National Institute for Health and Clinical Excellence

Colorectal cancer

The diagnosis and management of colorectal cancer

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NICE clinical guideline 131

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Contents

This guidance includes an update of NICE technology appraisal guidance 93 (published August 2005) and replaces it.

Introduction

Colorectal cancer is the third most common cancer 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.

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

Patient-centred care

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

Treatment and care should take into account patients' needs and preferences. People with colorectal cancer should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If patients do not have the capacity to make decisions, healthcare professionals should follow the Department of Health's advice on consent and the code of practice that accompanies the Mental Capacity Act. In Wales, healthcare professionals should follow advice on consent from the Welsh Government.

Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's needs. Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

If the patient agrees, families and carers should have the opportunity to be involved in decisions about treatment and care.

Families and carers should also be given the information and support they need.

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[1]) as second-line treatment or
  - XELOX (capecitabine plus oxaliplatin) as first-line treatment then FOLFIRI (folinic acid plus fluorouracil plus irinotecan) 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.

[1] At the time of publication (November 2011), irinotecan did not have UK marketing authorisation for second-line combination therapy. Informed consent should be obtained and documented.

1 Guidance

The following guidance is based on the best available evidence. The full guideline gives details of the methods and the evidence used to develop the guidance.

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 Referral for suspected cancer (NICE clinical guideline 27).

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.

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).

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.

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.

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.

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.

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.

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.

1.1.2.4 Do not use the findings of a digital rectal examination as part of the staging assessment.

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	• A threatened (< 1 mm) or breached resection margin **or** • Low tumours encroaching onto the inter-sphincteric plane **or** with levator involvement

Moderate	• Any cT3b or greater, in which the potential surgical margin is not threatened **or** • Any suspicious lymph node not threatening the surgical resection margin **or** • The presence of extramural vascular invasion[a]
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).

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.

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.

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).

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.

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.

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

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.

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.

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

1.2.2.3 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.

1.2.2.4 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.

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.

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

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.

1.2.2.8 If a self-expanding metallic stent is suitable (see recommendations 1.2.2.1–1.2.2.7) attempt insertion urgently and no longer than 24 hours after patients present with colonic obstruction.

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.

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

1.2.3.3 Discuss the risks and benefits of all treatment options with the patient after discussion in the MDT.

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

1.2.4 Laparoscopic surgery

The recommendations in this section are from Laparoscopic surgery for colorectal cancer (NICE technology appraisal guidance 105).

1.2.4.1 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.

1.2.4.2 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.

1.2.4.3 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.

1.2.5 Adjuvant chemotherapy in rectal cancer

1.2.5.1 Assess pathological staging after surgery, before deciding whether to offer adjuvant chemotherapy.

1.2.5.2 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.

1.2.6 Adjuvant chemotherapy for high-risk stage II colon cancer

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

1.2.7 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).

1.2.7.1 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.

1.2.7.2 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.

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.

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.

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.

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.

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.

1.3.3.3 Discuss all imaging with the patient following review by the appropriate anatomical site-specific MDT.

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.

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.

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.

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 firstline treatment then single agent irinotecan as second-line treatment **or**
- FOLFOX as first-line treatment then FOLFIRI (folinic acid plus fluorouracil plus irinotecan[3]) as second-line treatment **or**
- XELOX (capecitabine plus oxaliplatin) as first-line treatment then FOLFIRI (folinic acid plus fluorouracil plus irinotecan) as second-line treatment.

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.

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.

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.

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.

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.

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.

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 for the first-line treatment of metastatic colorectal cancer (NICE technology appraisal guidance 176).

Refer to Cetuximab for the treatment of metastatic colorectal cancer following failure of oxaliplatin-containing chemotherapy (terminated appraisal) (NICE technology appraisal 150).

Refer to Bevacizumab and cetuximab for the treatment of metastatic colorectal cancer (NICE technology appraisal guidance 118).

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.

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).

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.

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

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.

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.

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.

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.

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.

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.

[2] See Improving outcomes in colorectal cancer (NICE cancer service guidance)

[3] At the time of publication (November 2011), irinotecan did not have UK marketing authorisation for second-line combination therapy. Informed consent should be obtained and documented.

2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover. The scope of this guideline is available – click on 'How this guidance was produced'.

Groups that are covered

- Adults (18 years and older) with newly diagnosed adenocarcinoma of the colon.
- Adults with newly diagnosed adenocarcinoma of the rectum.
- Adults with relapsed adenocarcinoma of the colon.
- Adults with relapsed adenocarcinoma of the rectum.

Groups that are not covered

- Patients with anal cancer.
- Children (younger than 18) with colorectal cancer.
- Patients with primary or secondary lymphoma of the colon and rectum.
- Patients with pure small cell carcinoma of the colon and rectum.
- Patients with carcinoid tumours of the colon and rectum.
- Patients with high grade neuroendocrine tumours of the colon and rectum.
- Patients with adenocarcinoma with some neuroendocrine differentiation.
- Patients with gastrointestinal stromal tumours (GIST) or sarcoma of the colon and rectum.

How this guideline was developed

NICE commissioned the National Collaborating Centre for Cancer to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations. An independent Guideline Review Panel oversaw the development of the guideline (see appendix B).

There is more information about how NICE clinical guidelines are developed on the NICE website. A booklet, 'How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS' (fourth edition, published 2009), is available from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1739).

3 Implementation

NICE has developed tools to help organisations implement this guidance (see www.nice.org.uk/guidance/CG131).

4 Research recommendations

The Guideline Development Group has 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 (see section 5).

4.1 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.

4.2 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.

4.3 The most effective sequence to perform 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.

4.4 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.

4.5 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.

5 Other versions of this guideline

5.1 Full 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.

5.2 NICE pathway

The recommendations from this guideline have been incorporated into a NICE pathway.

5.3 'Understanding NICE guidance'

A summary for patients and carers ('Understanding NICE guidance') is available.

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N2677).

We encourage NHS and voluntary sector organisations to use text from this booklet in their own information about colorectal cancer.

6 Related NICE guidance

Published

- Microwave ablation for the treatment of liver metastases. NICE interventional procedure 406 (2011).
- Selective internal radiation therapy for non-resectable colorectal metastases in the liver. NICE interventional procedure 401 (2011).
- Colonoscopic surveillance for prevention of colorectal cancer in patients with ulcerative colitis, Crohn's disease or adenomas. NICE clinical guideline 118 (2011).
- Bevacizumab in combination with oxaliplatin and either fluorouracil plus folinic acid or capecitabine for the treatment of metastatic colorectal cancer. NICE technology appraisal guidance 212 (2010).
- Percutaneous radiofrequency ablation for primary or secondary lung cancers. NICE interventional procedure guidance 372 (2010).
- Cryotherapy for the treatment of liver metastases. NICE interventional procedure guidance 369 (2010).
- Cytoreduction surgery followed by hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis. NICE interventional procedure guidance 331 (2010).
- Cetuximab for the first-line treatment of metastatic colorectal cancer. NICE technology appraisal guidance 176 (2009).
- Radiofrequency ablation for colorectal liver metastases. NICE interventional procedure guidance 327 (2009).
- Metastatic spinal cord compression. NICE clinical guideline 75 (2008).
- Cetuximab for the treatment of metastatic colorectal cancer following failure of oxaliplatin-containing chemotherapy (terminated appraisal). NICE technology appraisal 150 (2008).
- Bevacizumab and cetuximab for the treatment of metastatic colorectal cancer. NICE technology appraisal guidance 118 (2007).

- Radiofrequency-assisted liver resection. NICE interventional procedure guidance 211 (2007).
- Preoperative high dose rate brachytherapy for rectal cancer. NICE interventional procedure guidance 201 (2006).
- Laparoscopic surgery for colorectal cancer. NICE technology appraisal guidance 105 (2006).
- Capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer. NICE technology appraisal guidance 100 (2006).
- Referral guidelines for suspected cancer. NICE clinical guideline 27 (2005).
- Laparoscopic liver resection. NICE interventional procedure guidance 135 (2005).
- Computed tomographic colonography (virtual colonoscopy). NICE interventional procedure guidance 129 (2005).
- Laparoscopic liver resection. NICE interventional procedure guidance 135 (2005).
- Improving supportive and palliative care for adults with cancer. Cancer service guidance (2004).
- Improving outcomes in colorectal cancers: manual update. Cancer service guidance (2004).
- Guidance on the use of capecitabine and tegafur with uracil for metastatic colorectal cancer. NICE technology appraisal guidance 61 (2003).

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

- Cetuximab (mono- or combination chemotherapy), bevacizumab (combination with non-oxaliplatin chemotherapy) and panitumumab (monotherapy) for the treatment of metastatic colorectal cancer after first-line chemotherapy (review of technology appraisal 150 and part-review of technology appraisal 118). NICE technology appraisal. Publication date to be confirmed.

7 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations. Please see our website for information about updating the guideline.

Appendix A: The Guideline Development Group, National Collaborating Centre and NICE project team

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Yvette Perston Colorectal Clinical Nurse Specialist, Cardiff and Vale NHS Trust

Mr Andrew Radcliffe Consultant Colorectal Surgeon, Cardiff and Vale NHS Trust (until May 2010)

Mr Andrew Renehan Senior Lecturer, University of Manchester/Honorary Consultant Surgeon, Christie Foundation NHS Trust

Cheryl Richardson Superintendent Radiographer (MRI), The Royal Marsden NHS Foundation Trust

Nick Ryan Patient and carer member

Dr Eamon Staunton GP, Hampshire

Dr Alasdair Taylor Consultant Radiologist, University Hospitals of Morecambe Bay NHS Trust

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Sabine Berendse Information Specialist

Bernadette Li [5] Health Economist

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Lynne Kincaid, Emilene Coventry Editors

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[4] Surgical Registrar, Cardiff University

[5] Research Fellow, London School of Hygiene and Tropical Medicine

[6] Research Associate, School of Social & Community Medicine, University of Bristol

Appendix B: The Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The panel includes members from the following perspectives: primary care, secondary care, lay, public health and industry.

Dr John Hyslop – Chair Consultant Radiologist, Royal Cornwall Hospital NHS Trust

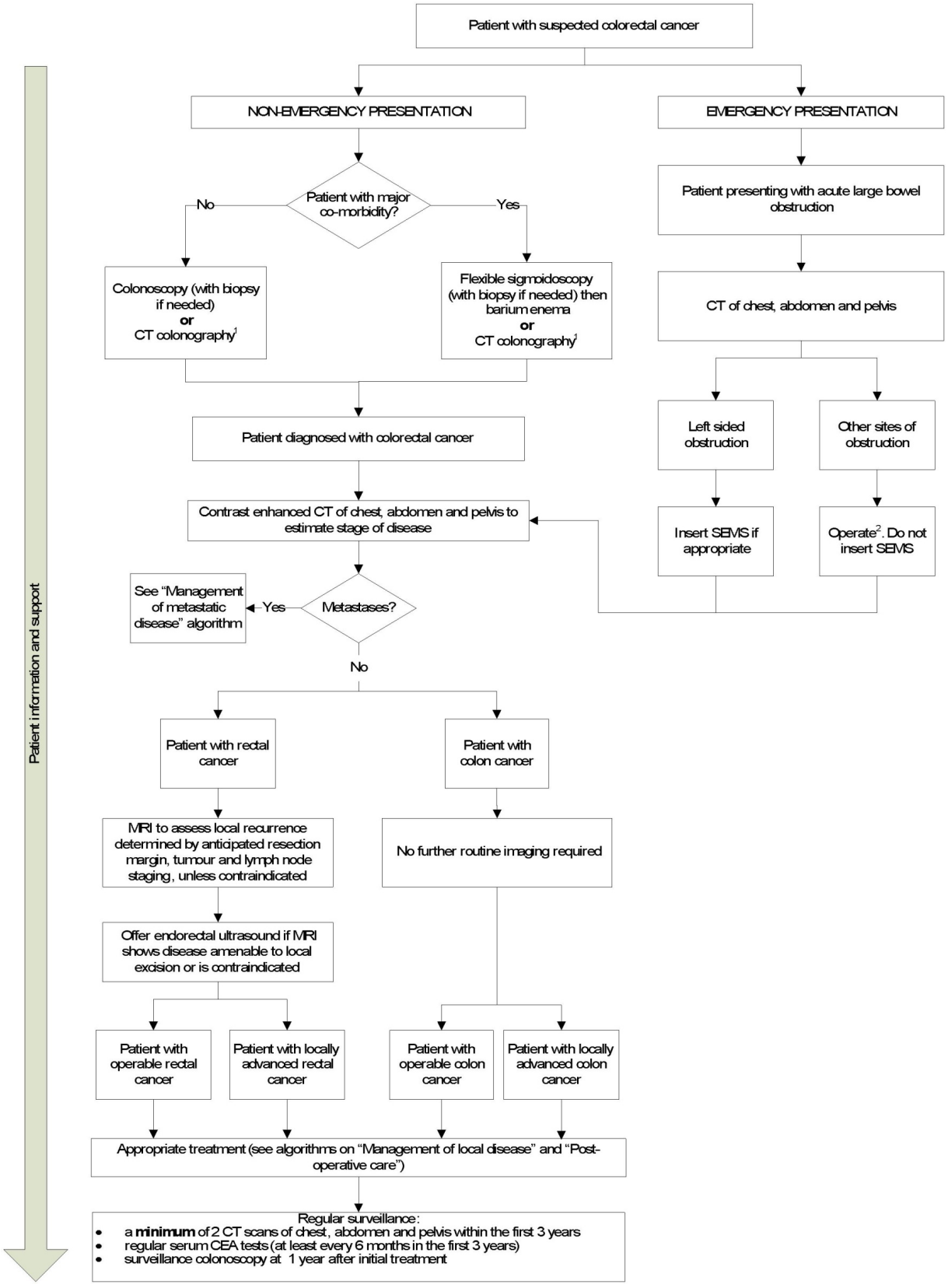
Dr Ash Paul Medical Director, Bedfordshire Primary Care Trust

Kieran Murphy Health Economics & Reimbursement Manager, Johnson & Johnson Medical Devices & Diagnostics (UK)

Sarah Fishburn Lay member

Appendix C: The algorithms

Overview of pathway

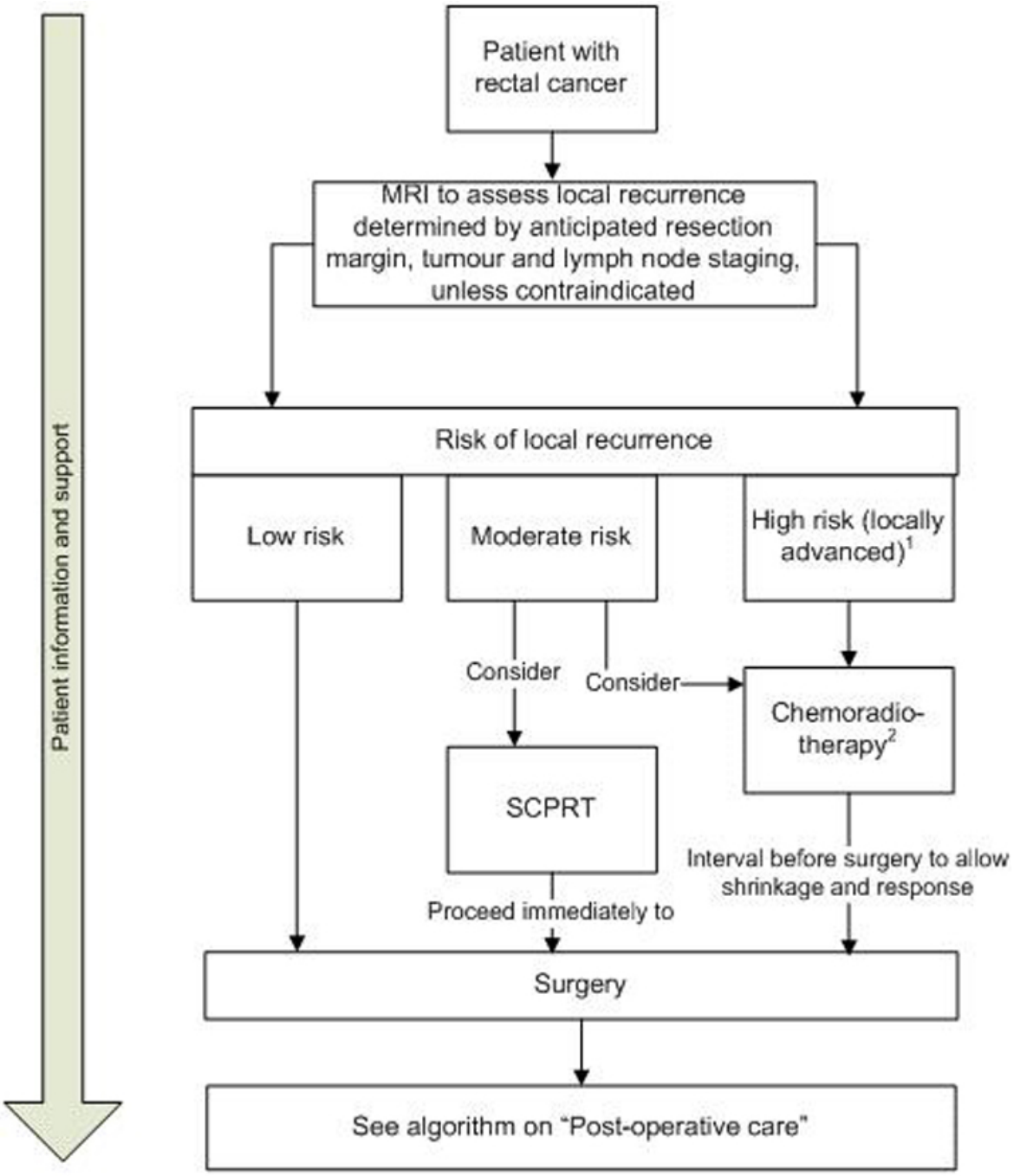


[1] If the local radiology service can demonstrate competency in this technique.

[2] This guideline does not make recommendations on what surgery is appropriate for this group of patients or when it is appropriate

CT = computed tomography; SEMS = self-expanding metallic stent; MRI = magnetic resonance imaging; CEA = carcinoembryonic antigen.

Management of local disease – patients with rectal cancer

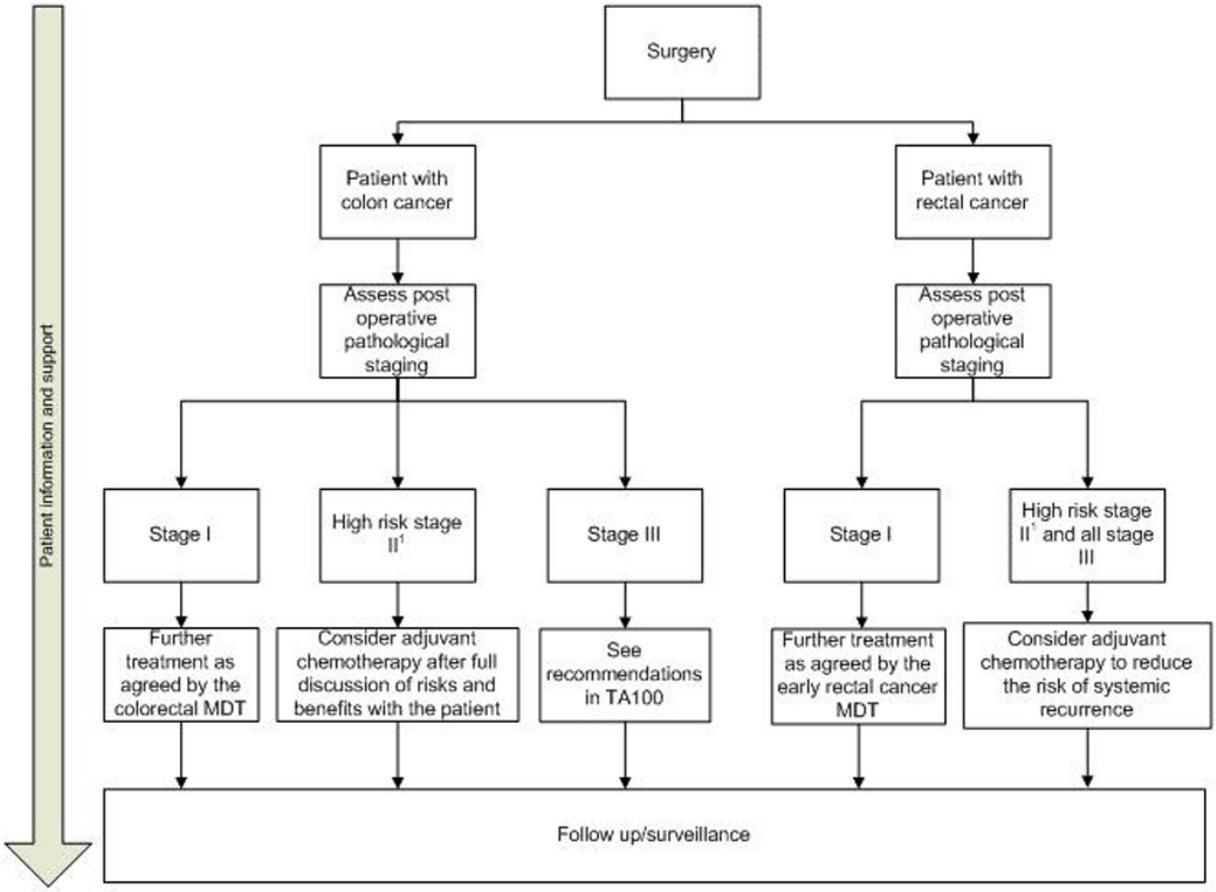


[1] Do not routinely offer preoperative chemotherapy alone to patients with locally advanced rectal cancer unless as part of a clinical trial.

[2] Do not offer preoperative chemoradiotherapy solely to facilitate sphincter-sparing surgery.

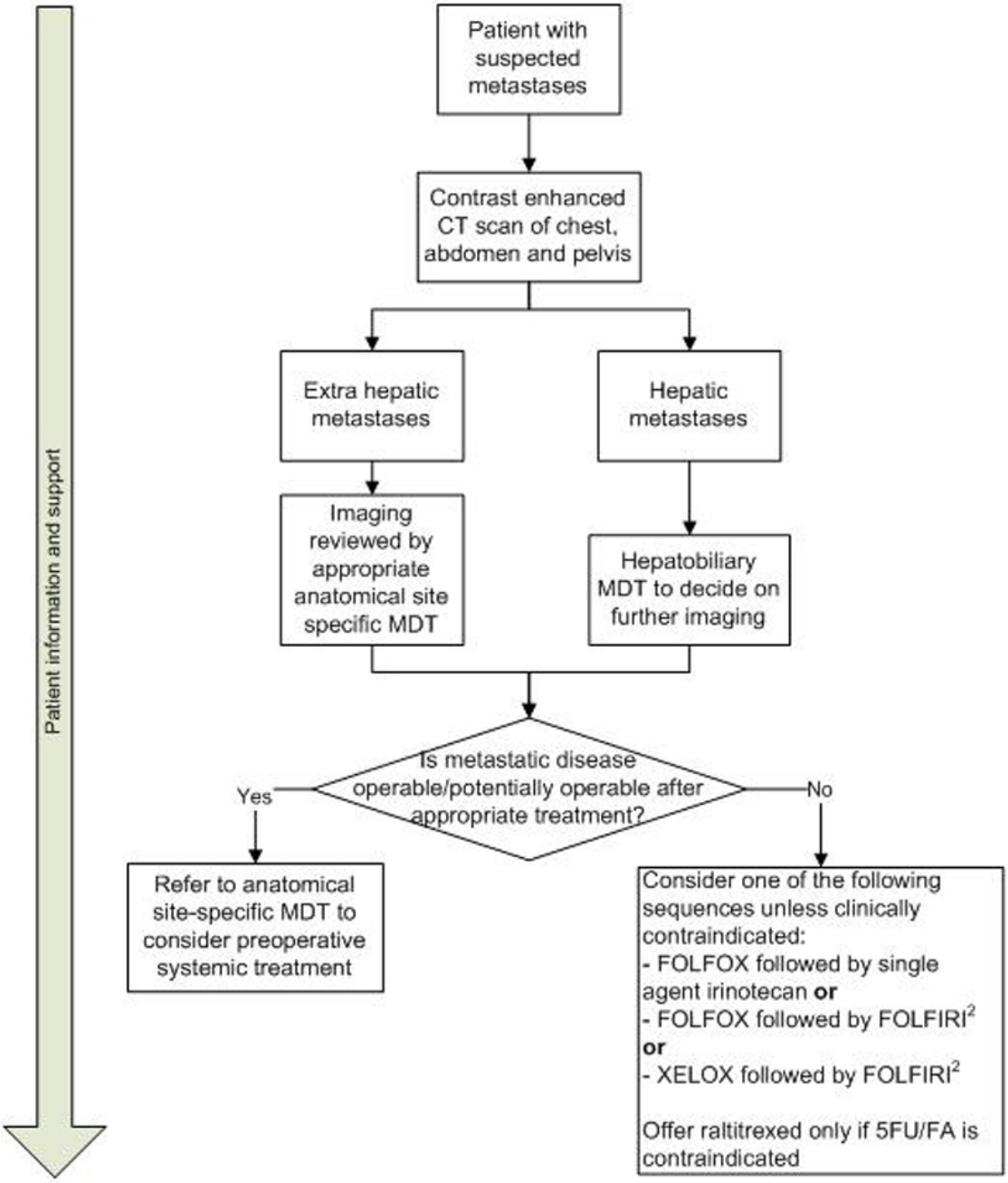
MRI = magnetic resonance imaging; SCPRT = short-course preoperative radiotherapy.

Postoperative care



[1] Postoperative care of patients with stage II colorectal cancer was not included in the scope of this guideline, therefore no recommendations have been made in this area.

Management of metastatic disease [1]



[1] Recommendations from TA61, TA118, TA176 and TA212 are also relevant to this group of patients.

[2] At the time of publication (November 2011), irinotecan did not have UK marketing authorisation for second-line combination therapy. Informed consent should be obtained and documented.CT = computed tomography; MDT = multidisciplinary team; FOLFOX = folinic acid plus fluorouracil

plus oxaliplatin; FOLFIRI = folinic acid plus fluorouracil plus irinotecan; XELOX = capecitabine plus oxaliplatin; 5FU/FA = 5fluorouracil and folinic acid.

About this guideline

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

The guideline was developed by the National Collaborating Centre for Cancer, which is based at the Velindre NHS Trust. The Collaborating Centre worked with a group of healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, who reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

The methods and processes for developing NICE clinical guidelines are described in The guidelines manual.

This guidance includes an update of NICE technology appraisal guidance 93 (published August 2005) and replaces it.

We have produced a summary of this guideline for patients and carers. Tools to help you put the guideline into practice and information about the evidence it is based on 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 summary of product characteristics of any drugs they are considering.

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 avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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