

# Colorectal cancer: diagnosis and management

Clinical guideline

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## Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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This guideline replaces TA93.

This guideline is the basis of QS20.

## Introduction

Recommendations on surgery and colonic stents in acute large bowel obstruction and on stage I rectal cancer in sections 1.2.2 and 1.2.4 were added in December 2014. The [addendum](#) contains details of the methods and evidence used to update these recommendations.

Colorectal cancer is one of the most common cancers in the UK after breast and lung cancer, with approximately 40,000 new cases registered each year. Occurrence of colorectal cancer is strongly related to age, with almost three-quarters of cases occurring in people aged 65 or over. Colorectal cancer is the second most common cause of cancer death in the UK.

Around half of people diagnosed with colorectal cancer survive for at least 5 years after diagnosis.

### *Recommendations about medicines*

The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

This guideline recommends some medicines for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or those with authority to give consent on their behalf) should provide informed consent, which should be documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information. Where recommendations have been made for the use of medicines outside their licensed indications ('off-label use'), these medicines are marked with a footnote in the recommendations.

## Patient-centred care

This guideline offers best practice advice on the care of patients with colorectal cancer.

Patients and healthcare professionals have rights and responsibilities as set out in the [NHS Constitution for England](#) – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. Healthcare professionals should follow the [Department of Health's advice on consent](#). If someone does not have capacity to make decisions, healthcare professionals should follow the [code of practice that accompanies the Mental Capacity Act](#) and the supplementary [code of practice on deprivation of liberty safeguards](#).

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in [patient experience in adult NHS services](#).

## Key priorities for implementation

The following recommendations have been identified as priorities for implementation.

### Diagnostic investigations

- Offer colonoscopy to patients without major comorbidity, to confirm a diagnosis of colorectal cancer. If a lesion suspicious of cancer is detected, perform a biopsy to obtain histological proof of diagnosis, unless it is contraindicated (for example, patients with a blood clotting disorder).

### Staging of colorectal cancer

- Offer contrast-enhanced computed tomography (CT) of the chest, abdomen and pelvis, to estimate the stage of disease, to all patients diagnosed with colorectal cancer unless it is contraindicated. No further routine imaging is needed for patients with colon cancer.
- Offer magnetic resonance imaging (MRI) to assess the risk of local recurrence, as determined by anticipated resection margin, tumour and lymph node staging, to all patients with rectal cancer unless it is contraindicated.

### Preoperative management of the primary tumour

- Do not offer short-course preoperative radiotherapy (SCPRT) or chemoradiotherapy to patients with low-risk operable rectal cancer (see [table 1](#) for risk groups), unless as part of a clinical trial.

### Colonic stents in acute large bowel obstruction

- If considering the use of a colonic stent in patients presenting with acute large bowel obstruction, offer CT of the chest, abdomen and pelvis to confirm the diagnosis of mechanical obstruction, and to determine whether the patient has metastatic disease or colonic perforation.

### Stage I colorectal cancer

- The colorectal multidisciplinary team (MDT) should consider further treatment for patients with locally excised, pathologically confirmed stage I cancer, taking into account pathological characteristics of the lesion, imaging results and previous treatments.

### Imaging hepatic metastases

- If the CT scan shows metastatic disease only in the liver and the patient has no contraindications to further treatment, a specialist hepatobiliary MDT should decide if further imaging to confirm surgery is suitable for the patient – or potentially suitable after further treatment – is needed.

### Chemotherapy for advanced and metastatic colorectal cancer

- When offering multiple chemotherapy drugs to patients with advanced and metastatic colorectal cancer, consider one of the following sequences of chemotherapy unless they are contraindicated:
  - FOLFOX (folinic acid plus fluorouracil plus oxaliplatin) as first-line treatment then single agent irinotecan as second-line treatment or
  - FOLFOX as first-line treatment then FOLFIRI (folinic acid plus fluorouracil plus irinotecan<sup>[1]</sup>) as second-line treatment or
  - XELOX (capecitabine plus oxaliplatin) as first-line treatment then FOLFIRI (folinic acid plus fluorouracil plus irinotecan<sup>[1]</sup>) as second-line treatment.

### Follow-up after apparently curative resection

- Offer patients regular surveillance with:
  - a minimum of two CTs of the chest, abdomen, and pelvis in the first 3 years and
  - regular serum carcinoembryonic antigen tests (at least every 6 months in the first 3 years).

### Information about bowel function

- Before starting treatment, offer all patients information on all treatment options available to them (including no treatment) and the potential benefits and risks of these treatments, including the effect on bowel function.

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<sup>[1]</sup> At the time of publication (November 2011), irinotecan did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

## 1 Recommendations

### 1.1 *Investigation, diagnosis and staging*

The recommendations in section 1.1 refer to people whose condition is being managed in secondary care. For recommendations for urgent referral from primary care for patients with suspected colorectal cancer see [suspected cancer: recognition and referral](#).

#### 1.1.1 Diagnostic investigations

1.1.1.1 Advise the patient that more than one investigation may be necessary to confirm or exclude a diagnosis of colorectal cancer. [2011]

1.1.1.2 Offer colonoscopy to patients without major comorbidity, to confirm a diagnosis of colorectal cancer. If a lesion suspicious of cancer is detected, perform a biopsy to obtain histological proof of diagnosis, unless it is contraindicated (for example, patients with a blood clotting disorder). [2011]

1.1.1.3 Offer flexible sigmoidoscopy then barium enema for patients with major comorbidity. If a lesion suspicious of cancer is detected perform a biopsy unless it is contraindicated. [2011]

1.1.1.4 Consider computed tomographic (CT) colonography as an alternative to colonoscopy or flexible sigmoidoscopy then barium enema, if the local radiology service can demonstrate competency in this technique. If a lesion suspicious of cancer is detected on CT colonography, offer a colonoscopy with biopsy to confirm the diagnosis, unless it is contraindicated. [2011]

1.1.1.5 Offer patients who have had an incomplete colonoscopy:

- repeat colonoscopy or
- CT colonography, if the local radiology service can demonstrate competency in this technique or
- barium enema. [2011]



## 1.1.2 Staging of colorectal cancer

- 1.1.2.1 Offer contrast-enhanced CT of the chest, abdomen and pelvis, to estimate the stage of disease, to all patients diagnosed with colorectal cancer unless it is contraindicated. No further routine imaging is needed for patients with colon cancer. [2011]
- 1.1.2.2 Offer magnetic resonance imaging (MRI) to assess the risk of local recurrence, as determined by anticipated resection margin, tumour and lymph node staging, to all patients with rectal cancer unless it is contraindicated. [2011]
- 1.1.2.3 Offer endorectal ultrasound to patients with rectal cancer if MRI shows disease amenable to local excision or if MRI is contraindicated. [2011]
- 1.1.2.4 Do not use the findings of a digital rectal examination as part of the staging assessment. [2011]

## 1.2 Management of local disease

### 1.2.1 Preoperative management of the primary tumour

For the purposes of this guideline we have defined three different risk groups of patients with rectal cancer, according to the risk of local recurrence. These groups are defined in table 1.

**Table 1 Risk of local recurrence for rectal tumours as predicted by MRI**

Risk of local recurrence	Characteristics of rectal tumours predicted by MRI
High	<ul style="list-style-type: none"> <li>• A threatened (&lt;1 mm) or breached resection margin or</li> <li>• Low tumours encroaching onto the inter-sphincteric plane or with levator involvement</li> </ul>

Moderate	<ul style="list-style-type: none"> <li>• Any cT3b or greater, in which the potential surgical margin is not threatened or</li> <li>• Any suspicious lymph node not threatening the surgical resection margin or</li> <li>• The presence of extramural vascular invasion<sup>[a]</sup></li> </ul>
Low	<ul style="list-style-type: none"> <li>• cT1 or cT2 or cT3a and</li> <li>• No lymph node involvement</li> </ul>
<p><sup>[a]</sup> This feature is also associated with high risk of systemic recurrence.</p>	

### Patients whose primary rectal tumour appears resectable at presentation

- 1.2.1.1 Discuss the risk of local recurrence, short-term and long-term morbidity and late effects with the patient after discussion in the multidisciplinary team (MDT). [2011]
- 1.2.1.2 Do not offer short-course preoperative radiotherapy (SCPRT) or chemoradiotherapy to patients with low-risk operable rectal cancer (see table 1 for risk groups), unless as part of a clinical trial. [2011]
- 1.2.1.3 Consider SCPRT then immediate surgery for patients with moderate-risk operable rectal cancer (see table 1 for risk groups). Consider preoperative chemoradiotherapy with an interval to allow tumour response and shrinkage before surgery for patients with tumours that are borderline between moderate and high risk. [2011]
- 1.2.1.4 Offer preoperative chemoradiotherapy with an interval before surgery to allow tumour response and shrinkage (rather than SCPRT), to patients with high-risk operable rectal cancer (see table 1 for risk groups). [2011]

### Patients whose primary colon or rectal tumour appears unresectable or borderline resectable

- 1.2.1.5 Discuss the risk of local recurrence and late toxicity with patients with rectal cancer after discussion in the MDT. [2011]

1.2.1.6 Offer preoperative chemoradiotherapy with an interval before surgery, to allow tumour response and shrinkage, to patients with high-risk locally advanced rectal cancer. [2011]

1.2.1.7 Do not offer preoperative chemoradiotherapy solely to facilitate sphincter-sparing surgery to patients with rectal cancer. [2011]

1.2.1.8 Do not routinely offer preoperative chemotherapy alone for patients with locally advanced colon or rectal cancer unless as part of a clinical trial. [2011]

## 1.2.2 Colonic stents in acute large bowel obstruction

1.2.2.1 If considering the use of a colonic stent in patients presenting with acute large bowel obstruction, offer CT of the chest, abdomen and pelvis to confirm the diagnosis of mechanical obstruction, and to determine whether the patient has metastatic disease or colonic perforation. [2011]

1.2.2.2 Do not use contrast enema studies as the only imaging modality in patients presenting with acute large bowel obstruction. [2011]

1.2.2.3 For patients with acute left-sided large bowel obstruction caused by colorectal cancer that is potentially curable, and for whom surgery is suitable:

- Resuscitate patients and explain to them and their family members or carers (as appropriate) that acute bowel obstruction can initially be managed either with emergency surgery or a colonic stent, and that there is no clear evidence that one treatment is better than the other. [new 2014]
- Offer patients the chance to take part in a randomised controlled trial<sup>[2]</sup> (if available) that compares emergency surgery with colonic stent insertion to initially manage acute bowel obstruction. [new 2014]

1.2.2.4 For patients with acute left-sided large bowel obstruction caused by colorectal cancer that is not potentially curable, or for whom surgery is unsuitable: [new 2014]

- Resuscitate patients with acute large bowel obstruction, then consider placing a self-expanding metallic stent to initially manage a left-sided complete or near-complete colonic obstruction. [2011]

- A consultant colorectal surgeon should consider inserting a colonic stent in patients presenting with acute large bowel obstruction. They should do this together with an endoscopist or a radiologist (or both) who is experienced in using colonic stents. [2011]

1.2.2.5 Do not place self-expanding metallic stents:

- in low rectal lesions or
- to relieve right-sided colonic obstruction or
- if there is clinical or radiological evidence of colonic perforation or peritonitis. [2011]

1.2.2.6 Do not dilate the tumour before inserting the self-expanding metallic stent. [2011]

1.2.2.7 Only a healthcare professional experienced in placing colonic stents who has access to fluoroscopic equipment and trained support staff should insert colonic stents. [2011]

### 1.2.3 Stage I colorectal cancer

1.2.3.1 The colorectal MDT should consider further treatment for patients with locally excised, pathologically confirmed stage I cancer, taking into account pathological characteristics of the lesion, imaging results and previous treatments. [2011]

1.2.3.2 Offer further treatment to patients whose tumour had involved resection margins (less than 1 mm). [2011]

### 1.2.4 Stage I rectal cancer

1.2.4.1 An early rectal cancer MDT<sup>[a]</sup> should decide which treatment to offer to patients with stage I rectal cancer, taking into account previous treatments, such as radiotherapy. [2011]

1.2.4.2 After discussion in the MDT responsible for the management of stage I rectal cancer, discuss uncertainties about the potential risks and benefits of all treatment options with patients and their family members and carers (as appropriate), taking into account each patient's circumstances. [new 2014]

1.2.4.3 Explain to patients and their family members or carers (as appropriate) that there is very little good-quality evidence comparing treatment options for stage I rectal cancer. [new 2014]

1.2.4.4 Offer patients the chance to take part in a randomised controlled trial (if available) that compares treatment options for stage I rectal cancer. [new 2014]

## 1.2.5 Laparoscopic surgery

The recommendations in this section are from [laparoscopic surgery for colorectal cancer](#) (NICE technology appraisal guidance 105).

1.2.5.1 Laparoscopic (including laparoscopically assisted) resection is recommended as an alternative to open resection for individuals with colorectal cancer in whom both laparoscopic and open surgery are considered suitable. [2006]

1.2.5.2 Laparoscopic colorectal surgery should be performed only by surgeons who have completed appropriate training in the technique and who perform this procedure often enough to maintain competence. The exact criteria to be used should be determined by the relevant national professional bodies. Cancer networks and constituent trusts should ensure that any local laparoscopic colorectal surgical practice meets these criteria as part of their clinical governance arrangements. [2006]

1.2.5.3 The decision about which of the procedures (open or laparoscopic) is undertaken should be made after informed discussion between the patient and the surgeon. In particular, they should consider:

- the suitability of the lesion for laparoscopic resection
- the risks and benefits of the two procedures
- the experience of the surgeon in both procedures. [2006]

## 1.2.6 Adjuvant chemotherapy in rectal cancer

1.2.6.1 Assess pathological staging after surgery, before deciding whether to offer adjuvant chemotherapy. [2011]

1.2.6.2 Consider adjuvant chemotherapy for patients with high-risk stage II and all stage III rectal cancer to reduce the risk of local and systemic recurrence. [2011]

## 1.2.7 Adjuvant chemotherapy for high-risk stage II colon cancer

1.2.7.1 Consider adjuvant chemotherapy after surgery for patients with high-risk stage II colon cancer. Fully discuss the risks and benefits with the patient. [2011]

## 1.2.8 Adjuvant chemotherapy for stage III colon cancer

The recommendations in this section are from [capecitabine and oxaliplatin in the adjuvant treatment of stage III \(Dukes' C\) colon cancer](#) (NICE technology appraisal guidance 100).

1.2.8.1 The following are recommended as options for the adjuvant treatment of patients with stage III (Dukes' C) colon cancer following surgery for the condition:

- capecitabine as monotherapy
- oxaliplatin in combination with 5-fluorouracil and folinic acid. [2006]

1.2.8.2 The choice of adjuvant treatment should be made jointly by the individual and the clinicians responsible for treatment. The decision should be made after an informed discussion between the clinicians and the patient; this discussion should take into account contraindications and the side-effect profile of the agent(s) and the method of administration as well as the clinical condition and preferences of the individual. [2006]

## 1.3 Management of metastatic disease

### 1.3.1 Patients presenting with stage IV colorectal cancer

1.3.1.1 Prioritise treatment to control symptoms if at any point the patient has symptoms from the primary tumour. [2011]

1.3.1.2 If both primary and metastatic tumours are considered resectable, anatomical site-specific MDTs should consider initial systemic treatment followed by surgery, after full discussion with the patient. The decision on whether the operations are done at the same time or separately should be made by the site-specialist MDTs in consultation with the patient. [2011]

### 1.3.2 Imaging hepatic metastases

- 1.3.2.1 If the CT scan shows metastatic disease only in the liver and the patient has no contraindications to further treatment, a specialist hepatobiliary MDT should decide if further imaging to confirm surgery is suitable for the patient – or potentially suitable after further treatment – is needed. [2011]

### 1.3.3 Imaging extra-hepatic metastases

- 1.3.3.1 Offer contrast-enhanced CT of the chest, abdomen and pelvis to patients being assessed for metastatic colorectal cancer. [2011]
- 1.3.3.2 If intracranial disease is suspected, offer contrast-enhanced MRI of the brain. Do not offer imaging of the head, neck and limbs unless involvement of these sites is suspected clinically. [2011]
- 1.3.3.3 Discuss all imaging with the patient following review by the appropriate anatomical site-specific MDT. [2011]
- 1.3.3.4 If the CT scan shows the patient may have extra-hepatic metastases that could be amenable to further radical surgery, an anatomical site-specific MDT should decide whether a positron emission tomography-CT (PET-CT) scan of the whole body is appropriate. [2011]
- 1.3.3.5 If contrast-enhanced CT suggests disease in the pelvis, offer an MRI of the pelvis and discuss in the colorectal cancer MDT. [2011]
- 1.3.3.6 If the diagnosis of extra-hepatic recurrence remains uncertain, keep the patient under clinical review and offer repeat imaging at intervals agreed between the healthcare professional and the patient. [2011]

### 1.3.4 Chemotherapy for advanced and metastatic colorectal cancer

#### Oxaliplatin and irinotecan in combination with fluoropyrimidines

- 1.3.4.1 When offering multiple chemotherapy drugs to patients with advanced and metastatic colorectal cancer, consider one of the following sequences of chemotherapy unless they are contraindicated:

- FOLFOX (folinic acid plus fluorouracil plus oxaliplatin) as first-line treatment then single agent irinotecan as second-line treatment or
- FOLFOX as first-line treatment then FOLFIRI (folinic acid plus fluorouracil plus irinotecan<sup>[4]</sup>) as second-line treatment or
- XELOX (capecitabine plus oxaliplatin) as first-line treatment then FOLFIRI (folinic acid plus fluorouracil plus irinotecan<sup>[4]</sup>) as second-line treatment. [2011]

1.3.4.2 Decide which combination and sequence of chemotherapy to use after full discussion of the side effects and the patient's preferences. [2011]

### Raltitrexed

1.3.4.3 Consider raltitrexed only for patients with advanced colorectal cancer who are intolerant to 5-fluorouracil and folinic acid, or for whom these drugs are not suitable (for example, patients who develop cardiotoxicity). Fully discuss the risks and benefits of raltitrexed with the patient. [2011]

1.3.4.4 Prospectively collect data on quality of life, toxicity, response rate, progression-free survival, and overall survival for all patients taking raltitrexed. [2011]

### Capecitabine and tegafur with uracil

The recommendations in this section are from [guidance on the use of capecitabine and tegafur with uracil for metastatic colorectal cancer](#) (NICE technology appraisal guidance 61).

1.3.4.5 Oral therapy with capecitabine is recommended as an option for the first-line treatment of metastatic colorectal cancer. [2003]

1.3.4.6 The choice of regimen (intravenous 5-fluorouracil and folinic acid or capecitabine) should be made jointly by the individual and the clinician(s) responsible for treatment. The decision should be made after an informed discussion between the clinician(s) and the patient; this discussion should take into account contraindications and the side-effect profile of the agents as well as the clinical condition and preferences of the individual. [2003]

1.3.4.7 The use of capecitabine to treat metastatic colorectal cancer should be supervised by oncologists who specialise in colorectal cancer. [2003]



## Biological agents in metastatic colorectal cancer

Refer to [Bevacizumab in combination with oxaliplatin and either 5FU or capecitabine for the treatment of metastatic colorectal cancer](#) (NICE technology appraisal guidance 212).

Refer to [Cetuximab, bevacizumab and panitumumab for the treatment of metastatic colorectal cancer after first-line chemotherapy: Cetuximab \(monotherapy or combination chemotherapy\), bevacizumab \(in combination with non-oxaliplatin chemotherapy\) and panitumumab \(monotherapy\) for the treatment of metastatic colorectal cancer after first-line chemotherapy](#) (NICE technology appraisal 242).

Refer to [Cetuximab and panitumumab for previously untreated metastatic colorectal cancer](#) (NICE technology appraisal 439).

### 1.4 Ongoing care and support

#### 1.4.1 Follow-up after apparently curative resection

1.4.1.1 Offer follow-up to all patients with primary colorectal cancer undergoing treatment with curative intent. Start follow-up at a clinic visit 4–6 weeks after potentially curative treatment. [2011]

1.4.1.2 Offer patients regular surveillance with:

- a minimum of two CTs of the chest, abdomen, and pelvis in the first 3 years and
- regular serum carcinoembryonic antigen tests (at least every 6 months in the first 3 years). [2011]

1.4.1.3 Offer a surveillance colonoscopy at 1 year after initial treatment. If this investigation is normal consider further colonoscopic follow-up after 5 years, and thereafter as determined by cancer networks. The timing of surveillance for patients with subsequent adenomas should be determined by the risk status of the adenoma. [2011]

1.4.1.4 Start reinvestigation if there is any clinical, radiological or biochemical suspicion of recurrent disease. [2011]

1.4.1.5 Stop regular follow-up:

- when the patient and the healthcare professional have discussed and agreed that the likely benefits no longer outweigh the risks of further tests or
- when the patient cannot tolerate further treatments. [2011]

## 1.4.2 Information about bowel function

- 1.4.2.1 Before starting treatment, offer all patients information on all treatment options available to them (including no treatment) and the potential benefits and risks of these treatments, including the effect on bowel function. [2011]
- 1.4.2.2 Before surgery, offer all patients information about the likelihood of having a stoma, why it might be necessary, and how long it might be needed for. [2011]
- 1.4.2.3 Ensure a trained stoma professional gives specific information on the care and management of stomas to all patients considering surgery that might result in a stoma. [2011]
- 1.4.2.4 After any treatment, offer all patients specific information on managing the effects of the treatment on their bowel function. This could include information on incontinence, diarrhoea, difficulty emptying bowels, bloating, excess flatus and diet, and where to go for help in the event of symptoms. [2011]
- 1.4.2.5 Offer verbal and written information in a way that is clearly understood by patients and free from jargon. Include information about support organisations or internet resources recommended by the clinical team. [2011]

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<sup>[2]</sup> At the time of publication (December 2014), the [CReST trial](#) was recruiting patients with acute bowel obstruction caused by suspected colorectal cancer for randomisation to either colonic stent insertion or emergency surgery.

<sup>[3]</sup> See [Improving outcomes in colorectal cancer](#) (NICE cancer service guidance)

<sup>[4]</sup> At the time of publication (November 2011), irinotecan did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

## 2 Research recommendations

In 2011, the Guideline Development Group made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the [full guideline](#).

As part of the 2014 update, the Standing Committee made an additional research recommendation on treatment options for stage I rectal cancer. This can be found in the [addendum](#).

### 2.1 *Treatment of patients with moderate-risk locally advanced rectal cancer*

The effectiveness of preoperative chemotherapy should be compared with SCPRT, chemoradiotherapy or surgery alone in patients with moderate-risk locally advanced rectal cancer. Outcomes of interest are local control, toxicity, overall survival, quality of life and cost effectiveness.

#### Why this is important

Variation exists as to whether or not patients with moderate-risk locally advanced rectal cancer are offered a preoperative treatment or not. If they are offered treatment, variation also exists as to whether it is with SCPRT or chemoradiotherapy. At present, preoperative chemotherapy, without radiotherapy, is limited to use in clinical trials. Patients with moderate-risk locally advanced rectal cancer are at risk of both local recurrence and systemic relapse, but the use of either form of radiotherapy carries the risk of significant morbidity, which may affect quality of life. It is therefore important to establish whether better outcomes can be achieved with preoperative chemotherapy or surgery alone, and whether there are groups of patients whose benefit from either SCPRT or chemoradiotherapy is greater than the risk of late effects.

### 2.2 *The value of prognostic factors in guiding optimal management in patients with locally excised, pathologically confirmed stage I cancer*

An observational study should be conducted, incorporating standardised assessment of pathological prognostic factors, to assess the value of the proposed prognostic factors in guiding optimal management in patients with locally excised, pathologically confirmed stage I cancer. Outcomes of interest are disease-free survival, overall survival, local and regional control, toxicity, cost effectiveness and quality of life.

## Why this is important

The NHS bowel cancer screening programme is detecting increasing numbers of stage I cancers, but the optimum management for these very early tumours is far from clear. The available studies looking at pathological risk factors have not used standardised features, either in terms of the factors included or the methods of assessment. Furthermore, although some consensus can be reached on the pathological risk factors that lead to poorer outcomes, there is no evidence about how these risk factors might be used to guide subsequent clinical management, particularly when the resection margins are considered to be clear. The therapeutic options are varied and there is no realistic prospect for a successful randomised control trial. Therefore, careful follow-up of patients whose tumours have been analysed in a standardised way to define specified pathological risk factors, and who have been treated with one of the possible options, could form the basis of an observational study.

### *2.3 The most effective sequence to perform magnetic resonance imaging (MRI and PET-CT) in patients with colorectal cancer metastasised to the liver to determine whether the metastasis is resectable*

A prospective trial should be conducted to investigate the most clinically-effective and cost-effective sequence in which to perform MRI and PET-CT, after an initial CT scan, in patients with colorectal cancer that has metastasised to the liver, to determine whether the metastasis is resectable. The outcomes of interest are reduction in inappropriate laparotomies and improvement in overall survival.

## Why this is important

Nearly 7% of all patients with liver metastases from colorectal cancer are now being considered for liver resection with curative intent. These operations are costly and have their own inherent risks, including futile laparotomy, which can be psychologically devastating for patients and carers. After the initial diagnosis of suspected liver metastases on diagnostic or follow-up CT scan, it is clear that PET-CT (which is patient-specific to detect incurable extra-hepatic disease) and MRI (which is liver-specific to accurately characterise detected liver lesions) both play roles in the decision algorithm when considering surgery. Both of these investigations are expensive and can lead to delays in starting appropriate treatment. Research is needed to determine the correct sequence of these investigations to reduce the rate of futile laparotomy, improve cost effectiveness of treatment, and ultimately improve overall survival.

## 2.4 *Follow-up after completion of oncological treatment*

Strategies to integrate oncological surveillance with optimising quality of life, reducing late effects, and detecting second cancers in survivors of colorectal cancer should be developed and explored.

### **Why this is important**

Traditionally, oncological surveillance has focused on the early detection of either local recurrence or distant metastases. Although there is increasing evidence that the early detection of such recurrences is worthwhile in terms of subsequent oncological outcomes there are other issues, which are particularly important to patients, that can be detected and managed by appropriate follow-up. The detection of late effects and impact on quality of life are particularly important and research into reducing the likelihood and managing the consequences of such effects makes this all the more relevant to patients. There are numerous different models of surveillance and research should aim to establish strategies that address patient concerns.

## 2.5 *Patient-reported outcome measures in colorectal cancer*

Colorectal cancer-specific patient-reported outcome measures (PROMs) should be developed for use in disease management and to inform outcome measures in future clinical trials.

### **Why this is important**

Quality of life and PROMs are now frequently being used as secondary endpoints in clinical trials of cancer management. However, some investigators continue to use non-disease-specific generic methodology for this purpose. The treatment of colorectal cancer leads to very specific side effects relating to bowel function and activities of daily living. The Guideline Development Group therefore believes that colorectal cancer-specific patient-reported outcome measures should be developed to standardise the interpretation of quality-of-life reporting as a secondary endpoint in future clinical trials in colorectal cancer.

### ***More information***

You can also see this guideline in the NICE Pathway on [colorectal cancer](#).

To find out what NICE has said on topics related to this guideline, see our web page on [colorectal cancer](#).

See also the guideline committee's discussion and the evidence reviews (in the [full guideline and addendum](#)), and information about [how the guideline was developed](#), including details of the committee.

## Update information

**July 2018:** Recommendations on the use of tegafur with uracil in section 1.3.4 have been updated.

**November 2017:** The reference to NICE technology appraisal guidance 176 in section 1.3.4 has been replaced with a reference to [cetuximab and panitumumab for previously untreated metastatic colorectal cancer](#) (NICE technology appraisal guidance 439).

**December 2014:** New recommendations on surgery and colonic stents in acute large bowel obstruction and on stage I rectal cancer have been added to sections 1.2.2 and 1.2.4.

Recommendations are marked as [new 2014], [2011], [2006] or [2003]:

[new 2014] indicates that the evidence has been reviewed and the recommendation has been added or updated.

[2011] indicates that the evidence has not been reviewed since the original guideline.

[2006] indicates that the evidence has not been reviewed since the publication of NICE technology appraisal guidance on [laparoscopic surgery for colorectal cancer](#) and [capecitabine and oxaliplatin in the adjuvant treatment of stage III \(Dukes' C\) colon cancer](#) respectively.

[2003] indicates that the evidence has not been reviewed since the publication of NICE technology appraisal guidance on [capecitabine and tegafur with uracil for metastatic colorectal cancer](#).

## Strength of recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline Development Group is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also [patient-centred care](#)).

## **Interventions that must (or must not) be used**

We usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally we use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

## **Interventions that should (or should not) be used – a 'strong' recommendation**

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer...') when we are confident that an intervention will not be of benefit for most patients.

## **Interventions that could be used**

We use 'consider' when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

## **Recommendation wording in guideline updates**

NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of 'The guidelines manual' (January 2009). This does not apply to any recommendations ending [2006] or [2003]. In particular, for recommendations labelled [2006] or [2003] the word 'consider' may not necessarily be used to denote the strength of the recommendation.

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## Accreditation

