomotic leak, and local recurrence rates.
- Rate of permanent stoma formation.
- Length of time before closure of temporary stoma.
- Proportion of emergency patients treated by members of the specialist colorectal cancer team.

## E. Resource implications

Some colorectal cancer MDTs will require additional training to enable them to provide total mesorectal excision for patients with rectal cancer. Although TME takes longer to carry out and may therefore be more costly initially, the reduction in local recurrence can be expected to reduce longer term costs of treatment.

Other recommendations in this section are not expected to require significant additional resources, except where recommendations made in the previous edition of this guidance have yet to be fully implemented. In particular, resources may be required to improve histopathology services.

# Radiotherapy in primary disease

## A. Recommendations

Each Cancer Network should develop evidence-based policy on radiotherapy for rectal cancer, which should be agreed and implemented by all radiotherapy Units and colorectal cancer multi-disciplinary teams (MDTs) in the Network. This may specify either routine pre-operative radiotherapy or selective post-operative radiotherapy, as in the Medical Research Council (MRC) CR07 trial; results from this trial, which are expected to become available in 2006, will show how the outcomes of these regimens differ. Radiotherapy is not likely to be appropriate for patients with primary colon cancer.

The potential benefits and risks of pre-operative radiotherapy (including both short- and long-term effects on bowel and sexual function) should be discussed with all patients with rectal cancer, so that they can make an informed choice about whether to accept it. Those who fulfil the inclusion criteria for the CRO7 trial should be encouraged to participate in it. Pre-operative radiotherapy should normally be given in a short course, using 3- or 4-field techniques to minimise the irradiated volume. Longer courses of pre-operative radiotherapy are appropriate for selected patients with invasive tumours, where shrinking the tumour would facilitate curative resection. If chemoradiotherapy is used, it should be an established regimen. Post-operative radiotherapy should be reserved for patients who are judged after surgery to be at high risk of recurrence.

When one radiotherapy Centre serves several Trusts, a clinical oncologist may need to provide assessment and advice for patients in one hospital and treat them in another. An experienced oncology nurse should be available to provide help, information and support for all patients, and to ensure that they receive adequate pain relief when required.

The radiotherapy service should conform with guidelines in *Quality Assurance in Radiotherapy*.<sup>86</sup>

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<sup>86</sup> Department of Health. *Quality Assurance in Radiotherapy: A quality management system for radiotherapy*. Department of Health circular, PL/CMO(94)7, Department of Health, 1994.

## B. Anticipated benefits

Pre-operative radiotherapy more than halves the risk of local recurrence and may improve five-year survival rates. However, these benefits are balanced by significant morbidity, so it is essential that those patients who are most likely to benefit should be clearly identified. The results of CRO7 are expected to provide valuable information to aid decision-making on radiotherapy for patients with rectal cancer. Post-operative radiotherapy can reduce local recurrence rates by a third, but is less effective than pre-operative radiotherapy and causes more adverse effects.

## C. Evidence

Note: the reliability and quality of evidence supporting the recommendations is graded as A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

Meta-analysis of individual patient data in randomised trials comparing radiotherapy plus conventional surgery with surgery alone for rectal cancer, shows that the addition of radiotherapy significantly reduces local recurrence rates. Pre-operative radiotherapy produces a greater proportional reduction in local recurrence than post-operative (57%, compared with 37%). Pre-operative radiotherapy also leads to a significant reduction in mortality rates among patients who receive a biological equivalent dose (BED) of 30 Gy or more.(A)

Modern treatment methods, using megavoltage equipment with a minimum of three fields to deliver radiotherapy to smaller volumes of tissue, reduce the toxicity of treatment. However, even this form of radiotherapy is likely to cause long-term problems with bowel function. Five to nine years after surgery, only 14% of 84 patients who had undergone pre-operative radiotherapy (BED 37.7 Gy over five to seven days, using modern techniques) in the context of a Swedish randomised controlled trial (RCT) assessed their bowel movement as excellent, compared with 32% of 87 patients who had had surgery alone. 7% of the irradiated group, but none of the controls, rated their bowel function as bad. Nearly half of those in the irradiated group had to use faecal incontinence pads, compared with 22% in the control group. Other problems, such as urgency of defaecation and loss of skin on the perineum, were also significantly more troublesome in irradiated patients.

Radiotherapy given before total mesorectal excision (TME) also reduces local recurrence, from 8.2% to 2.4% ( $p < 0.001$ ), but no reduction in mortality has been shown at a median of two years after surgery.(A) Two RCTs, currently in progress, are expected to throw further light on the issue of whether radiotherapy is worthwhile for

patients who undergo TME. In one of these (the Stockholm IV trial), all patients receive TME. The other (the MRC CRO7 trial) compares pre-operative radiotherapy for all patients with selective post-operative radiation for the 15-20% of patients whose excised tissue is found, on histological examination, to have tumour in the resection margins. TME is undertaken at the surgeon's discretion.

A small RCT (70 patients) found that the addition of chemotherapy to long course pre-operative radiotherapy (RT) for non-resectable rectal cancer produced significant reductions in local recurrence, but chemoradiotherapy (CRT) caused more acute toxicity than RT alone. The numbers surviving after five years were too small for differences between groups to achieve statistical significance.(A) The results of two larger trials are expected shortly.

## D. Measurement

### Structure

- Availability of radiotherapy and systems for providing pre-operative radiotherapy without significantly delaying surgery.

### Process

- Evidence that patients are fully informed and involved in decision-making about radiotherapy.
- Proportion of eligible patients entered into trials, for example MRC CRO7.
- Proportion of patients with rectal cancer offered pre-operative radiotherapy, in particular those who go on to have curative resection. This should be assessed in the context of local recurrence rates.

### Outcome

- Local recurrence rates after curative surgery for rectal cancer.
- Radiotherapy-related morbidity – including long-term effects on bowel function, sexual activity, and social life.
- Mortality rates at one and five years.

## E. Resource implications

It is not clear what impact on resource use these recommendations will have, since this will depend on local practice.

# Adjuvant chemotherapy

## A. Recommendations

Cancer Networks should agree guidelines on the use of adjuvant chemotherapy, which should be revised yearly in the light of new research evidence. Adjuvant therapy should be considered for all patients in reasonable health whose disease is sufficiently advanced that such treatment is likely to be beneficial. Judgements about a patient's fitness to receive chemotherapy should be made on the basis of his or her performance status and co-morbidity, rather than age.

The potential benefits and risks of chemotherapy should be discussed with patients for whom it is judged appropriate, so that they can make an informed choice about whether to accept it.

Systemic chemotherapy should be offered to all patients who, after surgery for Dukes' stage C colon or rectal cancer, are fit enough to tolerate it.<sup>87</sup> The multi-disciplinary team (MDT) should ensure that adjuvant chemotherapy is scheduled to begin within six weeks of surgery.

The standard treatment has been a course of 5-fluorouracil and folinic acid (FUFA), given intravenously over six months.

Chemotherapy for patients with metastatic disease (including those for whom liver resection may be appropriate) is discussed in Topic 10, *Recurrent and advanced disease*.

The place of chemotherapy in the treatment of patients with Dukes' stage B cancer must be a matter for discussion between patients and their oncologists. Eligible patients should be encouraged to take part in trials such as the National Cancer Research Network (NCRN) QUASAR1 trial. Chemotherapy is not recommended for patients with Dukes' stage A cancers.

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<sup>87</sup> See *Background* for explanation of Dukes' staging.

Chemotherapeutic agents require special care in delivery and dealing with adverse effects. There should be written protocols on the management of complications and toxicities. Intravenous chemotherapy should be given in a designated area under close supervision by oncologists and chemotherapy nurse specialists, with expert pharmacy and 24-hour laboratory support.

Patients receiving chemotherapy should have access to emergency care, information and advice from oncology trained staff on a 24-hour basis. They and their GPs should be given written information on what the side-effects are likely to be, and how best to cope with them.

## B. Anticipated benefits

The absolute increase in five-year survival rates achieved by FUFA chemotherapy in patients with Dukes' stage C colon cancer is between 4% and 13%. The survival benefit for patients with rectal cancer is believed to be similar, although the evidence is somewhat weaker.

## C. Evidence

Note: the reliability and quality of evidence supporting the recommendations is graded as A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

Around 25-30% of patients present with Dukes' stage C cancers. Meta-analysis of several randomised controlled trials (RCTs) shows that protracted systemic chemotherapy can improve survival in this group of patients, although the precise size of the benefit remains uncertain.(A)

Although some uncertainty remains about agents other than FUFA, it is now clear that treatment for six months is as effective as longer durations of up to a year.(A)

There are insufficient randomised data to provide clear evidence on the effectiveness of chemotherapy for patients with Dukes' stage B colorectal cancer. The proportional reduction in recurrence may be similar in stages B and C, but absolute benefits are likely to be less when the mortality rate is lower.(A: see evidence review for 1997 edition of this document.) However, when Dukes' stage B tumours have adverse features such as vascular invasion, peritoneal involvement, or perforation, or if the surgical margins are inflamed or

contain tumour, patients have a higher disease-related mortality rate and are therefore thought to be more likely to benefit from chemotherapy.<sup>88,89</sup>

Chemotherapy has not been tested in patients with Dukes' stage A disease.

## D. Measurement

### Structure

- Facilities for provision of chemotherapy under supervised conditions.

### Process

- Evidence that patients are fully informed and involved in decision-making about chemotherapy.
- Proportion of patients with locally advanced tumours who receive chemotherapy.
- Proportion of patients enrolled in trials of adjuvant chemotherapy.

## E. Resource implications

It is not clear what impact on resource use these recommendations will have, since this will depend on local practice.

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<sup>88</sup> Petersen VC, Baxter KJ, Love SB, Shepherd NA. Identification of objective pathological prognostic determinants and models of prognosis in Dukes' B colon cancer. *Gut* 2002;**51**:65-69.

<sup>89</sup> Lennon AM, Mulcahy MD, Hyland JMP, Lowry C, et al. Peritoneal involvement in stage II colon cancer. *Am J Clin Pathol* 2003;**119**:108-113.

# Anal cancer

## A. Recommendations

Anal cancer is a rare disease and specific expertise is important to optimise outcomes for patients. All patients with anal cancer, including those who have undergone local excision, should therefore be referred to multi-disciplinary anal cancer teams which can provide specialist management. These are described in Topic 3, *Multi-disciplinary teams*.

Patients for whom curative treatment is likely to be appropriate should have a computed tomography (CT) scan of the abdomen and pelvis or pelvic magnetic resonance imaging (MRI).

### **Primary treatment**

Concurrent chemoradiotherapy, using mitomycin C, 5-fluorouracil and radiation, is appropriate for most patients. Other forms of treatment, such as surgical excision, may be considered by anal cancer multi-disciplinary teams (MDTs), but surgery is usually reserved for salvage.

There are still some areas of uncertainty about optimum treatment, and eligible patients should be encouraged to participate in trials such as the Cancer Research UK (CRUK) ACT 2 trial.

### **Management of relapse**

All patients with suspected or confirmed relapse should be discussed by the anal cancer MDT. Those with confirmed locoregional recurrence should undergo cross sectional imaging and all treatment options, including surgery, should be considered by the MDT. Palliative radiotherapy, chemotherapy and palliative care should be discussed with patients who have metastatic disease or who are not sufficiently fit to undergo potentially curative treatment.

## B. Anticipated benefits

Increasing specialisation in the management of anal cancer will enhance the probability that patients receive appropriate treatment. This may include the use of less aggressive approaches for patients with early disease, is likely to improve outcomes for those with more advanced disease, and will facilitate improvements in the management of both acute and late adverse effects. Management by a suitably constituted MDT will ensure that patients receive the support of specialist nurses and psychosocial teams. The concentration of surgery for recurrent disease in the hands of specialists will provide a sufficient caseload for surgeons to develop techniques which minimise morbidity.

## C. Evidence

Note: the reliability and quality of evidence supporting the recommendations is graded as A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

Three randomised controlled trials (RCTs) have been performed to evaluate concurrent chemoradiotherapy (CRT) using mitomycin C, 5-fluorouracil (5FU) and radiotherapy (RT) to treat anal cancer. Two trials, by UKCCCR (n=585) and EORTC (n=110), compared radiotherapy alone with CRT. Both demonstrated a highly statistically significant reduction in locoregional failure, with improvements in colostomy-free survival (EORTC) and reduction in deaths from anal cancer (UKCCCR) with CRT, although neither showed any significant effect on overall survival. The RTOG trial tested the benefit of adding mitomycin C to 5FU and radiotherapy, and also demonstrated statistically significant improvements in colostomy-free and disease-free survival with this regimen.

The current NCRN phase III trial (ACT 2) is comparing two CRT schedules (mitomycin C, 5FU, and RT versus cisplatin, 5FU, and RT) and post-CRT adjuvant chemotherapy (cisplatin/5FU x2 versus control). The radiotherapy fields used in this trial are designed to improve outcomes and reduce acute toxicity.

## D. Measurement

### Process

- Evidence that patients are fully informed and involved in the decision-making process about treatment.
- Proportion of anal cancer patients treated by primary CRT.
- Proportion of eligible anal cancer patients entered into ACT 2 trial.

### Outcome

- Rate of disease recurrence at the original tumour site (local failure), and five-year survival rates of patients who undergo potentially curative treatment, with information on initial stage, co-morbidity, performance status and other features of case-mix.
- Audit of short-term and long-term adverse effects of treatment.

## E. Resource implications

No resource implications specific to these recommendations have been identified. There may be some support costs associated with the formalisation of supra-Network anal cancer MDTs. These have not been calculated as the number of patients involved is small.

# Follow-up

## A. Recommendations

All patients who develop recurrent or metastatic disease should be discussed by the colorectal cancer multi-disciplinary team (MDT) (see Topic 10, *Recurrent and advanced disease*). This section deals with patients who have had primary treatment and are believed to be tumour-free.

Follow-up for patients treated for anal cancer should be the responsibility of anal cancer MDTs. It is anticipated that the majority of these patients will be followed up by clinical oncologists.

### **Short-term follow-up**

Follow-up in the weeks after surgery for colorectal cancer should focus on post-operative problems, future planning (including the possible use of adjuvant therapy), and stoma management. Nursing and dietetic support should be provided for all patients. Clinical nurse specialists should specifically ask patients how they are coping with everyday life and provide appropriate advice and support, as well as arranging for patients to receive whatever other help they may need. (See Topic 1, *Patient-centred care*.)

Patients who did not undergo complete colonoscopy before surgery should be offered colonoscopy within six months of discharge. This can be regarded as completion of the initial diagnostic work-up, to identify individuals who have polyps or a tumour elsewhere in the colon. Similarly, patients who did not have a computed tomography (CT) scan of the liver before surgery should have such a scan within six months.

### **Longer term follow-up**

MDTs in each Network should agree follow-up guidelines for patients who have undergone curative surgery for colorectal cancer; these should be adopted throughout the Network and revised yearly in the light of new research evidence. In view of the continuing uncertainty about the effectiveness of different aspects and forms of follow-up, Networks should actively support the National Cancer Research Network (NCRN) trial of follow-up strategies (FACS). MDT members at participating Trusts should discuss the possibility of entry into this trial with all patients who meet the inclusion criteria.<sup>90</sup>

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<sup>90</sup> These are given in the trial protocol. There is no age limit but participants must have completed primary treatment with no evidence of cancer, have no concurrent serious illness, and no inherited syndrome causing colon cancer.

Colonoscopy may be offered at five-yearly intervals to check for new polyps or tumours; it should not normally be carried out more frequently when the patient has a 'clean' (polyp-free) colon,<sup>91</sup> but patients with five or more adenomas should be offered more frequent checks. Colonoscopy may not be beneficial for patients with clean colons and life-expectancy of less than 15 years, since they are very unlikely to develop a new colorectal tumour during this period.

Clinical nurse specialists should check that patients and their carers have their contact details, and that they are aware that they can talk to her or him after discharge from hospital if they are concerned about the disease or its consequences. Patients with stomas will require support for the rest of their lives.

Patients and their GPs should be given full information on symptoms which might signify cancer recurrence. They should have rapid access to the colorectal cancer team if they become aware of such symptoms so that treatment can be initiated as quickly as possible. They should be reassured that the risk of recurrence declines rapidly after the first two years after treatment, until by year five, recurrence is very unlikely.

## B. Anticipated benefits

Short-term follow-up is important to identify problems that the patient experiences after surgery so that remedial action may be taken. Colonoscopic examination may detect adenomas or carcinomas which were missed at the time of initial diagnosis and surgery, whilst liver CT can detect treatable metastatic disease. Longer term follow-up can provide useful information for audit of outcomes and is required in many clinical trials, but it is not clear what aspects of follow-up offer significant benefits for individual patients.

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<sup>91</sup> In this context, a "clean colon" means no evidence of significant polyps or tumour in the bowel.

## C. Evidence

Note: the reliability and quality of evidence supporting the recommendations is graded as A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

### Short-term follow-up

#### Post-treatment colonoscopy

A colonoscopic examination three years after removal of adenomas is as effective for detection of new potentially pathogenic adenomas as colonoscopy one year later.(A: see evidence review for 1997 edition of this document.) Most recurrences develop outside the bowel, in the liver, lung or abdominal cavity, and cannot, therefore, be identified by colonoscopy.

#### Hospital vs. GP follow-up

One small randomised controlled trial (RCT), which included patients who underwent surgery for colorectal cancer, compared immediate discharge to the GP with hospital follow-up over six months. GP follow-up was found to be equally satisfactory. Most patients who developed symptoms consulted their GP initially, regardless of the group to which they were allocated.(A: see evidence review for 1997 edition of this document.)

Follow-up in hospital will be compared with primary care-based follow-up in the recently-launched FACS trial. Results are not expected until 2008.

#### Longer term follow-up

Evidence published since the first edition of this guidance shows that follow-up can increase the probability of long-term survival after surgery for colorectal cancer, at least among patients with Dukes' stage B/C disease.(A) There have been two recent meta-analyses, both of which used data from the same five RCTs (n=1342), which show that more intensive follow-up is associated with significant improvements in five-year survival rates. Both reported a risk ratio for all-cause mortality of 0.81 (95% CI: 0.70 to 0.94).(A) These results should, however, be interpreted with caution because the trials on which they are based were small, the type of follow-up programmes evaluated varied widely, and there was significant heterogeneity between them. It was not clear what elements of the more intensive follow-up programme were important.

Two additional RCTs investigating follow-up were not included in these meta-analyses. In one of these (discussed in the previous edition of this guidance), levels of CEA (carcinoembryonic antigen, a cancer marker which can be detected in blood) levels were monitored and second-look surgery was considered when CEA rose in the intervention group. This trial closed when it was discovered that mortality levels in this group were significantly higher than in control patients.

The second trial varied follow-up strategies according to the risk of recurrence in individual patients. The five-year survival rate among patients who had risk-adapted follow-up was significantly greater than for those in the minimal follow-up group. The authors concluded that follow-up is efficient and cost-effective if patients at higher risk are followed up more intensively than those at lower risk.(A) Patients at greatest risk are those with more advanced tumours at the time of resection – particularly Dukes' stage C.

The liver is the most common site of recurrence after complete excision of the primary tumour and liver resection can lead to long-term survival in some patients. There has, therefore, been particular interest in the effectiveness of liver imaging in follow-up. Two RCTs (included in the meta-analyses) found that more frequent liver CT scans resulted in the detection of more asymptomatic metastases, but did not increase the number of curative liver resections. Two further studies of liver CT during follow-up reported accuracy rates of 87%.(B)

Eight proposed or on-going RCTs, designed to answer outstanding questions about the optimum follow-up after curative resection of colorectal cancer, have been identified. In the UK, the NCRN trial of follow-up strategies (FACS) aims to randomise 4890 patients to investigate the value of monitoring CEA in primary care and intensive hospital follow-up with CT and ultrasound scanning of the liver or abdomen. The detection of metastatic disease suitable for surgical treatment is a key feature of the study.

### **Follow-up in the NHS**

Follow-up practice by 140 consultant colorectal cancer surgeons in England and Wales in 1995 was very variable, ranging from a single routine appointment to regular out-patient appointments for more than 10 years. Most surgeons continued routine follow-up for two to five years after initial surgery. Surgeons who specialised in gastrointestinal disorders used colonoscopy significantly more frequently, whilst non-specialists were more likely to use barium enema. Routine imaging to detect asymptomatic liver metastases was relatively unusual; 23% used liver ultrasound and just 4% used liver CT.<sup>92</sup>(B)

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<sup>92</sup> Mella J, Biffin A, Radcliffe AG, Stamatakis JD, Steele RJ. Population-based audit of colorectal cancer management in two UK health regions. Colorectal Cancer Working Group, Royal College of Surgeons of England Clinical Epidemiology and Audit Unit. *Br J Surg* 1997;**84**:1731-1736.

## Cost-effectiveness of follow-up in the NHS

The relative cost-effectiveness of intensive and conventional follow-up strategies has been estimated using figures for NHS costs in 2002 and life expectancy data for the UK. Estimates of resource use and effects of follow-up strategies on survival were derived from the studies included in the meta-analyses discussed above.

Based on data from the four-study meta-analysis, which included only those trials in which surveillance was designed to detect extraluminal recurrence, costs per patient were calculated to be £4,758 for intensive follow-up and £2,279 for conventional follow-up. This represents an incremental cost per life-year gained by intensive follow-up of £3,007. Similar calculations based on the five-study meta-analysis produced a cost per life-year gained of £3,042. These results suggest that the cost-effectiveness of intensive follow-up after surgery for colorectal cancer compares favourably with that of other interventions which are currently widely used in the NHS.<sup>93</sup>

## Psychological and other outcomes

Follow-up may have positive or negative psychological outcomes. Positive outcomes include reassurance and support. Negative outcomes include false reassurance, increased anxiety, fear associated with early detection of an incurable recurrence, morbidity and mortality associated with operations done in response to abnormal test results, and distress caused by false-positive results.

Recurrence of colorectal cancer is usually symptomatic. Around 75% of recurrences produce symptoms between follow-up appointments, even if these are scheduled at three-monthly intervals. There is evidence that reassurance at follow-up consultations can lead some patients to fail to report symptoms promptly when they do occur between appointments. (B: see evidence review for 1997 edition of this document.)

## D. Measurement

### Structure

- Access to specialist treatment for recurrent colorectal cancer.
- Evidence that patients and their GPs have an agreed system for short-term follow-up and continuing access to hospital specialists when required.

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<sup>93</sup> Renehan AG, O'Dwyer ST, Whyne DK. Cost effectiveness analysis of intensive versus conventional follow-up after curative resection for colorectal cancer. *BMJ* 2004;**328**:81-84.

## E. Resource implications

The recommendations in this section are not expected to have any significant impact on resource use. Studies of costs of follow-up are summarised in the evidence review carried out for this guidance; these show considerable variability and it is not possible to draw any meaningful conclusions from them.

# Recurrent and advanced disease

## A. Recommendations

Cancer Networks should agree guidelines for the management of patients with recurrent and advanced disease. These guidelines should specify referral pathways to specialised multi-disciplinary teams (MDTs) for patients who are believed to have metastases confined to part of the liver or lung, for whom curative interventions may be possible.

All patients with recurrent or metastatic disease should be discussed by the colorectal cancer MDT when the recurrence is first discovered. Members of the team should discuss options for treating the disease and palliating symptoms with the patient. Treatment plans should be recorded for each patient and all treatment given should be audited against locally-agreed guidelines.

Any proposed treatments should be clearly explained to patients, who should be given realistic information both about potential effectiveness and adverse effects. Patients should be invited to become actively involved in decision-making about treatment options, if this is what they want. Patients', carers and families should be kept informed, and information given to family members should not be withheld from the patient (see Topic 1, *Patient-centred care*).

Specialist palliative care teams should be involved in caring for patients with advanced disease (see Topic 11, *Palliative care*). Palliative care specialists should be involved in the management of patients throughout their illness, but their contribution is especially important for those who develop symptoms which are difficult to control, or who have psychosocial problems.

### **Management of patients with localised liver or lung metastases**

Patients with metastases confined to limited areas of the liver or lung, and who are sufficiently fit to undergo further treatment after resection of the primary tumour, should be referred to a specialist MDT for an opinion on their management. Any patient for whom resection or ablation of liver metastases might be appropriate should be discussed by a specialist liver resection MDT (see Topic 3, *Multi-disciplinary teams*).

Liver resection teams should work with colorectal cancer teams within each Cancer Network to develop policies on chemotherapy for patients who are to receive liver resection. There should be close liaison between oncologists in colorectal cancer MDTs and the specialist team to which they refer patients with liver metastases. The oncologist from the referring MDT should be invited to join the specialist MDT for meetings at which these patients are to be discussed. Participation in clinical trials evaluating the role of adjuvant chemotherapy in addition to liver resection should be encouraged.

Pre-operative chemotherapy may be appropriate to shrink liver metastases; the National Institute for Clinical Excellence (NICE) recommends that the combination of oxaliplatin and FUFA should be considered for patients with metastases confined to the liver, whose disease might become resectable after chemotherapy.<sup>94</sup>

### **Interventions to reduce problems associated with advanced colorectal cancer**

A variety of interventions, including debulking surgery, stenting, chemotherapy and radiotherapy, may be used to relieve problems caused by locally advanced colorectal cancer. Colorectal cancer MDTs should consider which of these might be appropriate for individual patients.

#### **Palliative surgery and stent insertion**

Palliative surgery to reduce tumour bulk and relieve intestinal obstruction can have an important role in the management of patients with advanced colorectal cancer. Stenting should also be available to relieve bowel obstruction, particularly in frail patients and those with significant co-morbidity.

#### **Chemotherapy**

Patients with newly-diagnosed recurrent or metastatic disease should have the opportunity to discuss chemotherapy with an oncologist. The recommendations below are based on appraisals published by NICE before August 2003. The results of a number of large trials evaluating the role of current and new chemotherapeutic agents, used singly or in combination, and including some drugs that can be taken by mouth, have been reported recently; further results will become available during the next two years. The results of these trials are likely to influence care, particularly for advanced disease. An update of the appraisal guidance on drugs to treat advanced colorectal cancer is expected from NICE in late 2005.<sup>94</sup>

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<sup>94</sup> National Institute for Clinical Excellence. *Guidance on the use of irinotecan, oxaliplatin and raltitrexed for the treatment of advanced colorectal cancer*. Technology Appraisal Guidance No. 33. London: NICE, 2002 <[www.nice.org.uk](http://www.nice.org.uk)>.

The oncologist should assess the patient's suitability for palliative chemotherapy, which should usually be offered to patients with reasonable performance status (normally, those who are capable of getting up and looking after themselves). Initial chemotherapy treatment should normally be based on either infused FUFA or an oral fluoropyrimidine.<sup>95</sup> Trusts should have the infrastructure available to offer infusional chemotherapy delivered through central venous access catheters. Whatever form of chemotherapy is used, patients should be given full information about its nature, possible adverse effects, and what action they should take if problems develop. (See Topic 1, *Patient-centred care*.)

Palliative chemotherapy is normally given for a period of months, followed by radiological assessment of response. Intermittent use of 5FU-based chemotherapy may be as effective as continuous treatment until disease progression. Oncologists should discuss second line chemotherapy with patients whose cancer continues to progress.<sup>96</sup>

Participation in clinical trials evaluating palliative chemotherapy – for example, the Medical Research Council (MRC) CRO8 (FOCUS) trial of first-line irinotecan and oxaliplatin combination therapies – is strongly encouraged. Clinicians should discuss enrolment in such studies with suitable patients. Further studies are necessary to assess the effectiveness of chemotherapy in older patients, who form the majority of patients with colorectal cancer but who tend to be under-represented in trials.

### **Palliative radiotherapy**

Short courses of radiotherapy (one to five fractions) should be available without delay for patients with metastatic disease in the bones or lungs. Radiotherapy should also be offered to those patients with locally recurrent or advanced rectal cancer and pelvic pain, who have not previously undergone radiotherapy.

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<sup>95</sup> National Institute for Clinical Excellence. *Guidance on the use of capecitabine and tegafur with uracil for metastatic colorectal cancer*. Technology Appraisal No. 61. London: NICE, 2003 <[www.nice.org.uk](http://www.nice.org.uk)>.

<sup>96</sup> See NICE appraisals referenced above.

## B. Anticipated benefits

Surgery for metastases confined to the liver or lung can be curative when carried out by specialists with experience of this type of work. Although such resection is only appropriate for a minority of patients, it can increase five-year survival rates from close to zero to over 30%.<sup>97</sup> Pre-operative chemotherapy can produce a similar increase in survival rates in selected patients whose liver metastases are initially too extensive for surgery, by shrinking the tumour so that curative resection becomes possible.

In advanced or metastatic disease, early chemotherapy can increase survival time, reduce symptoms and improve quality of life; nevertheless, some patients who could benefit do not receive it. Chemotherapy can be particularly effective if it is given before symptoms develop – as they inevitably will if the disease has progressed beyond the point at which curative resection is possible.

Palliative surgery or stenting can relieve symptoms of locally advanced disease in some patients; for those with locally advanced rectal cancer for whom surgery may not be appropriate, radiotherapy can provide valuable palliation and may prolong survival in some patients. Palliative radiotherapy is also effective for pain relief in patients with bone metastases.

## C. Evidence

Note: the reliability and quality of evidence supporting the recommendations is graded as A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

### **Palliative stents**

The evidence on stenting is summarised in Topic 5, *Surgery and histopathology*. This shows that stents can provide effective and cost-effective palliation of intestinal obstruction in advanced colorectal cancer, obviating the need for a stoma or resection, often until death. They cause relatively few adverse effects.(B)

### **Surgery for liver and lung metastases**

Curative surgery is sometimes possible when metastases are small and localised. There are no good comparative studies but case series reports suggest five-year survival rates of 30-35% in selected patients.(B: see evidence review for 1997 edition of this document.) However, few patients can be treated successfully in this way.

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<sup>97</sup> Stangl R, Altendorf-Hofmann AA, Charnley RM, Scheele J. Factors influencing the natural history of colorectal liver metastases. *Lancet* 1994;**343**:1405-1410.

## Chemotherapy

Meta-analysis of individual patient data from 13 randomised controlled trials (1365 patients) shows that palliative chemotherapy increases median survival time by 3.7 months and reduces the risk of death by 35% (hazard ratio 0.65, 95% CI: 0.56 to 0.76). This represents an absolute improvement in survival rate of 16% at one year.(A) A second meta-analysis (seven trials, 614 patients) also reported significantly lower mortality rates with palliative chemotherapy for patients with metastatic colorectal cancer. In four of these studies, quality of life was found to be either similar or better in patients who received chemotherapy than in those who did not.

There have been two recent NICE appraisals of newer chemotherapeutic agents for advanced and metastatic disease. The evidence on which these appraisals were based is summarised on the NICE website.<sup>98</sup>

Chemotherapy given early in the course of metastatic disease produces better outcomes than chemotherapy given after symptoms have become severe, increasing survival by three to six months without increasing adverse effects on quality of life.(A)

## Palliative radiotherapy

External radiotherapy used alone eases pain in a high proportion of patients with locally advanced rectal cancer. In some patients, tumours have gone into complete remission or regressed sufficiently to permit curative surgery after prolonged fractionated radiotherapy of 45 to 50 Gy.

4-7% of patients develop bone metastases, for which palliative radiotherapy has been shown to be effective.(A: see evidence review for 1997 edition of this document.)

## D. Measurement

### Structure

- Systems allowing rapid access to the colorectal cancer treatment team for patients who develop symptoms of recurrent disease.

### Process

- Audit of treatment planned for each patient, treatment actually given, and delay between the decision to offer treatment and initiation of treatment.

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<sup>98</sup> National Institute for Clinical Excellence. *Guidance on the use of irinotecan, oxaliplatin and raltitrexed for the treatment of advanced colorectal cancer*. Technology Appraisal Guidance No. 33. London: NICE, 2002; also, *Guidance on the use of capecitabine and tegafur with uracil for metastatic colorectal cancer*. Technology Appraisal No. 61. London: NICE, 2003 <[www.nice.org.uk](http://www.nice.org.uk)>.

- Audit of outcomes, including symptoms and adverse effects of treatment.
- Protocols to guide symptom assessment and treatment and recording of data on their use.
- Audit of use of palliative treatment.

### **Outcome**

- Results of symptom control audits.
- Surveys of satisfaction with care.

## **E. Resource implications**

The use of chemotherapy for advanced and metastatic disease is likely to continue to increase, but oral chemotherapy may be less expensive than intravenous therapy.

Surgery for localised metastatic disease is likely to be undertaken more frequently. Such surgery is normally carried out in specialist tertiary Centres and additional resources are likely to be required to allow these Centres to expand the volume of surgery carried out. The cost of this expansion has not been calculated.

Palliative stenting is highly cost-effective and could conserve resources when used instead of palliative surgery.

# Palliative care

The National Institute for Clinical Excellence (NICE) guidance on supportive and palliative care for adults with cancer<sup>99</sup> will be published in 2004. It is intended to complement site-specific guidance, giving detailed recommendations on many issues relevant to this section as they apply to cancer care generally, with supporting evidence. The areas it covers are listed at the beginning of Topic 1, *Patient-centred care*.

## A. Recommendations

Most patients with advanced colorectal cancer stay in their own homes and GPs and district nurses play crucial roles in their care. Primary care teams should have access to advice from palliative care specialists, who should be involved in the management of all patients with advanced disease. Specialist nurses should remain in contact with patients throughout the course of their disease and aftercare.

Patients with advanced colorectal cancer may benefit both from treatment of the cancer (see Topic 10, *Recurrent and advanced disease*) and from palliative care. These are overlapping approaches to management.

### **Pain and symptom control**

Control of pain and other symptoms is crucial for patients suffering from advanced colorectal cancer. Palliative care specialists should be members of, and integrated with, colorectal cancer multi-disciplinary teams (MDTs); their role includes the provision of education and advice for other health professionals – in the community as well as in hospitals – and direct patient management. Specialist pain control is particularly important for patients with locally recurrent rectal cancer, in whom pain can be very severe and difficult to manage.

### **The palliative care team**

The role of the multi-disciplinary specialist palliative care team is described in the NICE guidance to which reference is made above.

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<sup>99</sup> National Institute for Clinical Excellence. Improving supportive and palliative care for adults with cancer.

## B. Anticipated benefits

Provision of effective palliative treatments and adequate pain control, combined with high quality care services, can improve quality of life for people with advanced colorectal cancer.

## C. Evidence

Note: the reliability and quality of evidence supporting the recommendations is graded as A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

A postal survey of GPs of 213 patients diagnosed with lung or colorectal cancer in a single (former) UK health Trust found that 20% of GPs were unwilling to define patients as needing palliative care, although an unambiguous diagnosis of incurable malignancy had been made by specialist hospital doctors in out-patient consultation letters or discharge summaries. Similar numbers of GPs expressed dissatisfaction with the promptness (26%), clarity about treatment and future management (16%), and adequacy (25%) of information provided by the hospital.(B)

## D. Measurement

### Structure

- Evidence that adequately resourced and staffed specialist palliative care services are available in hospitals, hospices and the community.
- Evidence that specialist pain relief services are available when required.
- Providers should demonstrate clear mechanisms for referral to, and communication between, primary care, community, hospice and hospital services involved in the delivery of general and specialist palliative care.

### Process

- Use of written guidance on symptom assessment and treatment.
- Proportion of patients referred to specialist palliative care services.

## **Outcome**

- Results of symptom control audits.
- Surveys of patients' and carers' satisfaction with care.

## **E. Resource implications**

Increased resources are required in some areas to create effective multi-disciplinary palliative care teams and to monitor outcomes.

# Economic implications of the manual update

A1

## Expansion of endoscopy services

### Summary

A cost impact exercise has identified the cost implications of the guidance update for colorectal cancers for England and Wales in one specific area: the expansion of endoscopy services for the diagnosis of colorectal cancer.

The current primary diagnostic approach varies between hospitals, but includes use of barium enema alone or in combination with flexible sigmoidoscopy, flexible sigmoidoscopy alone and/or colonoscopy. There has been a trend towards the increasing use of flexible sigmoidoscopy and colonoscopy over the last few years. Between 1995/6 and 2000/1 the number of colonoscopies increased by 66% and the number of flexible sigmoidoscopies increased by 86%.

Based on hospital episode statistics (HES) data for England for 2002/3 and a recent audit of endoscopy activity in Wales, current activity levels are estimated to be around 159,000 flexible sigmoidoscopies and 178,000 colonoscopies per annum for England and Wales. Based on a cost of flexible sigmoidoscopy of £57 and a cost of colonoscopy of £208, the total cost of these procedures is estimated to be around £45 million.

The cost impact analysis demonstrates the NHS impact of moving from the current position to a situation in which on average 85% of all referrals in England and Wales would receive a flexible sigmoidoscopy as the initial investigation and 15% would receive a full bowel examination, assumed to be a colonoscopy. In addition, 30% of those who received a flexible sigmoidoscopy are assumed to go on to require a whole bowel examination, again assumed to be a colonoscopy. This shift would result in approximately 266,000 additional flexible sigmoidoscopies (an increase of 180% over current levels), and 20,000 additional colonoscopies, (an increase of 11% over

current levels), in England and Wales each year over and above 2002/3 levels. Based on a cost of flexible sigmoidoscopy of £57 and a cost of colonoscopy of £208, the total cost of these additional procedures is estimated to be around £19.3 million (£15.2 million for flexible sigmoidoscopies and £4.1 million for colonoscopies), an increase of 42% over current levels.

Given the large investment in physical equipment and staff training necessary for the implementation of this guidance, it is likely that the volume of endoscopies will rise gradually over a number of years and therefore the full cost of implementation will not accrue for several years.

The cost estimates derived by the analysis are subject to significant uncertainty. In sensitivity analysis the cost estimates vary between £2 million, if it is assumed that only 10% of patients receive a colonoscopy following initial flexible sigmoidoscopy, and £44.6 million, using NHS reference (HRG) procedures costs for flexible sigmoidoscopy and colonoscopy.

Further work has been identified which would improve the robustness of the results. This analysis does, however, inform future analytical work by identifying current data gaps and the major areas of uncertainty.

A number of further cost implications have not been specifically addressed by this report, for example the major training implications relating to further expansion of endoscopy services. Supporting services such as histopathology will be stretched by the increase in endoscopy as the removal of more polyps and suspicious lesions from the lower gastro-intestinal (GI) tract generates increased demand for histopathological assessment of tissue samples. This expansion in histopathology workload will need to be adequately supported. The impact of new diagnostic tools on endoscopy activity and costs will need to be considered in future studies. Many leading Cancer Centres are now investing in diagnostic tools such as computed tomography (CT) colonography, potentially reducing the future need for invasive endoscopic procedures.

Cost savings may be achieved from reductions in the volumes of barium enemas and a reduction in the volume of inappropriate surgery. Further evidence is required to accurately quantify these potential costs savings.

# How this manual update was produced

## Summary of the methodology for producing the manual update

A2

The methods used for the production of the original guidance is described in Appendix 1 of the original document.

Prior to the commencement of the work on this manual update, a range of experts in all the main clinical disciplines were approached. They were asked what, if anything, had altered since the 1997 guidance sufficiently to necessitate changes or additions to the recommendations. Specifically, responses were sought on both those aspects of the manual (published in 1997) which were now felt to be outdated, and current issues of relevance not covered in the original manual.

Using the resulting material as the basis for discussion, an initial scoping meeting was held (a sub-group of the National Cancer Guidance Steering Group) to begin the identification of the issues for which evidence reviews would be required.

It was agreed with the Centre for Reviews and Dissemination (CRD) that the aim of these reviews would be focused. Areas would not be reviewed without some indication that significant new evidence, or changes in practice, might have occurred in the relevant fields.

An Editorial Group was then constituted representing appropriate disciplines/interests. It was chaired by Professor Bob Steele, a colorectal surgeon, who had been involved in the guidance work since its inception, and had been on the Editorial Group that prepared the original guidance.

The final set of review questions was refined and agreed between the evidence reviewers at CRD and the Editorial Group. As the evidence review progressed, Editorial Group meetings were held with the reviewers to critically examine the findings, and to agree the nature of revisions to be made to the manual and the recommendations in the light of the new evidence. These were drafted by the writer in an iterative process involving reviewers and Editorial Group members.

Draft versions of the revisions were subjected to external comment:

- Views on the key service issues were sought from those who commission the service, via a Focus Group, as the writing progressed.
- The full National Institute for Clinical Excellence (NICE) consultation processes were undertaken with stakeholders and through the 'open web-site'.

These comments were carefully reviewed.

A single topic, the expansion in endoscopy capacity, was selected and agreed by the Editorial Group for economic review. The implementation of the recommended shift in the use of diagnostic techniques for colorectal cancers was judged to be likely to carry the most significant cost implications for the NHS.

(NB: a full economic review was not part of the funded methodology when the original manual was developed.)

NICE prepared a lay summary of the manual, in accordance with the Institute's policy.

The proposed manual update, and the developer's responses to comments received, were reviewed by the NICE Guidelines Advisory Committee Panel, and signed off by the NICE Guidance 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.

The systematic reviews used to inform the manual are summarised in the document *Improving Outcomes in Colorectal Cancers: Research Evidence for the Manual Update*. This document includes details of all the studies to which the manual refers. It is available on the CD-ROM provided with this manual, and is also available in printed format as a CRD report (email: [crdpub@york.ac.uk](mailto:crdpub@york.ac.uk), Tel: 01904 433648).

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*(Participants in the production of the original guidance are given in the original manual appendices, available on the accompanying CD-ROM.)*

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A3

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A3

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# Glossary of terms

## **Abdomino-pelvic**

The area of the body from below the ribs and lungs to between the hip bones.

## **Acute**

Sudden or severe.

## **Adenocarcinomas**

Malignant growths of glandular tissue.

## **Adenomas**

Usually benign growths or cysts arising from epithelial tissue - the membrane-like tissue that lines internal and external surfaces of the body including organs, vessels and other small cavities. See *adenomatous polyps*.

## **Adenomatous polyps**

Tumours which normally protrude from the inner surface of the *bowel*. These tumours are generally benign when small, but may grow and become malignant.

## **Adjuvant chemotherapy**

The use of *chemotherapy* after initial treatment by surgery and/or *radiotherapy*. The aim of adjuvant therapy is to destroy any cancer that has spread.

## **Adjuvant radiotherapy**

The use of *radiotherapy* in association with treatment by surgery. This is used for rectal, rather than *colon*, cancer, and may be given before or after surgery to reduce the risk of *recurrence*.

## **Advanced disease**

Cancer that has spread from where it started to another part of the body. Locally advanced cancer usually means the cancer has grown outside the organ that it started in and into neighbouring body tissues. See *metastatic disease*.

## **Age-standardised incidence**

A method of more accurately comparing incidence rates between populations by removing differences in the age distributions of those populations.

**Anaemia**

A condition in which the number of red blood cells in the blood is below the normal range.

**Anal sphincter**

The muscle around the *anus*, essential for faecal *continence*.

**Anastomatic dehiscence**

Breakdown of the surgical re-connection of the *bowel*.

**Anastomatic leak**

Leakage from the surgical re-connection of the *bowel*.

**Anastomosis**

Re-connecting or joining together. In *bowel* surgery, the joining together of two pieces of *bowel* which have been cut to remove the intervening section.

**Anti-platelet therapy**

Therapy which decreases the clumping of blood platelets and so inhibits the formation of blood clots.

**Anus**

The muscular area at the very end of the *colon* where the *bowel* opens onto the outside of the body.

**Ascending colon**

Part of the *colon* located on the right hand side of the abdomen which rises from the *caecum* to below the liver.

**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, then reassessed.

**Barium enema**

Technique for examination of the *bowel*. Barium sulphate, introduced as a liquid into the *bowel* through the *anus*, is used to coat the inner surface of the *colon* and *rectum* so that it can be seen using x-rays.

**Biological equivalent dose (BED)**

Multiplication of the absorbed dose of radiation by a radiation weighting factor (which depends on the type and amount of radiation involved) in order to account for the effects different types of radiation have on tissue.

**Biopsy**

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

## **Bowel**

A general term for the small and large intestine.

## **Bowel preparation**

Clearing the *bowel* prior to *endoscopy* or surgery through the use of suppositories, an enema or the taking of laxatives followed by a *bowel* washout.

## **Caecum**

The first part of the *colon* located on the lower right hand side of the abdomen.

## **Cancer Networks**

The organisational model for cancer services to implement the NHS Cancer Plan, bringing together health service commissioners and providers, the voluntary sector and local authorities. There are currently 34 Cancer Networks covering between 600,000 and three million population, (two-thirds serve a population of between one and two million people).

## **Carcinoembryonic antigen (CEA)**

A protein found in the blood which may increase in quantity when a person has colorectal cancer.

## **Carcinoma**

Cancer of the epithelial tissue that covers all the body organs and lines all the body cavities. Most cancers are carcinomas.

## **Central venous catheter**

A thin plastic tube which is inserted into a vein in the chest through which blood tests can be taken and *intravenous chemotherapy* and blood transfusions can be given. Once in place it can remain in the vein for many months.

## **Chemoradiotherapy (CRT)**

Treatment that combines *chemotherapy* and *radiotherapy*.

## **Chemotherapy**

The use of drugs that kill cancer cells, or prevent or slow their growth. Second-line chemotherapy is the use of a second drug, or cocktail of drugs, where the cancer is not or is no longer responsive to the initial chemotherapy given. Infusional chemotherapy is given directly into a vein via a *central venous catheter*.

## **Chronic**

Long-lasting or slowly progressing.

### **Circumferential margin involvement**

Cancer cells in the tissue around the circumference of the segment of *bowel* where the cancer originated. Also used to describe tumour involvement in the circumference of tissue removed during surgery.

### **Clinical oncologist**

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

### **Colitis**

Inflammation of the *colon*.

### **Colon**

Part of the gastro-intestinal tract responsible for forming, storing and expelling waste matter. Also known as the large intestine.

### **Colonoscope**

A long, flexible, tubular instrument with a light at the end used to examine the inside of the *bowel*. A colonoscope is capable of reaching to the upper end of the *colon* and can be used for the removal of *polyps*.

### **Colonoscopist**

A person who examines patients using *colonoscopy*.

### **Colonoscopy**

Examination of the interior of the *bowel* using a *colonoscope* inserted through the *anus* (also see *sigmoidoscopy*).

### **Colostomy**

A procedure to create an opening of the *colon* onto the front of the abdomen. The opening is called a *stoma*. A bag is worn over the *stoma* to collect the stools.

### **Community**

Non-hospital based services.

### **Completion (colonoscopy)**

Completion is where the *colonoscopist* is able to inspect the whole *colon* by getting the tip of the *colonoscope* all the way to the *caecum*, where the large *bowel* ends.

### **Computed tomography (CT)**

An x-ray imaging technique.

### **CT colonography**

Examination of the interior of the *bowel* by using *computed tomographic (CT)* imaging to simulate the effect of a conventional *colonoscopy*.

**Continence**

Ability to control urination (urinary continence) or bowel movements (*faecal continence*).

**Crohn's disease**

A *chronic bowel* condition which is associated with a small increased risk of colorectal cancer.

**Curative resection**

Operation in which the surgeon believes that all cancer-containing tissue has been removed.

**Debulking**

Operation to remove as much of a large tumour as can be removed. This is done to make it easier to treat the cancer that is left.

**Descending colon**

Part of the *colon* which bends downwards on the left hand side of the abdomen and descends into the pelvis where it becomes the *sigmoid colon*.

**Double contrast barium enema**

Technique (see *barium enema*) in which the *bowel* is filled with air or gas between the introduction of barium and radiographic imaging. This allows accurate visualisation of the inner surface of the *bowel*.

**Dukes' stage**

Refers to the allocation of categories to groupings of tumours defined by internationally agreed criteria. Stages defined by Dukes range from stage A, which is cancer limited to the bowel wall, to stage C, where the cancer has spread to nearby lymph nodes. Stage D has been added to this system to include cancers with *metastatic* spread.

**Endoscopist**

A person who examines patients using *endoscopy*.

**Endoscopy**

Examination of the interior of the digestive system using a tubular device with a light at the end. For examination of the *lower gastrointestinal tract* a *colonoscope* or *sigmoidoscope* is inserted through the *anus*.

**Epidemiology**

The study of populations in order to determine the frequency and distribution of disease and to measure risks.

**Faecal incontinence**

Inability to control the escape of stool from the *rectum*.

**Faecal occult blood (FOB) test**

A chemical test that can pick up minute traces of blood in the faeces.

**Familial adenomatous polyposis (FAP)**

An inherited condition which leads to the development of huge numbers of colorectal *polyps* in early adulthood. Individuals who carry the FAP gene are likely to develop colorectal cancer by the age of 40 unless preventive action is taken.

**Field**

In *radiotherapy*, the area selected for treatment, on which the *radiotherapy* beam is focused.

**First degree relatives**

Parents, siblings, sons and daughters.

**Fistula**

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

**Flexible sigmoidoscopy**

See *sigmoidoscopy*.

**Fraction**

*Radiotherapy* is usually given over an extended period. The dose delivered each day is known as a fraction.

**Gastroenterologist**

A doctor who specialises in disorders of the digestive system including the liver.

**Grade (of tumour)**

The degree of similarity of the cancer cells to normal cells. Grade is assessed by a *pathologist*.

**Haemorrhoids**

Swelling of the veins in the anal canal. Also known as piles.

**Hepatobiliary**

Having to do with the liver and biliary tract.

**Hereditary non-polyposis colorectal cancer (HNPCC)**

An inherited condition which predisposes individuals to developing colorectal cancer at an unusually young age.

**Histopathologist**

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

**Hospice**

A place or service that provides specialist *palliative care* for patients with progressive, advanced disease.

**Ileum**

The last and longest section of the small intestine. The final portion, where it joins the large intestine (*colon*), is called the terminal ileum.

**Immunosuppression**

Suppression of the body's immune system.

**Inflammatory bowel disease**

Any condition in which the *bowel* is *chronically* inflamed, such as *Crohn's Disease* or *ulcerative colitis*.

**Interventional radiologist**

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

**Intra-luminal obstruction**

Obstruction within a tube - in this case the *bowel*.

**Intravenous (IV)**

Into a vein.

**Kappa**

Measure of agreement.

**Laparoscopic surgery**

Surgery performed using a laparoscope; a special type of *endoscope* inserted through a small incision in the abdominal wall.

**Local excision**

A small operation to remove an early cancer that has not spread away from where it started growing.

**Local failure or recurrence**

*Recurrence* of disease at the site of the original tumour following initial potentially curative treatment. Locoregional *recurrence* is where the tumour returns in the same area of the body.

**Lower GI**

The lower gastro-intestinal tract comprising the *colon*, *rectum* and *anus*.

**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 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). Specially designed coils may be used to produce high resolution images of particular areas of the body e.g. endorectal coils for rectal imaging.

**Margins of excision/resection; surgical margins**

The edges of the tissue removed during surgery.

**Medical oncologist**

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

**Meta-analysis**

The statistical analysis of the results of a collection of individual studies to synthesise their findings.

**Metastasis**

The spread of a cancer from the primary site to somewhere else via the bloodstream or the lymphatic system.

**Metastatic disease**

Cancer which has spread to a site distant from the original site.

**Occult proximal cancers**

Asymptomatic cancers further up the *colon* than the portion examined.

**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 causes and treatment of cancers.

**Opportunistic screening**

Early diagnosis involving the use of screening methods (e.g. *faecal occult blood test*) or diagnostic techniques (e.g. *flexible sigmoidoscopy*) appropriate to colorectal cancer in patients attending a health facility - usually primary care, for other reasons. Thus individuals are offered screening only when the opportunity presents, not through structured population based call services. The recipients would normally be in the relevant age groups and their presenting problem would not otherwise require such investigation.

**Palliation**

The alleviation of symptoms due to the underlying disease or its treatment.

**Palliative care**

Active, holistic care of patients with advanced, progressive illness which may no longer be curable. The aim is to achieve the best quality of life for patients and their families. Many aspects of palliative care are also applicable in earlier stages of the cancer journey in association with other treatments.

**Pathogenic**

Disease-producing.

**Pathologist**

A person who specialises in the diagnosis of disease through study of the microscopic structure of cells and tissues.

**Performance status**

A way of describing how much a person is able to do. The most common is the World Health Organisation scale which ranges from 0 (fully active) to 4 (bedridden).

**Perineum**

The area between the *anus* and the genital organs. Also known as the crotch.

**Peri-operative**

Around the time of surgery. Usually the time from admission to hospital to discharge following surgery.

**Peritonitis**

Inflammation of the peritoneum - the membrane which lines the walls of the abdomen and the organs within it.

**Plexus**

A network of nerves and/or blood vessels.

**Polypectomy**

Surgical removal of one or more *polyps*.

**Polyps**

See *adenomatous polyps*.

**Positron emission tomography (PET)**

A highly specialised imaging technique used to produce a computerised image of metabolic activity of body tissues.

**Primary disease**

Where the cancer started.

**Prophylaxis**

An intervention used to prevent an unwanted outcome.

**Protocol**

A policy or strategy which defines appropriate action.

**Psychosocial support**

Support concerned with psychological influence on social behaviour.

**Quality of life**

The individual's overall appraisal of his/her situation and subjective sense of well-being judged by questionnaire.

**Radiologist**

A doctor who specialises in creating and interpreting pictures of areas inside the body. The pictures are produced with x-rays, sound waves, or other types of energy.

**Radiotherapy**

The use of radiation, usually x-rays or gamma rays, to kill cancer cells.

**Randomised controlled trial (RCT)**

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 of effectiveness.

**Rectal endosonography**

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

**Rectum**

The end of the *bowel* where faeces are stored before being passed out of the body through the *anus*.

**Recurrence**

The return of cancer. See *local recurrence*.

**Remission**

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

**Salvage**

Treatment that is given after the cancer has not responded to other treatments.

**Sensitivity**

Proportion of people with disease who have a positive test result.

**Sigmoid colon**

The S shaped part of the large *bowel* located on the lower left of the abdomen.

**Sigmoidoscope**

A tubular instrument with a light at the end. Sigmoidoscopes may be flexible or rigid; flexible sigmoidoscopes are capable of reaching deeper into the bowel.

**Sigmoidoscopy**

Examination of the interior of the *rectum* and lower part of the *colon* (*sigmoid colon*) using a *sigmoidoscope* inserted through the *anus*.

**Specificity**

Proportion of people without disease who have a negative test result.

**Squamous cell carcinoma**

Cancer originating in squamous cells – thin, flat cells resembling fish scales – found in the tissue that forms the surface of the skin, the lining of the hollow organs of the body, and the respiratory and digestive tracts.

**Staging**

The allocation of categories defined by internationally agreed criteria. Staging helps determine treatment and indicates prognosis. There are two main classification systems in use for colorectal cancer - *Dukes' staging* and *TNM*.

**Stent**

A tubular device designed to hold open a tube or opening in the body, such as the *bowel*.

**Stenting**

Putting a *stent* in place.

**Stoma**

A surgically created opening through which the *bowel* is taken to the outer surface of the abdomen, sometimes necessary after surgical interventions for colorectal cancer.

**Supportive care**

Care that helps the patient and their family and carers to cope with cancer and its treatment throughout the cancer journey, and in the case of the family and carers, into bereavement. It aims to help the patient maximise the benefits of treatment and provide the best possible quality of life.

**Systemic**

Involving the whole body.

### **T1 Tumours (rectal)**

Small tumours that are confined to the inside wall of the *rectum*.

### **Temporary stoma**

A temporary *colostomy* done higher up the *bowel* to allow the part of the *bowel* operated on to heal. Once the operation site has healed, the *stoma* is closed up which allows the *bowel* to work normally.

### **Therapeutic colonoscopy**

See *Polypectomy*.

### **Thromboprophylaxis**

An intervention used to prevent thrombosis. See *anti-platelet therapy*.

### **TNM staging**

A staging classification system based on the depth of tumour invasion (T), lymph node involvement (N) and metastatic spread (M). This system is slowly superseding *Dukes' staging*.

### **Total mesorectal excision (TME)**

A technique for surgical removal of rectal cancer which involves meticulous dissection and excision of tissue surrounding the rectum.

### **Transverse colon**

Part of the *colon* which crosses the upper part of the abdomen from right to left between the *ascending* and *descending colon*.

### **Trusts**

In the context of this guidance, Trusts are organisations responsible for managing and/or delivering health services. There are a variety of Trusts, the two most common being Primary Care Trusts (PCTs) and NHS Trusts. PCTs are local organisations responsible for managing health services in a given local area. NHS Trusts manage hospitals, but can also provide services in the *community*.

### **Ulcerative colitis**

A disease which mainly affects the lining of the *colon* which becomes inflamed, swollen and covered in ulcers. This condition is associated with a small increased risk of colorectal cancer.

### **Ultrasound (US)**

High-frequency sound waves used to create images of structures and organs within the body. Intra-operative ultrasound is that carried out during surgery.

### **Vascular invasion**

Invasion of veins or lymphatic vessels by *carcinoma* cells, indicating a propensity for distant spread.

### **Virtual colonoscopy**

See *CT colonography*.

# Abbreviations

<b>5FU</b>	5-fluorouracil
<b>ACPGBI</b>	Association of Coloproctology of Great Britain and Ireland
<b>BED</b>	Biological equivalent dose
<b>BSG</b>	British Society of Gastroenterology
<b>CEA</b>	Carcinoembryonic antigen
<b>CEPOD</b>	Confidential enquiry into peri-operative deaths
<b>CHI</b>	Commission for Health Improvement
<b>CI</b>	Confidence interval
<b>CNS</b>	Clinical nurse specialist
<b>COG</b>	Clinical Outcomes Group
<b>CRT</b>	Chemoradiotherapy
<b>CRUK</b>	Cancer Research UK
<b>CT</b>	Computed tomography
<b>DGH</b>	District general hospital
<b>EORTC</b>	European Organisation for Research and Treatment of Cancer
<b>EPIC</b>	European Prospective Investigation into Cancer and Nutrition
<b>FACS</b>	NCRN trial of follow-up strategies
<b>FAP</b>	Familial adenomatous polyposis
<b>FOB</b>	Faecal occult blood
<b>FUFA</b>	5-fluorouracil and folinic acid
<b>GI</b>	Gastro-intestinal
<b>Gy</b>	Gray (unit of absorbed dose of radiation)
<b>HES</b>	Hospital episode statistics
<b>HIV</b>	Human immunodeficiency virus
<b>HNPCC</b>	Hereditary non-polyposis colorectal cancer
<b>HPB</b>	Hepatobiliary
<b>HPV</b>	Human papilloma virus or human papillovirus
<b>HRG</b>	Healthcare resource group
<b>IDA</b>	Iron deficiency anaemia
<b>MDT</b>	Multi-disciplinary team
<b>MRC</b>	Medical Research Council
<b>MRI</b>	Magnetic resonance imaging
<b>NO</b>	Node (see TNM)
<b>NCRN</b>	National Cancer Research Network
<b>NICE</b>	National Institute for Clinical Excellence
<b>NSAIDs</b>	Non-steroidal anti-inflammatory drugs
<b>ONS</b>	Office for National Statistics
<b>PET</b>	Positron emission tomography

<b>RCT</b>	Randomised controlled trial
<b>RR</b>	Relative risk
<b>RT</b>	Radiotherapy
<b>RTOG</b>	United States Radiation Therapy Oncology Group
<b>T1</b>	Tumour (see TNM)
<b>T3</b>	Tumour (see TNM)
<b>TME</b>	Total mesorectal excision
<b>TNM</b>	Tumour invasion, lymph node involvement and metastatic spread
<b>UKCCCR</b>	United Kingdom Co-ordinating Committee for Cancer Research
<b>US</b>	Ultrasound or United States
<b>WCRF</b>	World Cancer Research Fund



