

# Colorectal cancer

The diagnosis and management of colorectal cancer

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#### 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 have been added. The <u>addendum</u> to NICE guideline CG131 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 <u>Good practice in prescribing and managing medicines and devices</u> 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 <a href="NHS Constitution for England">NICE guidance is written to reflect these.</a>. 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 <a href="Department of Health's advice on consent">Department of Health's advice on consent</a>. If someone does not have capacity to make decisions, healthcare professionals should follow the <a href="Code of practice that accompanies the Mental Capacity Act">Capacity Act</a> and the supplementary <a href="Code of practice that accompanies the Mental Capacity Act">Code of practice on deprivation of liberty safeguards</a>.

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in <u>patient experience</u> 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 <u>table 1</u> 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 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.

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 <u>Good practice in prescribing and managing medicines and devices</u> for further information.

#### 1 Recommendations

The following guidance is based on the best available evidence. The <u>full guideline</u> gives details of the methods and the evidence used to develop the guidance. The <u>guideline addendum</u> gives details of the methods and the evidence used to develop the 2014 update.

The wording used in the recommendations in this guideline (for example, words such as 'offer' and 'consider') denotes the certainty with which the recommendation is made (the strength of the recommendation). See <u>about this guideline</u> for details.

# 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 <u>referral for suspected cancer</u> (NICE guideline CG27).

#### 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	Characteristics of rectal tumours predicted by MRI
recurrence	

High	A threatened (<1 mm) or breached resection margin or			
	Low tumours encroaching onto the inter-sphincteric plane <b>or</b> with levator involvement			
Moderate	<ul> <li>Any cT3b or greater, in which the potential surgical margin is not threatened or</li> </ul>			
	<ul> <li>Any suspicious lymph node not threatening the surgical resection margin or</li> </ul>			
	The presence of extramural vascular invasion[i]			
Low	• cT1 or cT2 or cT3a and			
	No lymph node involvement			
[a] This feature is	also associated with high risk of systemic recurrence.			

#### 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 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 <u>laparoscopic surgery for colorectal cancer</u> (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 <u>capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer</u> (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 either capecitabine or tegafur with uracil (in combination with folinic acid) 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 one of the oral therapies) 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 or tegafur with uracil to treat metastatic colorectal cancer should be supervised by oncologists who specialise in colorectal cancer. [2003]

# Biological agents in metastatic colorectal cancer

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

Refer to <u>Cetuximab for the first-line treatment of metastatic colorectal cancer</u> (NICE technology appraisal guidance 176).

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).

# 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]

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

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

<sup>&</sup>lt;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 <u>Good practice in prescribing and managing medicines and devices for further information</u>.

#### 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 <u>full guideline</u>.

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 <u>addendum</u>.

# 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.

#### 3 Other information

# 3.1 Scope and how this guideline was developed

The <u>scope</u> for the 2011 guideline covers the recommendations labelled **[2011]**. The recommendations labelled **[new 2014]** have been produced during the update.

#### How this guideline was developed

The original guideline (published in 2011) was developed by the National Collaborating Centre for Cancer, which is hosted by Velindre NHS Trust in Cardiff. The Collaborating Centre worked with a Guideline Development Group, comprising healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, which reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

NICE's Clinical Guidelines Update Programme updated this guideline in 2014. This guideline was updated using a Standing Committee of healthcare professionals, methodologists and lay members from a range of disciplines and localities, as well as topic experts.

See the methods and processes for developing NICE clinical guidelines.

# 3.2 Related NICE guidance

Details are correct at the time of publication of the guideline (December 2014). Further information is available on the NICE website.

#### **Published**

#### General

- Patient experience in adult NHS services (2012) NICE guidance CG138
- Medicines adherence (2009) NICE guideline CG76

#### **Condition-specific**

- Aflibercept in combination with irinotecan and fluorouracil-based therapy for treating metastatic colorectal cancer that has progressed following prior oxaliplatin-based chemotherapy (2014) NICE technology appraisal guidance 307
- Quality standard for colorectal cancer (2012) NICE quality standard 20
- <u>Cetuximab, bevacizumab and panitumumab for the treatment of metastatic colorectal cancer</u> <u>after first-line chemotherapy</u> (2012) NICE technology appraisal guidance 242
- Selective internal radiation therapy for non-resectable colorectal metastases in the liver
   (2011) NICE interventional procedure guidance 401
- Colonoscopic surveillance for prevention of colorectal cancer in people with ulcerative colitis.
   Crohn's disease or adenomas (2011) NICE guideline CG118
- Microwave ablation for the treatment of liver metastases (2011) NICE interventional procedure guidance 406
- Bevacizumab in combination with oxaliplatin and either fluorouracil plus folinic acid or capecitabine for the treatment of metastatic colorectal cancer (2010) NICE technology appraisal guidance 212
- <u>Percutaneous radiofrequency ablation for primary or secondary lung cancers</u> (2010) NICE interventional procedure guidance 372
- Cryotherapy for the treatment of liver metastases (2010) NICE interventional procedure guidance 369
- Cytoreduction surgery followed by hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis (2010) NICE interventional procedure guidance 331
- <u>Cetuximab for the first-line treatment of metastatic colorectal cancer</u> (2009) NICE technology appraisal guidance 176
- Radiofrequency ablation for colorectal liver metastases (2009) NICE interventional procedure guidance 327
- Metastatic spinal cord compression (2008) NICE guideline CG75

- <u>Cetuximab for the treatment of metastatic colorectal cancer following failure of oxaliplatin-containing chemotherapy (terminated appraisal)</u> (2008) NICE technology appraisal 150
- Bevacizumab and cetuximab for the treatment of metastatic colorectal cancer (2007) NICE technology appraisal guidance 118
- Radiofrequency-assisted liver resection (2007) NICE interventional procedure guidance 211
- Preoperative high dose rate brachytherapy for rectal cancer (2006) NICE interventional procedure guidance 201
- Laparoscopic surgery for colorectal cancer (2006) NICE technology appraisal guidance 105
- Capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer
   (2006) NICE technology appraisal guidance 100
- Referral guidelines for suspected cancer (2005) NICE guideline CG27
- Laparoscopic liver resection (2005) NICE interventional procedure guidance 135
- Computed tomographic colonography (virtual colonoscopy) (2005) NICE interventional procedure guidance 129
- <u>Laparoscopic liver resection</u> (2005) NICE interventional procedure guidance 135
- Improving supportive and palliative care for adults with cancer (2004) NICE cancer service guidance
- <u>Improving outcomes in colorectal cancers: manual update</u> (2004) NICE cancer service quidance
- Guidance on the use of capecitabine and tegafur with uracil for metastatic colorectal cancer (2003) NICE technology appraisal guidance 61

# **Under development**

NICE is developing the following guidance (details available from the NICE website):

• <u>Colorectal cancer (metastatic) – cetuximab (review TA176) and panitumumab (part review TA240) (1st line)</u>. NICE technology appraisal guidance. Publication expected April 2016.

# 4 Standing Committee B and NICE project team

# 4.1 Standing Committee B

The Committee members listed are those for the [2014] update. For the composition of the previous Guideline Development Group, see the <u>full quideline</u>.

#### **Standing Committee members**

#### Susan Bewley, Chair

Professor of Complex Obstetrics, Kings College London

#### Gita Bhutani

Clinical Psychologist, Lancashire Care NHS Foundation Trust

#### **Jennifer Bostock (until September 2014)**

Lay Member

#### **Simon Corbett**

Cardiologist, University Hospital Southampton NHS Foundation Trust

#### John Graham

Consultant Oncologist & Trust Cancer Lead Clinician, Taunton & Somerset Hospital

#### **Peter Hoskin**

Consultant in Clinical Oncology, Mount Vernon Hospital

#### **Roberta James**

Programme Lead, Scottish Intercollegiate Guidelines Network (SIGN)

#### **Asma Khalil**

Obstetrician, St George's Hospital University London

#### **Manoj Mistry**

Lay member

#### **Amaka Offiah**

Radiologist and Clinical Senior Lecturer, Sheffield University

#### **Mark Rodgers**

Research Fellow, University of York

#### Nicholas Steel

Clinical Senior Lecturer in Primary Care, Norwich Medical School

#### Sietse Wieringa

General Practitioner, Barts & the London School of Medicine & Dentistry

#### **Colorectal Cancer Topic-Specific Committee Members**

#### **Sunil Dolwani**

Consultant Gastroenterologist, Cardiff and Vale University Health Board

#### James Hill

Consultant Colorectal and General Surgeon, Central Manchester NHS Foundation Trust

#### **Clive Kay**

Consultant Radiologist, Bradford Teaching Hospitals NHS Trust

#### **Jonathan Tobutt**

Lay member

# 4.2 Clinical Guidelines Update Team

#### Phil Alderson

Clinical Advisor

#### **Emma Banks**

Coordinator

#### Jenny Craven

Information Scientist

#### **Paul Crosland**

**Health Economist** 

#### **Nicole Elliott**

Associate Director

#### **Kathryn Hopkins**

**Technical Analyst** 

#### Susannah Moon

Programme Manager

#### **Rebecca Parsons**

**Project Manager** 

#### **Charlotte Purves**

Administrator

#### **Toni Tan**

**Technical Advisor** 

# 4.3 NICE project team

#### **Mark Baker**

Clinical Lead

#### Ben Doak

**Guideline Commissioning Manager** 

#### **James Hall**

Senior Medical Editor

#### Alice Law

Communications Lead

#### **Barbara Meredith (until September 2014)**

Public Involvement Advisor

#### **Sharon Summers-Ma**

Guideline Lead

#### **Judith Thornton**

Technical Lead

#### Louisa Wall

Implementation Lead

#### **Jennifer Wells**

**Guideline Coordinator** 

#### **Erin Whittingham (from October 2014)**

Public Involvement Advisor

# 4.4 Declarations of interests

The following members of the Standing Committee made declarations of interest. All other members of the Committee stated that they had no interests to declare.

Standing Committee member	Interest declared	Type of interest	Decision taken
Susan Bewley	Self-employed academic and obstetric expert.	Personal pecuniary interest	Declare and participate
Susan Bewley	100 hour per annum teaching contract with Kings College London.	Personal pecuniary interest	Declare and participate

Susan	In the last 12 months received income or fees for:	Personal	Declare
Bewley	Research projects as a principal or co-investigator or giving expert advice (presently these include projects on major postpartum haemorrhage, the organisation of maternity care, gestation time for abortion).	pecuniary interest	and participate
	Academic supervision (PhD on implementation of external cephalic version, chair of 35/39 TSC on the timing of induction).		
	Teaching (BSc law and ethics tutor at KCL, occasional fees for lectures on obstetrics).		
	Medic-legal reports (approx. 2/year) and Medical Defence Union cases committee and council.		
	External reviews for NHS organisations related to my obstetric expertise (serious incident and maternal mortality investigations, RCOG review).		
	Chairing NICE GDG.		
	Expert advice to NHS Quest (development of a maternity 'safety thermometer').		
	Royalties from edited books.		
	Advice to Marie Stopes International about obstetric standards.		
Susan Bewley	Expenses paid to attend conferences to lecture on obstetric topics. In the last year this included speaking to a Human Rights conference at the Hague, the Royal Society of Edinburgh, and the International Society of Psychosomatic Obstetrics and Gynaecology, and attending the British Maternal Fetal Medicine Society conference. Received a community grant to attend the British HIV Association conference.	Personal pecuniary interest	Declare and participate

Susan Bewley	Joint intellectual property rights in a new neonatal resuscitation trolley, but these were negotiated to be handed over to Liverpool University and Inditherm. In return, the inventors have negotiated that a fee generated on the sale of each trolley will be given to charity.	Non-personal pecuniary interest	Declare and participate
Susan Bewley	Expressed views in publications about obstetric matters, largely based on evidence.	Personal non-pecuniary interest	Declare and participate
Susan Bewley	A trustee and committee member of Healthwatch (a charity devoted to evidence and "for treatments that work") and a trustee of Sophia (a charity devoted to women with HIV and the UK arm of the Global Coalition for Women and AIDS).	Personal non-pecuniary interest	Declare and participate
Susan Bewley	Member of the following editorial boards: Medical Law Review, International Journal of Childbirth, JASS (Journal Article Summary Service); Member of the London Clinical Senate; Member of the Mayor's Office for Policing and Crime Violence Against Women and Girls Panel; Member All-Parliamentary Party Group on Maternity; Trustee of Maternity Action (a charity which aims to end inequality and improve the health and wellbeing of pregnant women, partners and young children), one of seven members of the Women's Health and Equality Consortium which is a Strategic Partner of the Department of Health.	Personal non-pecuniary interest	Declare and participate
Susan Bewley	Expert advice to Salamander Trust (funded by WHO to perform a global community consultation of women living with HIV to inform Sexual and Reproductive Health and Human Rights guideline update).	Personal pecuniary interest	Declare and participate

Susan Bewley	Expenses paid to attend and present at 'Changing Motherhood' and 'Assisted reproduction that harms' conferences.	Personal pecuniary interest	Declare and participate
Gita Bhutani	Member of British Psychological Society; Division of Clinical Psychology; Faculty of Leadership and Management Committee Member.	Personal non-pecuniary interest	Declare and participate

			I
Jennifer	2013 – current, Lay Member/PPI Advisor – CEDAR		Declare
Bostock (Dec 13 – Sept 14)	Institute of Public Health, University of Cambridge.  2013 – current, PPI Board Member – NIHR School of Public Health, NIHR – University of Sheffield	non-pecuniary interest	and participate
	(host) & 7 others.		
	2011 – current, Lay Member – Advisory Group Healthcare Quality Improvement Partnership.		
	2011 – current, PPI Advisor, King's College London (MOVE IT & Pembury studies).		
	2010 – current, Lay Member – PPI research group, Healthcare Acquired Infection Research Network.		
	2010 – current, PPI Collaborator & Co-Applicant & Trial Steering Committee, Infection RCTrials: Oviva; ARREST & ASSIST + Co-app FAST-GAIN & FACT-MRC; St Thomas' Hospital & University of Oxford & University of Sussex.		
	2009 – current, Public Advisor, Dept of Population health University of Oxford.		
	2010 – current, Public Involvement Implementation Group – Core Member Quality & Outcomes of person-centred care policy research unit: LSE/ Oxford & Kent Universities.		
	2010 – current, Lay Reviewer, NIHR & Department of Health (Policy Research Programme).		
	2010 – current, Public Member – H Acquired Infection Research Network University of West London.		
	2006 – current, Committee Member – Lead Reviewer & Sub Com member & Proportionate Review analyst, NHS Research Ethics Committee (Institute of Psychiatry REC MCA flagged).		
	2010 – current, Lay Committee Member, NIHR: RfPB; PgfAR HS&DR & TCC.		

	2012 – current, Ethics Consultant – Scabies Study, Public Health England, University of Sussex & British Skin Foundation.  2010 – current, Visiting Guest Lecturer, Dept of Psychological Medicine: Kings College London.  2014 – current, Lay Reviewer & Ethics Advisor, King's Centre for Military Health.  2013 – current, Committee Member (Trauma) Royal College of Physicians, National Clinical Guidelines Centre.		
	2011 – current, Lay Research Advisor – Very Brief Interventions Project, University of Cambridge.		
	2013 – current, Research Design Service – PPI Consultant, Research Design Service – London & South Central.		
	2011 – current, Lay Member and Advisor, Guys & St Thomas' Biomedical Research Centre Advisory Group.		
	2011 – current, FAST-R Consultant (lay), Mental Health Research Network.		
	2014 – current, Lay Reviewer, Dept of Health: Policy Research Programme.		
	2011 – current, Lay Advisory Group Member, Health Quality Improvement Partnership.		
	2010 – current, Independent Mental Health Act Manager, Oxleas NHS FT.		
	2014 – current, Lay Research Advisor, Imperial – Faculty of Medicine.		
Simon Corbett	Network Service Adviser for the British Cardiovascular Society. This role incorporates the regional specialty adviser role for the Royal College of Physicians.	Personal non-pecuniary interest	Declare and participate

Simon Corbett	Acting Director for Clinical Effectiveness for employer (University Hospital Southampton NHS Foundation Trust). Part of this role involves the dissemination and implementation of NICE guidance in the Trust.	Personal non-pecuniary interest	Declare and participate
John Graham	Director of National Collaborating Centre for Cancer – this post is funded through a contract with NICE to produce NICE's clinical guidelines.	Non-personal pecuniary interest	Declare and participate
John Graham	Principal investigator for an ongoing clinical trial in prostate cancer with Custirsen funded by OncoGenex Technologies Inc and Teva Pharmaceutical Industries Ltd.	Non-personal pecuniary interest	Declare and participate
John Graham	Principal investigator for 8 ongoing clinical trials in breast and prostate cancer run via the National Cancer Research Network (not pharmaceutical industry funded).	Non-personal pecuniary interest	Declare and participate
John Graham	Member of the trial management groups for 2 prostate cancer trials: RT01 and CHHIP. Both are closed to recruitment but continuing to report trial results.	Personal non-pecuniary interest	Declare and participate
John Graham	Principal investigator for a study of radium-223 in prostate cancer that is funded by Bayer Pharmaceuticals. It is non-personal pecuniary and started on 12th June.	Non-personal pecuniary interest	Declare and participate
John Graham	In May 2014 I did some work for NICE International on a project with the Philippines Department of Health and received a consultancy fee, travel and subsistence payments.	Personal non-pecuniary interest	Declare and participate
Peter Hoskin	Research grant paid to department from Varian Medical (until Dec 2013).	Non-personal pecuniary interest	Declare and participate

Peter Hoskin	Investigator in research studies sponsored by various companies with payment for expenses to NHS Trust and department which fund research staff. Recent studies have been on behalf of Millenium, Astellas, Ipsen and Amgen.	Non-personal pecuniary interest	Declare and participate
Peter Hoskin	Fellow of the Royal College of Radiologists and member of Faculty Board, Specialist Training Board and Chair of Exam Board.	Personal non-pecuniary interest	Declare and participate
Peter Hoskin	Consultant to the IAEA; Undertake by invitation lectures and working group meetings for which expenses may be paid.	Personal pecuniary interest	Declare and participate
Peter Hoskin	Received reimbursement of travelling expenses and conference registration fee for attending the European Society of Radiation and Oncology (ESTRO) in December 2013.	Personal pecuniary interest	Declare and participate
Peter Hoskin	Chief investigator for a trial investigating brachytherapy +/- external bean radiotherapy, which received funding from Dept of Health and CRUK. Continues to follow those patients up and publish data from the study.	Non-personal pecuniary interest	Declare and participate
Peter Hoskin	Holds a research grant from Varian which pays the salary for a data manager working of HDR boost, for Brachytherapy in prostate cancer.	Non-personal pecuniary interest	Declare and participate
Peter Hoskin	Department reimbursed for studies on abiraterone by Cougar.	Non-personal pecuniary interest	Declare and participate
Peter Hoskin	Department reimbursed for studies on alpharadin by Astellas.	Non-personal pecuniary interest	Declare and participate
Peter Hoskin	Department reimbursed for studies on MDV 3100 by Medivation.	Non-personal pecuniary interest	Declare and participate

Peter	Department reimbursed for studies on Denosumab	Non-personal	Declare
Hoskin	for prostate cancer. Funded by Amgen.	pecuniary interest	and participate
Peter Hoskin	Department receives grants from Astellas for trials in prostate cancer.	Non-personal pecuniary interest	Declare and participate
Peter Hoskin	Department receives grants from Bayer for trials in prostate cancer.	Non-personal pecuniary interest	Declare and participate
Peter Hoskin	Department received grants from Millennium for trials in prostate cancer.	Non-personal pecuniary interest	Declare and participate
Peter Hoskin	Department received grants from Varian for trials in prostate cancer.	Non-personal pecuniary interest	Declare and participate
Peter Hoskin	Trustee for funding research within the unit/ department. Funded by Donations/Legacies. No Non-Hodgkin's lymphoma research has been funded in the last 12 months.	Personal non-pecuniary interest	Declare and participate
Peter Hoskin	Chair Steering Group for National Cancer Intelligence Network (NCIN).	Personal non-pecuniary interest	Declare and participate
Peter Hoskin	Member of the committee of Medical Aspects for Radiation Exposure (COMARE).	Personal non-pecuniary interest	Declare and participate
Peter Hoskin	Chair of the executive committee of GEC ESTRO Brachytherapy Group.	Personal non-pecuniary interest	Declare and participate
Peter Hoskin	Member of the faculty board of the Royal College of Radiologists.	Personal non-pecuniary interest	Declare and participate

Peter Hoskin	Member of the specialist training committee for the Royal college of Radiologists.	Personal non-pecuniary interest	Declare and participate
Peter Hoskin	Member of the specialist training advisory committee (STAC) for the Royal College of Radiologist.	Personal non-pecuniary interest	Declare and participate
Peter Hoskin	Editorial board member for the Journal of Clinical Oncology.	Personal non-pecuniary interest	Declare and participate
Peter Hoskin	Editorial board member for the Journal of Contemporary Brachytherapy.	Personal non-pecuniary interest	Declare and participate
Peter Hoskin	Member of the East of England senate.	Personal non-pecuniary interest	Declare and participate
Peter Hoskin	Member of the NICE standing committee for rapid updates / and non-Hodgkin's lymphoma GDG.	Personal non-pecuniary interest	Declare and participate
Roberta James	Programme Lead at Scottish Intercollegiate Guidelines Network (SIGN).	Personal pecuniary interest	Declare and participate
Roberta James	Validation of systematic review of guideline methodology, Belgian healthcare organisation KCE – one off payment.	Personal pecuniary interest	Declare and participate
Roberta James	Member of Guideline Implementability Research and Application network (GIRAnet).	Personal non-pecuniary interest	Declare and participate
Roberta James	Expert group member of Project on a Framework for Rating Evidence in Public Health (PRECEPT).	Personal non-pecuniary interest	Declare and participate

Asma Khalil	None.		No action
Manoj Mistry	Public member of Penine Care NHS FT as a carer for my sister. Attend monthly meetings.	Personal non-pecuniary interest	Declare and participate
Manoj Mistry	PPI representative for the Health Research Authority (HRA). Attended 2 meetings to date.	Personal non-pecuniary interest	Declare and participate
Manoj Mistry	PPI representative for the Health Quality Health Improvement Partnership (HQIP) (London). Attended meetings to date.	Personal non-pecuniary interest	Declare and participate
Manoj Mistry	PPI representative for the Primary Care Research in Manchester Engagement Resource (PRIMER) group at the University of Manchester. Attended 2 meetings to date.	Personal non-pecuniary interest	Declare and participate
Manoj Mistry	Carer representative on NICE Guideline Development Group: 'Transition between inpatient hospital settings and community or care home settings for adults with social care needs.' Attended 4 meetings to date.	Personal non-pecuniary interest	Declare and participate
Manoj Mistry	Appointed Lay representative for the MSc Clinical Science (Clinical Bio informatics) at the University of Manchester.	Personal non-pecuniary interest	Declare and participate
Manoj Mistry	Appointed 'Lay Educational Visitor' with the Health and Care Professions Council. (HCPC London).	Personal non-pecuniary interest	Declare and participate
Amaka Offiah	Provision of expert advice to Her Majesty's Courts in cases of suspected child abuse.	Personal pecuniary interest	Declare and participate
Amaka Offiah	Recipient of honoraria and expenses for lectures and guidelines development from BioMarin.	Personal pecuniary interest	Declare and participate

Amaka Offiah	Chairperson Skeletal Dysplasia Group for Teaching and Research.	Personal non-pecuniary interest	Declare and participate
Amaka Offiah	Chairperson Child Abuse Taskforce of the European Society of Paediatric Radiology.	Personal non-pecuniary interest	Declare and participate
Amaka Offiah	Member Joint RCR/RCPCH NAI Working Party for Guideline Update – Imaging in Suspected Non-Accidental Injury.	Personal non-pecuniary interest	Declare and participate
Amaka Offiah	Member of the Royal College of Radiology Academic Committee.	Personal non-pecuniary interest	Declare and participate
Amaka Offiah	Committee member of the International Consortium for Vertebral Anomalies and Scoliosis.	Personal non-pecuniary interest	Declare and participate
Amaka Offiah	Member of South Yorkshire (Sheffield) Research Ethics Committee.	Personal non-pecuniary interest	Declare and participate
Amaka Offiah	Medical Academic Staff Committee Representative of the Yorkshire Regional Council of the BMA.	Personal non-pecuniary interest	Declare and participate
Amaka Offiah	Partner Governor of the Sheffield Children's NHS Foundation Trust (representing the University of Sheffield).	Personal non-pecuniary interest	Declare and participate
Amaka Offiah	Editorial Committee Member of the journal Paediatric Radiology.	Personal non-pecuniary interest	Declare and participate
Amaka Offiah	Recipient of research funding from NIHR, ARUK, The Sheffield Children's Charity, Skeletal Dysplasia Group for Teaching and Research.	Non-personal pecuniary interest	Declare and participate

Mark Rodgers	Associate editor of the journal Systematic Reviews that publishes research on health and social care.	Personal non-pecuniary interest	Declare and participate
Mark Rodgers	Research fellow in health services research; has provided independent academic reviews of clinical effectiveness and diagnostic accuracy evidence for funders including NIHR and NICE.	Personal non-pecuniary interest	Declare and participate
Nicholas Steel	Currently finishing work as the principal investigator on a National Institute of Health Research (NIHR) funded project on: 'Are NICE clinical guidelines for primary care based on evidence from primary care?'.	Non-personal pecuniary interest	Declare and participate
Nicholas Steel	National Institute for Health Research (NIHR) Health Services & Delivery Research Programme Healthcare Delivery Research Panel member.	Personal non-pecuniary interest	Declare and participate
Nicholas Steel	NIHR Regional Advisory Committee for the Research for Patient Benefit Programme East of England region.	Personal non-pecuniary interest	Declare and participate
Nicholas Steel	Norfolk & Suffolk Primary & Community Care Research Steering Group.	Personal non-pecuniary interest	Declare and participate
Nicholas Steel	Advisory Committee on Clinical Excellence Awards (ACCEA) East of England.	Personal non-pecuniary interest	Declare and participate
Nicholas Steel	'Implementation Science' Editorial Board member.	Personal non-pecuniary interest	Declare and participate
Nicholas Steel	'Quality in Primary Care' Editorial Board member.	Personal non-pecuniary interest	Declare and participate

Nicholas Steel	Faculty of Public Health Part A MFPH Examiner.	Personal non-pecuniary interest	Declare and participate
Nicholas Steel	Faculty of Public Health Part A MFPH Development Committee.	Personal non-pecuniary interest	Declare and participate
Nicholas Steel	Honorary Public Health Academic Consultant, Public Health England.	Personal non-pecuniary interest	Declare and participate
Nicholas Steel	Research grant: 'Are NICE clinical guidelines for primary care based on evidence from primary care?' (Chief Investigator) – National Institute for Health Research, RfPB.	Personal non-pecuniary interest	Declare and participate
Nicholas Steel	Publication in press: Steel N, Abdelhamid A, Stokes T, Edwards H, Fleetcroft R, Howe A, Qureshi N. Publications cited in national clinical guidelines for primary care were of uncertain relevance: literature review. In Press Journal of Clinical Epidemiology.	Personal non-pecuniary interest	Declare and participate
Sietse Wieringa	At the Centre for Primary care & Public Health at Barts & The London School of Medicine & Dentistry/Queen Mary University I am working on a literature review of 'mindlines' (related to communities of practice) and a qualitative study of a large group of GPs on a virtual social network sharing medical knowledge. I am funded for this via an NIHR In practice fellowship.	Personal pecuniary interest	Declare and participate
Sietse Wieringa	I co-own a small social enterprise called Zorgldee that develops ideas to help GPs to collaborate.  There are no current funders.	Personal pecuniary interest	Declare and participate

Sietse Wieringa	Board member of the Platform of Medical Leadership in the Netherlands, via which I am involved in a mixed methods study for the development of a medical leadership competency framework. The study group receives funds from KNMG (Royal Dutch College of Medicine) and SBOH which receives its funds from the Dutch Ministry of Health.	Non-personal pecuniary interest	Declare and participate
Sietse Wieringa	Member of Generation Next, a think tank and network of young GPs. It's indirectly funded by the Ministry of Health.	Personal non-pecuniary interest	Declare and participate
Sietse Wieringa	Member of NHG (Dutch GP Society), which produces guidelines and I worked for this organisation in the past.	Personal non-pecuniary interest	Declare and participate
Topic- specific member	Interest declared	Type of interest	Decision taken
Clive Kay	I am on the Steering Committee of UKRC CTAAC-funded randomised multi-centre study of colorectal stenting versus surgery in colonic obstruction (the CReST trail).	Non-personal pecuniary interest	Declare and participate
Clive Kay	I have been fully involved in Trial Design, patient selection, protocol development and grant application. I am the Lead National Radiologist for the Trail. I review all the serious adverse incidents.	Non-personal pecuniary interest	Declare and participate
James Hill	I am the chief investigator for the CReST trial of stenting vs surgery for the management of patients with obstructing carcinoma of the left colon. This is a CRUK funded multicentre trial which is expected to stop randomisation at the end of 2014.	Personal non-pecuniary interest	Declare and participate
Jonathan Tobutt	None.		No action

Sunil	None.	No action
Dolwani		

# About this guideline

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions.

NICE guidelines are developed in accordance with a <u>scope</u> that defines what the guideline will and will not cover.

The original guideline (published in 2011) was developed by the National Collaborating Centre for Cancer, which is hosted by Velindre NHS Trust in Cardiff. The Collaborating Centre worked with a Guideline Development Group, comprising healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, which reviewed the evidence and drafted the recommendations.

NICE's Clinical Guidelines Update Programme updated this guideline in 2014. This guideline was updated using a Standing Committee of healthcare professionals, methodologists and lay members from a range of disciplines and localities, as well as topic experts.

The recommendations were finalised after public consultation.

The methods and processes for developing NICE clinical guidelines are described in <u>The</u> guidelines manual.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

## **Update information**

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 <u>iaparoscopic surgery for colorectal cancer</u> and <u>capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer</u> respectively
- [2003] indicates that the evidence has not been reviewed since the publication of NICE technology appraisal guidance on <u>capecitabine and tegafur with uracil for metastatic colorectal cancer</u>.

# 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] (see 'Update information' above for details about how recommendations are labelled). In particular, for recommendations labelled [2006] or [2003] the word 'consider' may not necessarily be used to denote the strength of the recommendation.

## Other versions of this guideline

The full guideline, 'Colorectal cancer: the diagnosis and management of colorectal cancer' contains details of the methods and evidence used to develop the guideline. It is published by the National Collaborating Centre for Cancer.

The recommendations from this guideline have been incorporated into a <u>NICE Pathway</u>.

We have produced information for the public about this guideline.

# **Implementation**

<u>Implementation tools and resources</u> to help you put the guideline into practice are also available.

# Your responsibility

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summaries of product characteristics of any drugs.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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