# **Complete Summary**

#### **GUIDELINE TITLE**

Guidelines for the management of colorectal cancer.

# **BIBLIOGRAPHIC SOURCE(S)**

Association of Coloproctology of Great Britain and Ireland. Guidelines for the management of colorectal cancer. London (UK): Association of Coloproctology of Great Britain and Ireland; 2007. 117 p. [468 references]

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Association of Coloproctology of Great Britain and Ireland. Guidelines for the management of colorectal cancer. London (UK): Association of Coloproctology of Great Britain and Ireland; 2001. 87 p.

## \*\* REGULATORY ALERT \*\*

# FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse**: This guideline references a drug(s) for which important revised regulatory information has been released.

• February 28, 2008, Heparin Sodium Injection: The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.

# **COMPLETE SUMMARY CONTENT**

\*\* REGULATORY ALERT \*\*

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS OUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

## SCOPE

# **DISEASE/CONDITION(S)**

- Colorectal cancer
- Anal cancer

# **GUIDELINE CATEGORY**

Diagnosis
Evaluation
Management
Risk Assessment
Treatment

## **CLINICAL SPECIALTY**

Colon and Rectal Surgery Family Practice Gastroenterology Internal Medicine Oncology Pathology Radiation Oncology Radiology Surgery

# **INTENDED USERS**

Advanced Practice Nurses Allied Health Personnel Nurses Physician Assistants Physicians Public Health Departments

# **GUIDELINE OBJECTIVE(S)**

- To assist clinicians in clinical decision-making and practice by removing uncertainty in areas where it is possible to do so
- To describe the gold standard of good clinical care and to proscribe unacceptable clinical standards

## **TARGET POPULATION**

Patients of all ages with symptoms of colorectal and anal cancer 2 of 22

## INTERVENTIONS AND PRACTICES CONSIDERED

# **Diagnosis/Risk Assessment**

- 1. Risk assessment based on symptoms
- 2. Fast tracking high-risk patients to 2-week clinic/referral with urgent appointment
- 3. Clinical investigations:
  - Sigmoidoscopy (flexible or rigid)
  - Double-contrast barium enema
  - Colonoscopy
  - Computed tomography (CT) colonography
- 4. Preoperative assessment and staging of disease by CT scan, magnetic resonance imaging (MRI) scan, and/or endorectal ultrasound
- 5. Preoperative histology
- 6. Gastrointestinal surveillance based on high, high/moderate, moderate, or low risk criteria, including family history, pathological criteria, or presence of a pathogenic gene mutation

# **Management/Treatment**

- 1. Access to and initiation of therapy
- 2. Preparation for surgery
  - Informed consent
    - Stoma nurse consultation
    - Preparations for blood transfusion
    - Bowel preparation
    - Thromboprophylaxis
    - Antibiotic prophylaxis
- 3. Classification of rectal tumour
- 4. Surgical technique
  - Mesorectal excision: low anterior resection vs abdomino-perineal resection
  - Anastomotic technique
  - Temporary defunctioning stoma
  - Cytocidal washout of rectal stump
  - Local excision
- 5. Laparoscopic surgery
- 6. Record keeping
- 7. Management of patients presenting as emergencies
- 8. Adjuvant radiotherapy and chemotherapy (after discussion with a multi-disciplinary team [MDT])
- 9. Palliative care
- 10. Colonoscopic follow-up
- 11. Histopathologic examination and reporting
- 12. Management of squamous anal cancer
  - Biopsy of suspicious lesion
  - Local staging using anal ultrasound and MRI
  - Anorectal excision
  - Concurrent chemo-radiotherapy

## **MAJOR OUTCOMES CONSIDERED**

- Risk of colorectal cancer
- Sensitivity and specificity of diagnostic tests
- Rates of curative resection
- Operative mortality
- Wound infection
- Anastomotic dehiscence
- Recurrence rates

#### **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

# DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

## **NUMBER OF SOURCE DOCUMENTS**

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

# RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

## **Levels of Evidence**

Ia: Evidence obtained from meta-analysis of randomized controlled trials

**Ib**: Evidence obtained from at least one randomised controlled trial

**IIa**: Evidence obtained from at least one well-designed controlled study without randomisation

**IIb**: Evidence obtained from at least one other type of well-designed quasi-experimental study

**III**: Evidence obtained from well-designed non-experimental descriptive studies such as comparative studies, correlation studies, and case studies

**IV**: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

# METHODS USED TO ANALYZE THE EVIDENCE

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

# METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

An initial steering group set up by the Royal College of Surgeons of England in 1994 decided to develop colorectal cancer guidelines using three approaches: i) carrying out a literature review in areas where there might be an unequivocal scientific basis for recommendations; ii) defining reasonable practice using the results of contemporary audits of the management of all patients presenting with colorectal cancer in Trent, Wales and Wessex; and iii) describing current consensus where there is no research evidence on which recommendations might be based. This has been complemented with information from the literature to provide "gold standards" at which to aim.

This edition of the guidelines follows the pattern of previous editions, using a small drafting committee to produce a document which is circulated to an expert advisory group composed of representatives of the main groups involved with the management of colorectal cancer. For the first time, anal cancer has been incorporated into these guidelines. This edition of the guidelines was organised and funded by the Association of Coloproctology for Great Britain and Ireland.

Around the time the original guidelines were published, two documents appeared which had a significant impact on the provision of colorectal cancer care. These were the Calman Hine report (Department of Health 1995) and Guidance on Commissioning Cancer Services (NHS Executive 1997). These two documents led to significant changes in the way in which care was provided, from being predominantly organised and delivered by individual surgeons, to a multidisciplinary team (MDT) based approach.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

# **Grades of Recommendation**

**A**: Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation (levels Ia, Ib)

**B**: Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendation (levels IIa, IIb, III).

**C**: Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates absence of directly applicable clinical studies of good quality (level IV)

**Note**: Every recommendation carries a grading according to this system. However, the grade cannot be regarded as an absolute indication of the strength of the guideline; although poor research has been omitted or flagged as such in the text, the cited studies are of variable quality. Thus, a guideline may have a grading below that usually associated with the evidence grading if the research is considered to be of poor quality. Some recommendations cover topics which are not amenable to formal studies, but represent good clinical practice (e.g. informed consent). These items are labeled as **GCP** (good clinical practice) in this summary.

#### **COST ANALYSIS**

Published cost analyses were reviewed.

#### METHOD OF GUIDELINE VALIDATION

Not stated

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Not applicable

## RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

The levels of evidence (Ia to IV) and grades of recommendations (A to C and GCP [**Good Clinical Practice**]) are defined at the end of the "Major Recommendations" field.

## **Investigations**

# The Process of Referral and Investigations

It is recommended that patients with higher-risk symptoms should be fast-tracked either in dedicated 2-week clinics or with urgent appointments in routine clinics. Patients so referred should be investigated with sigmoidoscopy (flexible or rigid), and when appropriate by high quality double contrast barium enema, or colonoscopy or computed tomography (CT) colonography. A barium enema should always be complemented by sigmoidoscopy. **B** 

Pre-operative histology must be obtained from all rectal tumours. **C** 

Colonoscopists should audit their performance and achieve quality and safety standards consistent with British Society for Gastroenterology guidance published in "Quality and Safety Indicators in Endoscopy". **B** 

It is acceptable for non-consultant staff to perform double contrast barium enemas, colonoscopy and CT colonography, provided they have completed a recognised training programme and the examinations are performed to strict protocols and supervised by a consultant with appropriate training and experience. **C** 

# **Preoperative Assessment of the Stage of Disease**

With the exception of patients with peritonitis who require emergency surgery, all patients with colon or rectal cancer should have pre-operative staging using CT scanning of the thorax and abdomen and pelvis to determine the local extent of the disease and the presence of lung or liver metastases. Patients with rectal cancer should also have magnetic resonance imaging (MRI) scans of the pelvis to assess tumour stage and involvement of adjacent organs. Endorectal ultrasound scanning should be performed to assess early rectal cancers when local excision is being considered. **B** 

# High Penetrance Autosomal Dominant Disease

People with a greatly elevated personal risk of gastrointestinal malignancy should be identified on the basis of family history criteria and/or pathological criteria and/or presence of a pathogenic mutation in a gene known to be responsible for a colorectal cancer susceptibility syndrome. These patients, and those with a relative who is known to have such a mutation, should be referred to the Regional Genetics Centre for formal counseling and mutation analysis. **B** 

Surveillance is not required for individuals who do not carry the mutation that has been shown to be causative in affected relatives. Hence, a negative gene test from an accredited genetics laboratory in families with characterised mutations means that GI surveillance should cease. **B** 

Hereditary Non-polyposis Colorectal Cancer (HNPCC)

<u>Large Bowel Surveillance and Surgery for HNPCC Family Members and MMR Gene</u> Carriers

Total colonic surveillance (at least biennial) should begin at age 25 years, or 5 years younger than the age at diagnosis for the first cancer case in the family, whichever is the earlier. Surveillance should continue to age 75 years or until it has been demonstrated that the individual does not carry the causative mutation. **B** 

Any patient with a colorectal malignancy who is a member of a family which is known to carry a mutation in an MMR (mismatch repair) gene should be counseled and offered a surgical procedure that includes both a cancer control element and prophylaxis. At present there are no data supporting, or against, offering primary prophylactic surgery for patients who do not yet have cancer. **C** 

<u>Upper Gastrointestinal Surveillance for HNPCC Family Members and MMR Gene</u> <u>Carriers</u> In families with hereditary nonpolyposis colorectal cancer (HNPCC) where there have been cases of gastric cancer, biennial upper gastrointestinal (GI) endoscopy should commence at age 50 years, or 5 years earlier than the first gastric cancer case in the family, whichever is the earlier. Surveillance should continue to 75yrs or until the causative mutation in that family has been excluded. **C** 

Familial Adenomatous Polyposis (FAP)

# Prophylactic Colorectal Surgery

Patients with familial adenomatous polyposis (FAP) should be advised to undergo prophylactic colectomy between the age of 16 and 20 years. The operation of choice is proctocolectomy and ileoanal pouch, but colectomy and ileorectal anastomosis may be appropriate for patients with relatively few polyps. **C** 

Peutz-Jeghers Syndrome (PJS)

Large bowel surveillance by colonoscopy or flexible sigmoidoscopy with barium enema is recommended 3 yearly from age 18 years. **C** 

Juvenile Polyposis Syndrome (JPS)

## Colorectal Surveillance for JPS

Surveillance of the whole of the large bowel by colonoscopy or flexible sigmoidoscopy with double-contrast barium enema is recommended 1 to 2 yearly for individuals believed to have juvenile polyposis syndrome (JPS) from age 15 to 18 years, or even younger if the patient has presented with symptoms. Screening intervals could be extended at age 35 years in at-risk individuals, but documented gene carriers or affected cases should be kept under surveillance until age 70 years and prophylactic surgery discussed. **C** 

Family History and Personal Colorectal Cancer Risk

The risk of future colorectal neoplasia in individuals with close relatives who have developed colorectal cancer should be estimated using family history information. **B** 

High-Moderate Risk

Individuals who meet high-moderate risk criteria should be offered 5 yearly colonoscopy from age 55 until 75 years if the colon is clear of neoplasia. If polyps are found, they should be removed by snare polypectomy and histologically characterised. Patients with adenomas should have 3 yearly colonoscopy. **B** 

# Moderate Risk

Individuals who meet moderate risk criteria should be offered a single colonoscopy at age 55 years. Any polyps must be snared and histologically characterised. If adenomatous polyp is confirmed, then adenoma surveillance quidance applies. If the colon is clear of neoplasia, the individual should be

reassured and discharged with recommendations relevant to population risk (e.g. uptake of faecal occult blood test [FOBT] screening). **B** 

In all cases where surveillance is appropriate, total colonoscopy is to be preferred, because of the risk of proximal colonic lesions and the opportunity for snare polypectomy. When complete colonoscopy cannot be achieved, the patient should be offered a double contrast barium enema on the same day. Flexible sigmoidoscopy and barium enema (with targeted follow-up colonoscopy) is an acceptable alternative to colonoscopy. **B** 

Low Risk

People at low risk should be reassured. It should be emphasised that their risk level is only marginally greater than that of the wider population, and that they should avail themselves of population-based screening measures. **B** 

Referrals made solely on the basis of family history are best centralised to facilitate audit. This has resource implications, and might be done through the Regional Genetics Service. Audit should include documentation of family history, level of risk assigned and correlation with outcome measures including: proportion of consultands offered screening, screening-related complications, and long term cancer incidence/mortality in screened and unscreened groups through National Health Service (NHS) flagging. **C** 

# **Treatment**

#### **Access**

Waiting Times

Treatment should begin within 31 days of discussion with the patient of the decision to treat.  ${\bf B}$ 

The Multidisciplinary Team (MDT)

All patients with colorectal cancer should have the benefit of a suitably informed surgical opinion and their management should be discussed by the multidisciplinary team. **GCP** 

Patients with colorectal cancer should have access to a colorectal nurse specialist for advice and support from the time they receive the diagnosis. **GCP** 

Surgical Specialisation

Surgery for colorectal cancer should only be carried out by surgeons with appropriate training and experience, working as part of a multidisciplinary team. **B** 

# Table. Summary Chart of Recommended Treatment Options for Rectal Cancer

MRI STAGING	Upper Rectum	Mid Rectum	Lower Rectum
EARLY STAGE	Surgery	Surgery	Surgery <sup>1</sup>
T1-2N0			
CRM clear			
INTERMEDIATE STAGE	Discuss with patient: SCPRT + surgery or surgery	Discuss with patient: SCPRT + surgery or surgery	Discuss with patient: SCPRT + surgery or CRT +
Early T3N0 or N1	surgery or surgery	surgery or surgery	surgery
CRM clear			
Discuss with patient:			
ADVANCED STAGE	CRT + surgery	CRT + surgery	CRT + surgery
CRM threatened by			
tumour or involved			
nodes or tumour beyond CRM or			
involved internal			
iliac/obturator nodes			

MRI = magnetic resonance imaging; CRM = circumferential resection margins; SCPRT = short course preoperative radiotherapy; CRT = chemoradiotherapy

 $^1$ Consider endoluminal ultrasound for detailed T stage and use surgery alone for T1 and non full thickness T2 lesions

#### **Process**

Preparation for Surgery

# Informed Consent

It is important that patients with colorectal cancer are offered the opportunity to ask questions and to have important information repeated. Provision of information should be an essential part of every consultation.  ${\bf B}$ 

All patients undergoing surgery for colorectal cancer should give informed consent. Informed consent implies being given information about the likely benefits and risks of the proposed treatment and details of any alternatives. Informed consent should be obtained by the operating surgeon where possible. **C** 

# Preparation for Stoma Formation

The patient should be seen by a stoma nurse prior to surgery (Saunders, 1976), and the referral should be made at the earliest opportunity to allow adequate time for preparation.  $\bf C$ 

# Cross-matching

Blood transfusion should not be withheld if there is a clinical indication to give it, and preparations for blood transfusion should be made in all patients undergoing surgery for colorectal cancer except where an individual patient refuses. **C** 

## **Bowel Preparation**

Bowel preparation should not be used routinely before colorectal cancer resection.  ${\bf R}$ 

# Thromboembolism Prophylaxis

A combination of graduated compression stockings and heparin should be used for thrombo-prophylaxis for patients undergoing colorectal surgery. **A** 

# **Antibiotic Prophylaxis**

All patients undergoing surgery for colorectal cancer should have antibiotic prophylaxis. It is not clear which regime is most appropriate, but a single dose of an appropriate intravenous antibiotic given shortly before surgery is normally effective. **A** 

Wound infection rates after elective surgery for colorectal cancer should be less than 10%. **A** 

## Rates of Curative Resection

The term curative resection should be based on surgical and histological confirmation of complete excision. Surgeons should expect to achieve an overall curative resection rate of 60%, but it is appreciated that this will depend at least in part on the stage at which patients present. **B** 

#### Definition of Rectal Tumour

Any tumour whose distal margin is seen at 15 cm or less from the anal verge using a rigid sigmoidoscope should be classified as rectal. **C** 

## Surgical Technique

## Resection

It is recommended that total mesorectal excision should be performed for tumours in the lower two-thirds of the rectum, either as part of a low anterior resection or an abdominoperineal excision of the rectum (APER). In tumours of the upper rectum the mesorectum should be divided no less than 5 cm below the lower margin of the tumour. Care should be taken to preserve the pelvic autonomic nerves and plexuses, and perforation of the tumour during operation should be avoided. **B** 

#### Anastomosis

Although no definite recommendations can be made regarding anastomotic technique, the interrupted serosubmucosal method has the lowest reported leak rate and stapling facilitates ultra-low pelvic anastomoses. **B** 

Cytocidal washout of the rectal stump should be used prior to anastomosis. GCP

Surgeons should carefully audit their leak rate for colorectal surgery, and should expect to achieve an overall rate below 8% for anterior resections and below 4% for other types of resection. **B** 

Surgeons should expect to achieve an operative mortality of less than 20% for emergency surgery and less than 7% for elective surgery for colorectal cancer. **B** 

After anterior resection and total mesorectal excision, the judicious use of a temporary defunctioning stoma is recommended, and the formation of a colonic pouch should be considered. **B** 

## Rates of Permanent Stoma Formation

It is difficult to determine what the ideal ratio of anterior resection to APER should be, but it is recommended that the overall proportion of resectable rectal cancers treated by APER should be less than 30%. If distal clearance of 1 cm can be achieved, a low rectal cancer may be suitable for anterior resection. If a surgeon has any doubt regarding the choice between these two operations, an experienced second opinion should be sought. **GCP** 

#### Local Excision

Local excision in rectal cancer is appropriate only for pT1 cancers which are graded well or moderately well differentiated and less than 3 cm in diameter. Subsequent histopathological examination of cancers treated by local excision may, however, identify a proportion which require more radical surgery. **B** 

# Laparoscopic Surgery

All laparoscopic colorectal operations should be performed by properly trained surgeons in colorectal surgery. These surgeons should have undergone preceptorship laparoscopic training, particularly in rectal procedures. Their results should be carefully audited both in the local hospital multidisciplinary setting and also submitted to the Association of Coloproctology of Great Britain and Ireland colorectal cancer database. **C** 

# Record Keeping

There are existing guidelines issued by the Royal College of Surgeons (RCS, 1990), and it is recommended that these should be adhered to for patients with colorectal cancer. **C** 

A check-list should be used to construct an operation note for patients undergoing surgery for colorectal cancer. See Appendix 2 in the original guideline document.  $\bf c$ 

Meetings of the Multidisciplinary Team (MDT) should be on a regular basis to allow timely decision making on all colorectal cancer patients. Meetings should include a register of attendance. Records of cases discussed and decisions made must also be recorded.  ${\bf C}$ 

Management of Patients Presenting As Emergencies

In patients presenting with apparent obstruction, CT scanning should be carried out before operation to exclude pseudo-obstruction.  ${\bf C}$ 

Emergency surgery should be carried out during daytime hours as far as possible, by surgeons and anaesthetists who are members of a colorectal cancer MDT. Stoma formation should be carried out in the patient's interests only. **C** 

The overall mortality for emergency/urgent surgery should be less than 25%. **GCP** 

In patients with large bowel obstruction the insertion of an expanding stent is an acceptable treatment option, where adequate local expertise exists, either as palliation or as a bridge to surgery. **B** 

Adjuvant Radiotherapy in Resectable Rectal Cancer

Radiotherapy and chemotherapy for colorectal cancer should only be given after discussion at the Multi Disciplinary Team (MDT) Meeting and under the direction of recognised oncologists, within facilities conforming to national guidelines. **C** 

All patients should be made aware of the common and serious short and long term side effects of radiotherapy and chemotherapy, the expected benefits and the other options available, before treatment begins. **GCP** 

Patients with resectable rectal cancer should be considered for preoperative short course radiotherapy (25Gy in 5 fractions in 1 week) with surgery performed within 1 week of completion of radiation. However, in certain cases the MDT may decide that the benefits of treating patients with lower risk disease will not justify the additional toxicity of radiotherapy. **A** 

When local staging indicates that radiotherapy (with synchronous chemotherapy) would be appropriate to downstage the tumour, a dose of 45 Gy in 25 fractions over 5 weeks, with or without a reduced volume boost dose of 5.4 to 9 Gy in 3 to 5 fractions, is recommended. **B** 

If the addition of radiotherapy to surgery is deemed necessary for rectal cancer, it should ideally be given pre-operatively. However, in cases with well established predictive factors of local recurrence (e.g. evidence of tumour at the circumferential resection margin, mesorectal lymph node involvement and extramural vascular invasion), post operative radiotherapy and chemotherapy

should be considered for patients who did not receive preoperative radiotherapy. A dose of 45 Gy in 25 fractions over 5 weeks with a planned boost dose of 5.4-9 Gy in 3 to 5 fractions is recommended. **A** 

A planned radiotherapy volume using three or four fields given pre-operatively is recommended for rectal cancers as this results in less morbidity and mortality. **B** 

MDTs should prospectively audit the outcomes of all patients with rectal cancer managed by the team in terms of curative resection rate (R0), postoperative morbidity and mortality, locoregional recurrence and overall survival. **B** 

# **Chemotherapy for Colorectal Cancer**

Adjuvant Chemotherapy

## Node Positive Disease

Fluoropyrimidines as monotherapy or oxaliplatin in combination with 5-fluorouracil (5FU) and folinic acid should be considered as options for the adjuvant treatment of patients with node positive colorectal cancer following potentially curative surgery. **A** 

In general a higher risk, otherwise fit, patient should be offered oxaliplatin based adjuvant therapy. **A** 

## Node Negative Disease

Patients with high risk node negative colorectal cancer should be individually counselled by an oncologist with regard to their level of risk and the possible benefits of flouropyrimidine based chemotherapy. **A** 

Chemotherapy for Advanced Disease

# Inoperable Primary Disease

In fit patients with inoperable but non-metastatic rectal carcinoma primary chemo-radiation should be offered, prior to re-staging and potentially curative resection considered if appropriate. **B** 

# Operable Metastatic Disease

Fit patients with resectable or potentially resectable liver or lung metastases should be reviewed in the MDT with a hepatobiliary (or thoracic) surgeon and colorectal oncologist, to evaluate operability and to decide on a combined plan of management to optimise the chance of achieving complete resection of all metastatic disease. **B** 

## Inoperable Metastatic Disease

Patients with unresectable metastatic disease should be discussed by the MDT and should be referred to the palliative care team. If appropriate, they should also be referred to an oncologist for consideration of palliative chemotherapy. **C** 

Palliative treatment using fluoropyrimidines alone or 5FU in combination with oxaliplatin or irinotecan are National Institute for Health and Clinical Excellence (NICE) approved for the treatment of metastatic colorectal cancer. **A** 

#### **Treatment of Advanced Disease**

Palliative Care

Surgeons and oncologists who deal with colorectal cancer should make it a priority to build close links with palliative care specialists and units. **B** 

All clinicians who deal with colorectal cancer should be trained in communication skills, in the control of pain and other cancer symptoms. **C** 

It is important that patients with colorectal cancer are offered the opportunity to ask questions and to have important information repeated. Information giving should be seen as an essential part of every consultation.  $\bf C$ 

## Follow-Up

# **Reasons for Follow-Up**

Evidence to support or refute any survival value for regular follow-up is not available. In the absence of hard evidence it is reasonable to offer a single CT scan of the abdomen and thorax to asymptomatic fit patients at sometime during the first two years after resection for the purpose of detecting respectable liver metastases. **B** 

Colonoscopic follow-up yields treatable adenomatous polyps and cancer. If such a policy is pursued, it is recommended that a "clean" colon should be examined by colonoscopy at 5 yearly intervals. Patients should be counseled about the potential complications of colonoscopy. **B** 

In the absence of evidence from randomised trials, the most persuasive arguments for routine follow-up are patient support and audit. Evidence suggests that patients' preference is for follow-up, but by whom and where may depend on local circumstances. All patients should have ready access to specialist nursing staff throughout the period of follow-up. **C** 

Follow-up should cease in elderly or frail patients by agreement between the patient and their treating clinician. **GCP** 

Each MDT should audit the survival rates of the patients they manage. Data from each hospital should be submitted both to Cancer Registries and to the National Bowel Cancer Audit Programme (NBOCAP). Audit should include both clinical information and non-clinical variables such as socio-economic status. **GCP** 

Adequate staff and information technology facilities must be available for this essential part of colorectal cancer care. **GCP** 

Audit should be structured with particular reference to outcome measures, and should be regarded as a routine part of a consultant's work. It may be facilitated by the use of a database such as that promoted by the Association of Coloproctology. If other "local" databases are used, field definitions should match those of the Association's data dictionary, to ensure conformity of data collection (see Appendix 4 in the original guideline document). **C** 

# **Histopathology Reporting**

All resected colorectal tumours should be submitted for histopathological examination, which should reach acceptable quality standards as outlined in the original guideline document. **B** 

Pathology reports should contain information on all of the data items contained in the Joint National Guidelines Minimum Data Set for Colorectal Cancer Histopathology Reports. **C** 

Pathology laboratories should store stained histology slides for a minimum of 10 years, and tissue blocks from specimens indefinitely, in order to facilitate future case review, clinical audit, and research. **B** 

Pathological examination of colorectal cancer specimens should be carried out in laboratories which perform to high technical standards such as those required for Clinical Pathology Accreditation, and that participate in external quality assessment schemes and regular audit of technical procedures and diagnosis. **B** 

# **Management of Anal Cancer**

Squamous anal cancer is rare and has a varied presentation. Any suspicious anal ulcer or lesion should be biopsied, if necessary under general anaesthetic. **GCP** 

Local staging of the disease should be carried out using a combination of examination under anaesthesia, anal ultrasound and MRI. CT should be used to evaluate the possibility of distant metastases. **B** 

Small anal margin cancers (less than two cm and well differentiated) can be locally excised provided clear margins are obtained. Larger lesions up to 5 cm (i.e., T2 or less can also be considered for excision by the anal cancer MDT). **C** 

Anal canal lesions should usually be treated by concurrent chemoradiotherapy. 5FU and Mitomycin C or Cisplatin are usually used but there is some uncertainty as to the best regimen. Wherever possible, patients should be considered for randomisation within one of the ongoing trials. **A** 

Anorectal excision should be reserved for residual or recurrent disease and for severe complications of radiotherapy. Patients may prefer primary anorectal excision. The data suggest that the outcome is the same for early lesions. **A** 

There is no agreed follow-up protocol. Its aims should be: Identification of local failure, detection of metastases, to provide data for audit, etc. **GCP** 

Consideration should be given to surveillance in high-risk groups (i.e., those with human papillomavirus [HPV], human immunodeficiency virus [HIV] or other forms of immunosuppression). **B** 

All patients with anal cancer should be discussed by a specialist Anal Cancer MDT which should include at least one surgeon who specialises in surgery for anal cancer, a clinical oncologist with specific expertise in the management of anal cancer, histopathologist, radiologist, clinical nurse specialist, etc, as outlined in the NICE guidelines. This allows access to the necessary expertise in all disciplines and allows comparison of outcomes between centres. **GCP** 

#### Definitions:

#### Levels of Evidence

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grading below that is usually associated with the evidence grading if the research is considered to be of poor quality. Some recommendations cover topics which are not amenable to formal studies, but represent good clinical practice (e.g., informed consent). These items are labeled as **GCP** (good clinical practice) in this summary.

# CLINICAL ALGORITHM(S)

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

## REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## **POTENTIAL BENEFITS**

Appropriate management of colorectal and anal cancer

#### **POTENTIAL HARMS**

- Complications of invasive diagnostic and screening procedures (i.e. discomfort, perforation, bleeding)
- Complications of excessive sedation during invasive diagnostic and screening procedures
- Complications of surgery leading to morbidity and mortality (i.e. deep vein thrombosis, infection, bleeding, perforation of tumour, anastomotic dehiscence)
- Short-term and long-term side effects and complications of radiotherapy
- Short-term and long-term side effects of chemotherapy
- Permanent stoma formation following surgical intervention

## **QUALIFYING STATEMENTS**

# **QUALIFYING STATEMENTS**

Guidelines are not intended to create a rigid framework where there is a reasonable difference of opinion, but the range of opinion may be informed by participation in appropriate clinical trials and national audits, which can help to set standards of care. Furthermore, participation in national audits and clinical trials

can help identify areas of best practice which can then be disseminated to improve patient care for all.

## **IMPLEMENTATION OF THE GUIDELINE**

### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

## **Facilitation of Audit, Quality Assurance, and Clinical Governance**

Audit is the only means by which clinical outcomes can be measured and it is likely to underpin the new initiative of clinical governance. Accurate, relevant, reliable data in which clinicians have confidence is an absolute prerequisite for audit and demands organised and disciplined methods of collection. The Association of Coloproctology of Great Britain and Ireland has produced a minimum data set which may help to overcome some, but not all, of the pitfalls in data collection for colorectal cancer audit. Fundamental to the data set is a data dictionary, which precisely defines each field to ensure conformity of interpretation. The data set and data dictionary are freely available on the internet on <a href="www.canceruk.net/">www.canceruk.net/</a>. Data collection forms are included in Appendix 4 of the original guideline document. It is only by audit that surgeons can evaluate their results against professional standards. Information from audit provides the stimulus to investigate and perhaps modify personal practice.

If guidelines are to be of value, surgeons must audit their results, and for this some form of follow-up is essential. This might be by regular surgeon/patient contact or through review by clinical nurse specialists, primary care, or postal contact. In the absence of supportive evidence local circumstances may dictate local practice.

#### **IMPLEMENTATION TOOLS**

Audit Criteria/Indicators Chart Documentation/Checklists/Forms

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

## **IOM CARE NEED**

End of Life Care Living with Illness Staying Healthy

## **IOM DOMAIN**

# **IDENTIFYING INFORMATION AND AVAILABILITY**

# **BIBLIOGRAPHIC SOURCE(S)**

Association of Coloproctology of Great Britain and Ireland. Guidelines for the management of colorectal cancer. London (UK): Association of Coloproctology of Great Britain and Ireland; 2007. 117 p. [468 references]

## **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

### **DATE RELEASED**

2001 (revised 2007)

# **GUIDELINE DEVELOPER(S)**

Association of Coloproctology of Britain and Ireland - Medical Specialty Society

## **SOURCE(S) OF FUNDING**

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# **GUIDELINE COMMITTEE**

Expert Advisory Group Drafting Committee

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Prof JH Scholefield (Chairman); Prof CG Marks; Prof TS Maughan; Prof NA Shepherd; Prof RJC Steele; Mr MR Thompson; Mr WJ Cunliffe; Dr I Geh; Dr M Hill; Dr A Hartley; Mr A Radcliffe; Dr E Levine; Dr A Higginson; Prof GT Williams; Prof P Quirke; Prof M G Dunlop

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Association of Coloproctology of Great Britain and Ireland. Guidelines for the management of colorectal cancer. London (UK): Association of Coloproctology of Great Britain and Ireland; 2001. 87 p.

## **GUIDELINE AVAILABILITY**

Electronic copies: None available

Print copies: Available from the Association of Coloproctology of Britain and Ireland at The Royal College of Surgeons of England, 35-43 Lincoln's Inn Fields, London, WC2A 3PE

## **AVAILABILITY OF COMPANION DOCUMENTS**

Appendices 1–6 of the original guideline document provide audit information and checklists for colorectal cancer surgery, staging (colorectal and anal), and histopathology reporting.

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

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