



Regional Colorectal Cancer Network Guidelines for the Management of Colorectal Cancer

Document Purpose	<p>This guidance has been produced to support:</p> <ul style="list-style-type: none"> • The management of patients with suspected colorectal cancer • The management of patients diagnosed with colorectal cancer <p>Treatment decisions are made by weighing a range of factors, which cannot all be accounted for in a single clinical management guideline.</p> <p>This guidance provides a description of the range of treatment options available for a clinical scenario.</p> <p>Individual clinical management strategies are best discussed at a multidisciplinary meeting (MDM).</p>
Authors	<p>Dr Myles Nelson, Consultant Radiologist Marguerite Greenhill, Colorectal Nurse Specialist Annette Mawhinney, Palliative Care Nurse Specialist Mary Jo Thompson, Colorectal/Stoma Nurse Specialist Mr Kevin McCallion, Consultant Surgeon Dr Robert Harte, Consultant Oncologist Dr Maurice Loughrey, Consultant Pathologist</p>
Editor	<p>Mr Roy Maxwell, Consultant Surgeon and Chair, NICaN Regional Colorectal Cancer Group</p>
Consultation Process	<p>Consultation and review was via the authors and the NICaN Regional Colorectal Cancer Group</p>
Review Date (must be within two years)	<p>December 2011</p>

Document History

Version	Date Issued	Brief Summary of Change
Draft 1	21 st May 09	Draft for discussion at Regional Colorectal Cancer Group Meeting
Draft 2	7 th Sept 09	Draft for discussion at Regional Colorectal Cancer Group Meeting 8 th Sept
Draft 3	12 th October 2009	Draft for electronic consultation
Draft 4	24 th November 2009	Draft for electronic consultation (amended following last consultation and final benchmark against peer review requirements)
Draft 5	12 th December	Document formally ratified (subject to amendments agreed at CRC Regional Group meeting). See Appendix 2 for a copy of the minutes.

Contents

1.0	Introduction	5
2.0	Network Configuration of Colorectal Services (N08-1A-205d)	7
3.0	Referral Guidelines	8
3.1	Primary Care Referral (N08-1C-103C)	8
3.2	Referral following surgical emergency (ND_2D_217; see also paragraph 6.6) ...	8
3.3	Agreed secondary to tertiary referral policy (N08-2D-218)	9
3.31	Rectal cancer	9
3.32	Agreed guidelines on referral between teams for anal cancer (ND08-2D-233) ...	9
3.33	Agreed guidelines for referral of patients with liver metastases (ND08_2D_234; see Section 12).....	9
4.0	Clinical Responsibilities Across the Patient Pathway	11
5.0	Imaging Protocol (N08-2D-235)	12
5.1	Introduction	12
5.2	Examination of the large bowel.....	12
5.3	Staging	12
5.4	Surveillance / follow-up.....	14
5.5	Detection of Recurrent or Metastatic Disease	15
6.0	Pathology (N08-2D-235)	17
6.1	Introduction.....	17
6.2	Blood Tests	17
6.3	Specimen Types.....	17
6.4	Specimen Examination.....	18
6.5	Dataset for Reporting	18
6.6	Grading And Staging Conventions	20
6.7	Use Of Ancillary Laboratory Techniques	20
6.8	Audit	21
6.9	Referral for Review or Specialist Opinion.....	21
7.0	Management of Surgical Emergencies (N08-2D-217).....	23
8.0	Clinical Guidelines for the Treatment of Cancers of the Colon (08-2D-230)	24
8.1	Introduction.....	24
8.2	Treatment Options.....	24
8.3	Follow-Up	25
8.3.1	Open Access.....	25
8.3.2	Short-term follow-up	25
8.3.4	Long-term follow-up	25
8.3.5	Follow-up for palliative colorectal cancers	27
9.0	Guidelines for the Management of Early Rectal Cancer (08-2D-230)	28
9.1	Introduction.....	28
9.2	Staging	28
9.3	Treatment.....	28
9.4	Palliative Care	29

10.0 Stenting Guideline (N08C-112d)	30
10.1 Introduction.....	30
10.2 Palliative care	30
10.3 Bridge to surgery	30
10.4 Service provision and personnel	31
11.0 Systemic Therapies Colorectal Cancer (N08-2D-230)	34
11.1 Radiotherapy	34
11.2 Adjuvant treatments	34
11.3 Palliative treatments	34
12.0 Guidelines For The Management Of Patients With Anal Cancer (08-2D-231 & 08-2D-233)	35
12.1 Introduction.....	35
12.2 Referral for specialist treatment.....	35
12.3 Diagnosis & staging.....	35
12.4 MDM.....	37
12.5 Management.....	37
12.6 Summary of chemo radiation treatment protocols	38
12.7 Follow up	38
12.8 Management of recurrent local disease / distant metastases	39
13.0 Management Of Patients With Colorectal Metastases (N08-2D-232 & N08-2D-234)	41
13.1 Introduction.....	41
13.2 Referral and management.....	41
13.3 Staging protocol	42
13.4 Multi Disciplinary Team Involvement	42
13.5 Following surgery	43
13.6 Chemotherapy and neo-adjuvant chemotherapy.....	43
13.7 Follow-up.....	43
14.0 Colorectal Nursing	45
15.0 Supportive and Palliative Care	45
16.0 Psychosocial Support and Access to Financial Advice	46
Appendix 1: Regional Care pathways	47
Appendix 2: NSSG minutes recording ratification of CMG	54

1.0 Introduction

Every year 36,100 people in the UK are diagnosed with colorectal cancer and around 100 new cases are diagnosed each day. It is the third most common cancer after breast and lung, both in the UK and in the world, and every year it causes 16,100 deaths in the UK alone¹.

In Northern Ireland in 2007, there were 755 new cases of colorectal cancer; 388 in men and 367 in women. In the same year, the lifetime odds of developing this type of cancer were calculated as approximately 1-in-31 for men and 1-in-41 for women². It is the second most common male cancer death and the third most common female cancer death; in 2007 there 162 male and 145 female deaths from colorectal cancer in the region.

Surgical operation (including hepatic resection) offers the only proven potential curative prospect.

Chemotherapy and Radiotherapy have a significant role in neo-adjuvant, adjuvant and palliative care.

Potentially curative operations are defined as those procedures in which metastases have been excluded by pre-operative imaging, and all tumour has been removed at surgery and confirmed by post-operative histological examination of the specimen.

Palliative procedures are carried out for relief of symptoms in circumstances where the tumour is not curable because of its local extent or distant spread.

The disease is classified according the Dukes pathological staging criteria as:

- A** Tumour limited to the bowel wall and no lymph node metastases (5-year survival 90%)
 - B** Tumour extends beyond the muscularis propria of the bowel wall but no lymph node metastases are present (5-year survival 60-70%)
 - C** Lymph node metastases are present (5-year survival 35-50%)
- (Dukes D = Metastatic spread³)

TNM (abbr.)⁴

Primary Tumour (T)

T0 No evidence of primary tumour

T1 Tumour extends into submucosa

T2 Tumour extends into muscularis propria **T3** Tumour extends through muscularis propria into subserosa on into non-peritonealized pericolic or perirectal tissues

¹ Cancer Research UK, April 2008 <http://infocancerresearchuk.org/cancerstats/types/bowel/incidence/?a=5441>

² Northern Ireland Cancer Registry, <http://www.qub.ac.uk/research-centres/nicr/FileStore/PDF/Fileupload,169119,en.pdf>, April 08

³ Association of Coloproctology of Great Britain and Ireland, Guidelines on the management of colorectal cancer, 2007 pp105

⁴ From 'Cancer principles and practice of oncology, 5th Editioni, Vincent T.DeVita Jr, Samuel Hellmen, Steven A.Rosenberg; Lippincott-Raven IN Association of Coloproctology of Great Britain and Ireland, Guidelines on the management of colorectal cancer, 2007 pp110

T4 Tumour extends directly into other the organs or tissues or tumour perforates the visceral peritoneum of the specimen

Regional Lymph Nodes (N)

N0 No LN metastases

N1 Metastatic tumour in 1 to 3 pericolic or preirectal lymph nodes

N2 Metastatic tumour in 4 or more pericolic or preirectal lymph nodes

Distant Metastases (M)

M0 No distant metastases

M1 Distant metastases present

2.0 Network Configuration of Colorectal Services (N08-1A-205d)

NICaN has five colorectal cancer MDTs which diagnose and treat colon and rectal cancer. These are held at the following locations:

- Altnagelvin Hospital – Western HSS Trust
- Antrim Area Hospital – Northern HSS Trust
- Royal Victoria Hospital (RVH) – Belfast HSS Trust
- Craigavon Area Hospital – Southern HSS Trust
- Ulster Hospital – South Eastern Trust

The catchment populations of these MDTs are shown below:

Colorectal MDT	Catchment⁵
Altnagelvin Hospital	296,909
Antrim Area Hospital	453,824
Craigavon Area Hospital	348,657
Royal Victoria Hospital	334,528
Ulster Hospital	341,085
Total	1,775,003

Each MDT meets on a weekly basis. All MDTs have named surgeons who deal with early rectal cancer. Anal cancers are referred to either the Belfast or SE Trust MDTs.

⁵ Catchment populations based on NISRA projected population figures by electoral ward for 2008.

3.0 Referral Guidelines

3.1 Primary Care Referral (N08-1C-103C)

Patients can be referred to their local hospital as “red flags” (i.e. suspect cancer) by their GP under the following NICE guidance:

Criteria for urgent referral for suspected colorectal cancer⁶

1. any age – palpable rectal mass (intraluminal and not pelvic; a pelvic mass outside the bowel would warrant an urgent referral to a urologist or gynaecologist)
2. 40 years and above - rectal bleeding with a change in bowel habit to looser stools +/- increased stool frequency persisting 6 weeks or more
3. 60 years and above - rectal bleeding persisting for 6 weeks or more without a change in bowel habit and without anal symptoms
4. 60 years and above change in bowel habit to looser stools and/or more frequent stools persistent for 6 weeks or more without rectal bleeding
5. Any age – with right lower abdominal mass consistent with involvement of the large bowel
6. Men of any age with unexplained iron deficiency anaemia and a Hb of 11g/100ml or below
7. Non menstruating women with unexplained iron deficiency anaemia and Hb of 10g/100ml or below

Patients who describe symptoms which do not entirely fulfil the criteria but are a source of concern to the GP can be referred urgently to the colorectal service outwith the red flag system.

Referrals should be faxed to local hospital appointment offices within 24 hours.

The appointments office will put the patient’s details onto PAS on the day that it is received. The CaPPs system receives automatic updates from PAS which alert the patient navigator to the fact that a new red flag referral has been received.

Each diagnostic unit has their own internal arrangements to ensure that patients are seen within the agreed waiting times standards. However, in general, the patient is contacted by the appointments office, either by phone or letter, to arrange an appointment.

3.2 Referral following surgical emergency (ND_2D_217; see also paragraph 6.6)

Following emergency admission, patients found to have colorectal cancer should be referred to the colorectal team by the end of the first working day.

1. Following discovery of a colorectal carcinoma in the course of investigations by a non-colorectal team, the patient should be referred to a named surgical member of the locality colorectal MDT. Following discussion at the multidisciplinary team meeting (MDM) the patient may be accepted under the care of one of the members which could be an oncologist or palliative care physician for instance.

⁶ NICaN Referral guidance for suspected cancer, May 2007 www.cancerni.net

2. Such referral should occur by the end of the first working day for the patient to be discussed at the next available MDM and to ensure the minimum delay.
3. Following direct access to endoscopy the consultant responsible for the endoscopy list (even if the endoscopy is carried out by a junior doctor or nurse endoscopist) is responsible for ensuring that where appropriate, investigation pathways are immediately commenced (if the tumour is clinically likely to be a carcinoma) and that the patient is discussed at the next appropriate MDM. This may depend on the timing of the meeting relative to biopsy results being available etc.
4. Following discovery of a metastasis by another MDT possibly of CRC origin, a member of the other MDT should either present the patient to the colorectal MDM or ensure a formal referral to a colorectal MDT member who can present the case at the next MDM.

3.3 Agreed secondary to tertiary referral policy (N08-2D-218)

3.31 Rectal cancer

Selected early rectal cancers can be treated by local resection. Most trans-anal techniques are performed by MDTs within the Network. The only surgical technique not available locally is TEMS surgery. Patients with early rectal cancer who are considered suitable for TEMS should be referred to an appropriate UK centre for surgery by day 28 in the pathway. Figure 1 outlines the investigations that would be expected to be completed locally prior to referral.

Where the MDT feels a patient may benefit from oncological treatment a referral is made directly to one of the CRC oncologists at the Cancer Centre. Full patient details (i.e. MDT report with management plan, oncology referral proforma, operation notes and diagnostics results) should be forwarded within 24 hours of the MDM.

3.32 Agreed guidelines on referral between teams for anal cancer (ND08-2D-233)

The majority of patients with anal cancer are treated non-surgically. Oncology referrals will be made via the MDM directly to one of the CRC oncologists at the Cancer Centre. Full patient details (i.e. MDM report with management plan, oncology referral proforma, operation notes and diagnostics results) should be forwarded within 24 hours of the MDM.

A small number of patients who relapse may require salvage surgery. These patients should be referred to either the Belfast or South Eastern Trust MDTs for specialist treatment. Figure 1 outlines the investigations that would be expected to be completed locally and forwarded with the referral.

3.33 Agreed guidelines for referral of patients with liver metastases (ND08_2D_234; see Section 12)

Patients who have potentially resectable liver metastases should be referred to the specialist HPB MDT in the Royal Victoria Hospital to evaluate operability and develop an appropriate management plan.

FIGURE 1: INVESTIGATIONS TO BE COMPLETED AT CANCER UNIT TO BE FORWARDED WITH REFERRAL FOR SPECIALIST TREATMENT

Rectal Cancer	Anal Cancer	Liver metastases
<ul style="list-style-type: none"> • Biopsy • Barium Enema or colonoscopy to image the whole bowel • CT of chest, abdomen and pelvis • MRI and/or Endorectal Ultrasound 	<ul style="list-style-type: none"> • Biopsy • CT of chest, abdomen and pelvis • MRI +/- endorectal ultrasound 	<ul style="list-style-type: none"> • Spiral CT of the chest, abdomen and pelvis – contemporary scan • TESLA MRI scan of the liver • Colonoscopy (before or after resection of the primary) • PET scanning in patients with high risk primary disease (T4(perforated); C2 (apical node))

Immediately the diagnosis has been confirmed, Cancer Units should make arrangements for the results of these investigations to be presented at next MDM in either Belfast or SE Trust.

- CT Colonography is an acceptable means of combining the CT and the colon imaging in one investigation.
- If the reason for transfer is not related to the primary tumour e.g. cardiac co-morbidity, transfer should be made in sufficient time to allow assessment of that co-morbidity before commencing treatment.

4.0 Clinical Responsibilities Across the Patient Pathway (N08-1C-107a)

Stage of Clinical Care	Responsible Clinician(s)
Prior to First appointment with Secondary care	General Practitioner
After first hospital visit	Hospital consultant
Primary Surgery (assuming surgical intervention)	Surgeon accepting responsibility at the MDM
Primary non-surgical oncological intervention (Radiation and/or Chemotherapy)	Oncologist accepting responsibility at the MDM - patient passed back to the Surgeon when this phase is concluded
Post surgery – oncology treatment required	Oncologist accepting responsibility at the MDM - patient passed back to the Surgeon when this phase is concluded
Follow up will depend on the treatments given	Normally the Consultant Surgeon.
Palliative Care required	Palliative care consultant accepting responsibility at the MDM / General practitioner. Other relevant modality e.g. colonic stenting
Treatment for metastatic disease	Clinician in the relevant treatment modality e.g. Hepatic / Thoracic surgeon, Oncologist etc

General principles

1. All through the patient pathway there should be ongoing access to the Clinical Nurse Specialists and MDT.
2. Decisions can be made determining the care of the patient within a single modality by the responsible clinician.
3. Decisions concerning modalities not covered by the currently responsible clinician should be referred back to an MDM for wider discussion.
4. For endoscopy initial events the consultant responsible for the list must ensure that the patient is entered for the next appropriate MDM and that if they are not going to provide the next stage that the patient has been accepted by another clinician.
5. This policy should not inhibit referral for support from other clinician, e.g. Palliative radiotherapy.
6. Timely and detailed communication with the patient Primary Care colleagues is mandatory at all times.

5.0 Imaging Protocol (N08-2D-235)

5.1 Introduction

The preferred method of establishing a definitive diagnosis of colorectal cancer is with endoscopy (either sigmoidoscopy or colonoscopy) and biopsy.

Histological confirmation of a tumour should be sought preoperatively in all tumours if at all feasible. If histology cannot be obtained, the findings of radiological investigations should be discussed at the MDM and a management plan determined on the merits of each individual case.

5.2 Examination of the large bowel

Flexible (or rigid) sigmoidoscopy +/- double contrast barium enema (DCBE) or Colonoscopy or CT Colonography

If a previously undiagnosed colorectal cancer is made with a high degree of confidence on the basis of radiological imaging, the reporting radiologist should ensure that the examination is reported urgently as per Diagnostic Reporting Turnaround Times (DRTT). The urgent report should be sent to the referring clinician within 48hrs. In addition a copy of the report should be sent to the local MDT coordinator to enable the patient to be discussed at the next MDM.

5.3 Staging

The diagnosis of colorectal cancer will usually be made by endoscopic, histopathological or radiological methods, either alone or in combination. All patients who are considered potentially fit for treatment should undergo the appropriate staging investigations as a matter of urgency.

If staging is not performed pre-operatively then a formal staging CT should be performed once the patient has recovered from the surgery and prior to any proposed adjuvant therapy.

Colonic Cancer

All of the colon should be examined for synchronous cancer/polyp. This may be done by colonoscopy or sigmoidoscopy and barium enema or CT colonography. Where obstruction precludes full assessment prior to surgery, the colon should be examined within the next six months.

Staging for local extent and metastases

CT examination of Chest, abdomen and pelvis.

Technique

Oral contrast and IV contrast multi detector CT acquisition - Chest in arterial phase followed by abdomen/pelvis in portal venous phase. As per RCR guidelines (4)

Completion Colonoscopy in patients undergoing initial flexible Sigmoidoscopy where it is judged possible to intubate safely beyond the identified cancer or DCBE or CT Colonography where it would not be safe to do so.

Rectal cancer

MRI is used in the pre-operative staging of rectal tumours, to help determine operability vs. neo-adjuvant or palliative treatment MRI of the pelvis is also used in determination of long or short course radiotherapy. Repeat Pelvic MRI and CT chest abdomen and pelvis may be required following long course radiotherapy. MRI may also be used at the same time as Pelvic imaging to help distinguish benign from metastatic liver lesions.

All of the colon should be examined for synchronous lesions as for colon cancer.

Local Staging

Pelvic MRI +/- endoluminal ultrasound

Technique

IV buscopan Pelvic MRI. As per RCR guidelines (4)

Staging for metastases

CT examination of Chest, abdomen and pelvis.

Technique

Oral contrast and IV contrast multi detector CT (MDCT) acquisition - Chest in arterial phase followed by abdomen/pelvis in portal venous phase. As per RCR guidelines (4)

Anal Cancer

Local Staging

Pelvic MRI (if required following discussion at MDM)

Technique

IV buscopan Pelvic MRI. As per RCR guidelines (4)

Staging for metastases

CT examination of Chest, abdomen and pelvis.

Technique

Oral contrast and IV contrast multi detector CT acquisition - Chest in arterial phase followed by abdomen/pelvis in portal venous phase. As per RCR guidelines (4)

Metastatic Disease Confirmation

1. Liver:
 - a. Contrast MRI
 - b. IV Multiphase Contrast MDCT
 - c. Ultrasound (with or without Ultrasound contrast agent)

2. Lungs
 - a. IV contrast MDCT Chest

- b. +/- MDCT guided Lung Biopsy (if required following discussion at MDM)
3. CT PET scan - Where there is suspicion of metastatic disease and after discussion at MDM, a CT PET scan, if required, may be performed either pre- or post-operatively of the primary bowel surgery.

5.4 Surveillance / follow-up

The aim of follow-up is to identify potentially curable recurrent disease in patients who are otherwise fit to undergo further treatment. Follow-up may increase the probability of long-term survival following surgery for colorectal cancer, particularly in patients with Dukes' stage B or C disease.

The liver is the most common site of recurrence after complete excision of the primary tumour and liver resection can lead to long-term survival in some patients.

Research has indicated that surveillance including CT imaging, can detect early recurrence. This allows more prompt treatment and may improve patient survival. Most colorectal cancer recurrence happens in first 2 years. Effective therapies are emerging, with more intensive intervention have been shown to be effective in selected patients groups with early relapse.

However, at the present time there is no robust guidance on a standardised effective approach for follow up. The Association of Coloproctology of Great Britain and Ireland 'Guidelines on the management of colorectal cancer' (2007) recommends that it is reasonable to undertake CT scan in asymptomatic patients at some time in the first two post operative years after curative resection. The Royal College of Radiologists and the SIGN Guideline do not specify the frequency for CT scanning.

The Oncology Association Guidelines state thatRichard / Robert to provide detail

In the absence of robust guidance the following guidance has been agreed:

1. BSG guidelines suggest that patients with an adenoma-free colon should undergo colonoscopy as a minimum every 5 years until age 70. Patients who have adenomas should be offered follow-up as per BSG guidelines.

Patients should be counselled about the potential complications of colonoscopy.

2. As a minimum a single CT scan of the chest abdomen and pelvis in otherwise asymptomatic fit patients should be offered during the first two years post resection, in order to detect potentially resectable liver metastases. .

Where judged clinically appropriate and depending on clinical context and staging, annual CT scans of chest abdomen and pelvis in the first three years following surgery may be appropriate.

CT scans should be reported as per DRTT.

3. CT PET should be considered in the following cases:

- Patients with one confirmed elevated CEA level with a negative or equivocal CT.
- Distinguishing between fibrosis from recurrent disease, particularly within the pelvis.
- Excluding distant metastases in patients being considered for liver and or lung resection after case discussion at the hepatobiliary or lung MDM.

If patient is being considered for CT PET then their case should be discussed first at the MDM prior to requesting the CT PET.

CT PET scan should be reported as per DRTT

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

5.5 Detection of Recurrent or Metastatic Disease

Full Staging

CT examination of Chest, abdomen and pelvis.

Technique

Oral contrast and IV contrast multi detector CT (MDCT) acquisition - Chest in arterial phase followed by abdomen/pelvis in portal venous phase. As per RCR guidelines (4)

Hydronephrosis / hydroureter are usually indicative of local pelvic disease recurrence on follow up scans after initial treatment.

Patients with steadily increasing CEA levels invariably have recurrent disease, which can often be demonstrated after careful review of the images⁷.

Patients identified as having recurrent or metastatic disease should have their radiological reports forwarded to the referring clinician and MDT co-ordinator to enable rapid entry into an appropriate management pathway as per DRTT.

References

1. Association of Coloproctology of Great Britain and Ireland, Guidelines on the Management of Colorectal cancer, 2007 – Investigations
2. British Society of Gastroenterologists. (2002) *Guidelines for colorectal cancer screening in high risk groups.*

⁷ CEA is not specific for colorectal cancer and is only elevated in around 80% of patients with advanced disease.

3. NICE (2004) Improving Outcomes in Colorectal Cancer.

4. Royal College of Radiologists 'Recommendations for Cross-Sectional Imaging in Cancer Management' Ref No: RCR (06)1 (published second edition 2006)

6.0 Pathology (N08-2D-235)

6.1 Introduction

These guidelines are supplementary to the following national guidance:

- Dataset for colorectal cancer histopathology reports issued by the Royal College of Pathologists (2007)
- UKCCCR Handbook for the Clinico-Pathological Assessment and Staging of Colorectal Cancer
- Improving outcomes in colorectal cancers (NICE, May 2004)
- Reporting lesions in the NHS bowel Cancer screening programme - Guidelines from the Bowel Cancer Screening Programme Pathology Group 2007

All colorectal cancer cases should be reviewed by a Colorectal Cancer multidisciplinary team which has a histopathologist as a core member. There should be a nominated Lead colorectal pathologist for the service. The lead and their appointed deputy should participate in colorectal MDMs, in a bowel screening EQA scheme and in local audit (including an assessment of consistency of reporting, as appropriate to the site).

All other histopathologists reporting colorectal samples should be enrolled in an EQA scheme that includes a GI pathology component.

If there is a significant discrepancy with the clinical/radiological findings the pathological material from diagnostic colorectal specimens should be reviewed, if possible by a second pathologist with an interest in colorectal cancer.

Histological proof of colorectal adenocarcinoma should be obtained where possible for all clinically suspicious cases, prior to definitive treatment.

All biopsy diagnoses of “flat” colonic epithelial dysplasia should be confirmed by a second pathologist with a GI interest before issuing a report. Their name will be included as the reviewing pathologist. Polypoid adenomas need not be reviewed routinely.

Specimens should be reported to an agreed timeframe so as to allow appropriate clinical decision making at a planned colorectal MDM (usually within 5 working days).

6.2 Blood Tests

Haemoglobin

Electrolytes, urea and creatinine

Liver function tests

CEA

6.3 Specimen Types

Diagnostic:

Colonic and rectal biopsies

Needle core biopsies (abdominal masses or liver metastases)

Therapeutic:

Colectomy
Anterior resection
Abdomino-perineal resection (APR)
Trans anal resection of tumour (TART)
Endoscopic mucosal resection (EMR) specimens
Snare polypectomy

6.4 Specimen Examination

Each pathology service should establish a defined protocol for each type of diagnostic and therapeutic colorectal specimen type received by the laboratory, taking into account the above guidance. The protocols should be regularly reviewed and updated by the Lead colorectal pathologist in consultation with other pathologists who participate in service delivery.

Colorectal tissue should only be removed and stored for the purposes of research if it is surplus to the requirements of the diagnostic process. Appropriate patient consent and ethical approval should be obtained.

Digital images of all radical surgical resection specimens are desirable, but following TME, either anterior resection or abdominoperineal resection, digital images are particularly important for audit purposes. As a minimum, the following images are recommended:

- An image of the mesorectal excision margin for purposes of surgical audit
- A cross section slice of tumour showing maximum penetration beyond the muscularis propria for radiological audit
- If the circumferential margin is involved, an image of showing the site of involvement for correlation with pre-operative imaging is desirable

6.5 Dataset for Reporting

Cancer resection specimens should be reported according to the guidance issued in the Dataset for Colorectal Cancer of the Royal College of Pathologists, appropriate to the specimen type.

Diagnostic specimens:

Tumour type
Tumour grade

Therapeutic resections:

Colectomies, Anterior Resection and Abdominoperineal resections

Relevant RCPaTh Dataset with local modifications

Pre op radiotherapy (short course or long course chemoradiotherapy)
Response to radiotherapy/chemoradiotherapy
Specimen type
Quality of TME (rectal tumours) i.e. on mesorectal fascia, within mesorectum, or reaching muscularis propria
Site of tumour
Length of resection

Maximum tumour diameter
Distance from nearest cut end
Presence of tumour perforation (site of perforation i.e serosal or retroperitoneal)
Relation to peritoneal reflection (rectal tumours)
Distance from dentate line (APR only)
Invasive tumour type
Invasive tumour grade (by predominant grade)
Local invasion
Distance beyond muscularis propria for pT3 and above
Peritoneal spread
Extramural vascular invasion
Number of nodes examined
Number of involved nodes
Status of apical node
Distance to non-peritonealised resection margin
Other relevant pathology (adenoma, synchronous carcinoma, FAP, UC or Crohn's)
Dukes stage
TMN staging system
Whether resection complete

The dataset items should be reported in a proforma either within or instead of the free text part of the pathology report, or as a separate proforma. Departments and MDTs should work towards recording and storing the dataset items as individually categorised items in a relational database, so as to allow electronic retrieval through the Cancer Patient Pathways System and to facilitate the use of pathology data in clinical audit, service planning and monitoring, research and quality assurance.

Local Resections

Tumour type
Tumour size
Tumour grade – based on worst grade present
Depth of invasion (Haggitt, Kikuchi and/or mm from muscularis mucosa))
Distance of tumour from resection margins
Lymphatic or vascular invasion within stalk

Haggitt level is appropriate for carcinoma arising within pedunculated polyps:

- level 0 intramucosal,
- level 1 confined to head of polyp,
- level 2 invades the neck of the polyp,
- level 3 invades the stalk,
- level 4 invades submucosa below level of stalk

Haggitt level cannot always be assessed on polypectomies, in which case depth of invasion in mm should be given Kikuchi level may be appropriate for some sessile polyp cancers;

- sm1 superficial third of the submucosa
- sm2 middle third of the submucosa
- sm3 deep third of the submucosa

Other Endoscopic Resections (EMR, TART, TEMS)

Tumour size
Tumour type
Tumour grade
Depth of invasion
Distance from deep margin
Distance from lateral margin, including orientation

Laboratories should use an agreed diagnostic coding system (eg. SNOMED).
All malignancies must be reported to the Northern Ireland Cancer Registry.

6.6 Grading And Staging Conventions

Dysplasia grading:

Revised Vienna classification of gastrointestinal epithelial neoplasia. Dysplasia in polyps should be categorised as either low grade or high grade

Tumour grading:

WHO invasive carcinoma grade system

Tumour staging:

TNM classification of malignant tumours.

(As agreed by the Royal College of Pathologists and the Pathology section of the British Society of Gastroenterology, staging will continue to be based on the 5th edition and not the 6th)

Dukes stage

Tumour Regression:

The RCPaTh recommends that for tumour staging following neoadjuvant therapy, only the presence of tumour cells in the surgical specimen is taken to determine the stage.

Fibrosis, haemorrhage, necrosis, inflammation and acellular mucus are ignored. Cases with complete regression are therefore recorded as ypT0. The recommended categories are:

- No residual tumour cells or mucus
- Mucus lakes (surrounded by a host response) without tumour cells
- Minimal residual tumour, i.e. only occasional microscopic tumour foci are identified with difficulty
- No marked regression

However, regression based only on the histological appearance may give a false impression of response to chemoradiotherapy. The degree of response clinically may be much greater. MDTs will have to decide locally how best to record overall response as this may affect consideration of future chemotherapy.

6.7 Use Of Ancillary Laboratory Techniques

All laboratories providing a Pathology service in the network must have at least conditional laboratory (eg CPA) accreditation and ensure participation in an appropriate external quality assurance programme which demonstrates satisfactory laboratory performance.

Immunohistochemical procedures which may be of value include the following:

Diagnostic scenario	Immunohistochemical markers	Notes
Intra-abdominal malignancy ? primary	CK7, CK20, CEA, CA125, TTF1, S100, PSA, CK19, CDX2	
Neuroendocrine differentiation	CD56, Synaptophysin, Chromogranin	TTF1 if metastatic cancer being considered
GIST	CD117, CD34, Desmin, SMA, S100	
Epithelial dysplasia	p53	
Genetic screening for mismatch repair genes	h-MLH1, h-MSH2	If requested by the Genetics Dept

6.8 Audit

All pathologists who reporting on colorectal cancer specimens should also participate in audit. Audit may take the form of:

- review of compliance with procedures for specimen examination and reporting
- completeness of datasets
- systematic logging of diagnostic agreement/disagreement during review of cases for MDMs
- review of diagnostic consistency between pathologists using data from cases in EQA circulations or blind circulations
- number of confirmed cancers discussed at MDM
- participation in regional audit as organized by the Network Site Specific Group

The results of the audit process should be discussed with all pathologists who participate in service delivery and used to inform the development of reporting protocols.

6.9 Referral for Review or Specialist Opinion

6.9.1 Referral for treatment

All patients referred for treatment at a hospital within the Cancer Network following diagnosis elsewhere must be reviewed and discussed at the treating hospital's MDM.

The complete diagnostic pathology report must be available at the MDM, and when appropriate, the histological/cytological material should be reviewed prior to the meeting. This is particularly important if there is a significant discrepancy with the clinical / radiological findings. Pathological material should be requested at least 5 working days before and received at least 3 days before the relevant MDM to allow sufficient time for review.

A formal report should be issued by the reviewing pathologist to the responsible clinician at the treating hospital. The results of the review should be sent to the original pathologist, either by copy of the review report or by letter.

Where patients have been referred for oncology treatment, requests for specialist biomarker studies will be co-ordinated between the treating oncology service, their local pathology service and the referring hospital's pathology service, as appropriate. The oncology service must agree a mechanism for requesting tests and the relevant pathological material with their local pathology service. Requests for pathological material should be made in good time to ensure that results are available at the MDM where the patient is to be discussed.

6.9.2 Referral for specialist opinion

All colorectal lymphomas should be referred to the Haematological Malignancy Diagnostic Service for phenotypic analysis and confirmation of diagnosis.

In cases of diagnostic difficulty, referral may be made to the lead pathologist of the relevant specialist MDT in the network, although referral to other specialists within or outwith the network is equally appropriate in individual cases. Cases referred for individual specialist or second opinion will be dealt with by the individual pathologist and a report issued by them. Where relevant, tissue blocks should be made available to allow any further investigations that are deemed appropriate. The result of the review should be communicated to the referring pathologist by letter and also by fax/telephone as appropriate. In instances when the patient is referred for an opinion by a specialist multidisciplinary team the case should be referred to the Lead Pathologist of the appropriate MDT and dealt with according to specialist team/Cancer Centre MDT guidelines.

References

1. The Royal College of Pathologists (2007) *Dataset for colorectal cancer* (2nd Edition).
2. UICC (1998) *TNM Classification of Malignant Tumours* (5th edition)
3. UICC (2002) *TNM Classification of Malignant Tumours* (6th edition) L.H. Sobin and C. Wittekind (Eds).
4. WHO (2000) *Classification of Tumours. Pathology and Genetics of Tumours of the Digestive System*
5. Dixon, M. F. (2002) Gastrointestinal epithelial neoplasia: Vienna revisited. *Gut* 2002;51:130-131
6. The Royal College of Pathologists (2004) *Guidelines on inter-departmental dispatch of samples from patients sent to another hospital or centre for assessment and/or treatment.*
7. NICE (2004) *Improving outcomes in colorectal cancer.*
8. Mandard, A.M., Dalibard, F, Mandard, J.C., et al (1994) Pathologic assessment of tumor regression after preoperative chemoradiotherapy of esophageal carcinoma: Clinicopathologic correlations. *Cancer* 73:2680-2686, 1994
9. Haggitt, R.C., Glotzbach, R.E., Soffer, E.E., et al. (1985) Prognostic factors in colorectal carcinomas arising in adenomas: implications for lesions removed by endoscopic polypectomy. *Gastroenterology*, 89:328–36.
10. Reporting lesions in the NHS bowel Cancer screening programme - Guidelines from the Bowel Cancer Screening Programme Pathology Group 2007

7.0 Management of Surgical Emergencies (N08-2D-217)

Emergency surgery may by necessity be undertaken by surgeons who are not members of the colorectal MDT.

In the absence of (imminent) perforation or life threatening bleeding the patient should be stabilised and referred by the emergency team to a colorectal surgeon by the end of the first working day, if practicable, so that their management can be transferred to the relevant CRC MDT.

Where emergency surgery is required, wherever possible preparation for surgery should be completed as below and in all cases antibiotic and DVT prophylaxis should be administered.

- Informed consent
- Group & Hold / Cross-matching
- Thrombo -embolism prophylaxis
- Antibacterial prophylaxis
- Provision of stoma information when required

The patient should be transferred to the care of the CRC MDT at the earliest possible opportunity to allow the development of an appropriate treatment and care plan.

References

Guidelines for the management of colorectal cancer, 3rd Ed. 2007, Association of Coloproctology of Great Britain and Ireland.

8.0 Clinical Guidelines for the Treatment of Cancers of the Colon (08-2D-230)

8.1 Introduction

Local MDTs provide the mechanism for appropriate treatment decisions for patients with a diagnosis of colorectal cancer.

MDMs will normally be held on a weekly basis.

MDTs will have an operational policy consistent with the agreed Network policies and guidelines.

All elective patients with colorectal cancer, regardless of route of referral or diagnosis, should be discussed at the Colorectal MDM to agree treatment plans prior to the commencement of treatment. The colorectal care pathway is outlined in Appendix 1.

8.2 Treatment Options

Scenario	Treatment Options
No evidence of distant metastases	Radical segmental resection Palliative care if patient unfit for or declines active treatment
Scenario	Treatment Options
Resectable distant metastases	Radical segmental resection with post-operative chemotherapy and staged resection of metastases Radical segmental resection with simultaneous resection of metastases Palliative segmental resection for symptoms if patient considered unfit for extended treatment plan Palliative care if patient unfit for or declines active treatment
Extensive distant metastases	Advanced disease chemotherapy and palliative care Advanced disease chemotherapy with palliative resection or colonic stent for direct symptoms Palliative care if patient unfit for or declines active treatment

Following “curative” resection	
Dukes’ A	No additional treatment required
Dukes’ B	Referral to oncologist for discussion of potential benefit of adjuvant chemotherapy MDT agreement that additional treatment inappropriate
Dukes’ C	Referral to oncologist for adjuvant chemotherapy MDT agreement that additional treatment inappropriate

Patients should be informed about and encouraged to participate in clinical trials of both surgical and medical treatments as appropriate.

8.3 Follow-Up

8.3.1 Open Access

Colorectal cancer follow-up is the responsibility of the MDT. All patients should be able to access the MDT promptly. Any patient that contacts a member of the MDT with worrying symptoms should be seen within 2 weeks. If necessary, their case should be discussed by the MDT.

8.3.2 Short-term follow-up

Initial follow-up should focus on post-operative problems, planning for possible adjuvant therapy and stoma management. Patients who have not undergone complete colonoscopy prior to surgery should be offered a colonoscopy within 6 months of discharge or upon completion of adjuvant chemotherapy. This is, in effect, completion of the initial diagnostic work up to identify individuals who have adenomas or carcinomas elsewhere in the colon.

8.3.4 Long-term follow-up

The debate continues on the subject of patient follow up after curative treatment for colorectal cancer. However, there is some evidence to suggest that intensive follow-up can increase the probability of long-term survival after surgery for colorectal cancer, at least among patients with Dukes’ stage B/C disease.

The aim of follow-up is to identify potentially curable recurrent disease in patients who are fit to undergo further treatment.

Possible benefits from long-term follow up are:

- Detection of potentially curable recurrent or metastatic disease.
- Detection of asymptomatic recurrence when early chemotherapy may improve quality of life and prolong survival.
- Detection of metachronous tumours.

- Provision of psychological support by patient / doctor contact.
- Facilitation of audit, clinical governance and continuing professional development.
- Survival rates

Recommendations for long-term follow-up

1. The frequency of follow-up should be based on the risk of recurrence and the patient's individual circumstances and wishes. Longterm follow-up for colorectal cancer should include regular appointments every 4-6 months for 2 years with review every 6-12 months for a further 3 years. Each visit should include clinical examination, LFT, FBC and CEA.
2. BSG guidelines suggest that patients with an adenoma-free colon should undergo colonoscopy as a minimum every 5 years until age 70. Patients who have adenomas should be offered follow-up in accordance with BSG guidelines.

Patients should be counselled about the potential complications of colonoscopy.

3. As a minimum a single CT scan of the chest abdomen and pelvis in otherwise asymptomatic fit patients should be offered during the first two years post resection, in order to detect potentially resectable liver metastases. .

Where judged clinically appropriate and depending on clinical context and staging, annual CT scans of chest abdomen and pelvis in the first three years following surgery may be appropriate.

CT scans should be reported as per DRTT.

4. CT PET should be considered in the following cases:
 - Patients with one confirmed elevated CEA level with a negative or equivocal CT.
 - Distinguishing between fibrosis from recurrent disease, particularly within the pelvis.
 - Excluding distant metastases in patients being considered for liver and or lung resection after case discussion at the hepatobiliary or lung MDM.

If patient is being considered for CT PET then their case should be discussed first at the MDM prior to requesting the CT PET.

CT PET scan should be reported as per DRTT

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

8.3.5 Follow-up for palliative colorectal cancers

Follow up will be the responsibility of the oncologist and needs to be tailored to individual patient needs in collaboration with palliative care.

References

Association of Coloproctology of Great Britain and Ireland (2007) *Guidelines on the Management of Colorectal Cancer*

NICE (2004) *Improving Outcomes in Colorectal Cancer*.

Royal College of Radiologists (2006) *'Recommendations for Cross-Sectional Imaging in Cancer Management'* Ref No: RCR (06)1

British Society of Gastroenterologists. (2002) *Guidelines for colorectal cancer screening in high risk groups*.

9.0 Guidelines for the Management of Early Rectal Cancer (08-2D-230)

9.1 Introduction

The primary treatment of rectal cancer is through surgery and the long term outcome is related to achieving a complete resection of the tumour with negative resection margins. Preoperative imaging and clinical assessment is used to identify patients who will benefit from additional therapy to improve the likelihood of a good outcome and cure. The major prognostic factors are related to the degree of penetration of the tumour through the bowel wall, tumour histological grade, the relationship of tumour to the circumferential resection margin and the presence or absence of nodal involvement. The care pathway for rectal cancer is illustrated in Appendix 1.

9.2 Staging

All rectal cancers in whom a curative procedure is being considered should be fully staged. Complete pre-operative staging should include:

- digital rectal examination
- rigid sigmoidoscopy with biopsy
- MRI of the pelvis
- CT of the chest, abdomen and pelvis.

The proximal large bowel should be evaluated with colonoscopy, barium enema or CT colonography.

9.3 Treatment

Specific aims of surgery for rectal tumours:

- Total mesorectal excision for middle and lower third tumours for potentially curative patients
- Division of mesorectum at least 5cm beyond upper rectal tumours
- Preservation of the pelvic autonomic plexus
- Sphincter preservation where possible
- Consideration of local resection / TEMS in suitable patients*

As a consequence of the localised nature of T1 tumours (i.e. invasive carcinomas that have not invaded the muscularis propria) they have a high cure rate. Early rectal cancers can be treated effectively by local excision alone thus avoiding complex major surgery with its inherent risks. All local MDTs provide the full range of trans-anal surgical techniques with the exception of Transanal Endoscopic Microsurgery (TEM). TEM is not currently available locally. However, it should be considered as a treatment option. Patient with lesions deemed suitable for TEM should be referred to an appropriate UK centre for surgical management.

All patients with rectal carcinoma should be considered for preoperative radiotherapy either with the goal of reducing local recurrence or to down stage.

9.4 Palliative Care

Early links should be made to the palliative care team where the treatment intent is not curative or where the patient's symptoms are difficult to manage,

References

Bach S, Lane L, Merrie A, Mortensen NJ Stage 1 rectal cancer: Transanal Endoscopic Microsurgery or Radical Resection? 2006 Colorectal Disease 8.19 abstract O54 Gateshead 2006.

Kikuchi R, Takano M, Koichi T et al. 1995 Management of early invasive colorectal rectal cancer. Dis Col Rectum 38 :1286-1295

Mentges B, Buess G, Effinger G, Manncke K, Becker HD 1997 Indications and results of local treatment of rectal cancer. Br J Surg 84:348-351

Winde G, Nottberg H, Keller R, Schmid KW, Bunte H 1996 Surgical cure for early rectal carcinomas (T1). Transanal Endoscopic Microsurgery vs. anterior resection. Dis Colon Rectum 39:969-976

10.0 Stenting Guideline (N08C-112d)

10.1 Introduction

The objective of this guideline is to ensure that stenting is considered for, and available to, patients with malignant obstruction of the colon. The decision on when stenting should be used is based on factors relating to the tumour and to patient factors, and should be individualised. Before deciding whether to place a stent, the anatomy of the stricture should be defined radiologically, usually on fluoroscopy with water-soluble contrast. Stenting may be undertaken:

- (a) to palliate malignant obstruction in patients with incurable disease
- (b) as a bridge to resectional surgery in patients with acute left-sided malignant obstruction

The procedure is carried out by an endoscopist or endoscopist and interventional radiologist.

Inclusion criteria

Patients with malignant obstruction of the colon should be considered for stenting.

Relative exclusion criteria

- (a) Rectal lesions where the distal end of the stent would encroach on the lower rectum / anal canal.
- (b) Patients with signs of peritonitis and/or perforation.
- (c) Patients with closed loop obstruction and right iliac fossa tenderness.

10.2 Palliative care

Stenting may be used to palliate malignant obstruction, either due to primary cancer arising in the colon, or extrinsic compression of the colon by cancer. The patients will have irresectable cancer, either locally or at distant site(s). Obstructing lesions in patients unfit for surgery may be palliated by stenting.

10.3 Bridge to surgery

Stenting is an alternative to urgent surgery in patients with acute large bowel obstruction, subject to the exclusions listed above. The potential advantage is that a stoma may be avoided in those for whom primary anastomosis is not appropriate. The main potential risk is of stent erosion and perforation.

Stenting should be undertaken with caution where there is sharp angulation adjacent to the tumour. The increased risk of migration in such cases can be minimised by deploying a longer stent.

Stenting may take a considerable amount of time in difficult cases. Patients should be adequately resuscitated before commencing the procedure and their vital signs monitored throughout as for colonoscopy.

10.4 Service provision and personnel

The timing of stent placement depends upon the circumstances of the individual case. For palliative cases not acutely obstructed timing should take account of other priorities for the patient and availability of the service, but should usually be made available within 5 working days. In cases of impending obstruction the service should be available within 24 hours.

For patients with acute obstruction, stenting is optimally done as soon as the necessary investigations (CT & contrast enema) are completed and the patient has been fluid-resuscitated. The degree of urgency will depend upon the severity of obstruction, but would usually be within 24 hours.

Stenting may be undertaken by a competent colonoscopist and /or an interventional radiologist.

A named lead colonoscopist and / or interventional radiologist should be identified in each hospital trust.

Each trust will agree and record competent stentors. *Any personnel submitted as a competent stentor should be able to demonstrate that they are maintaining their expertise by such evidence as for example continuing professional development activity or an audit of their procedures.*

10.5 List of NSSG competent stentors (N08-2D-219)

See Table over leaf.

	Named competent stentors	Profession
Belfast HSC Trust	Dr Michael Mitchell Dr Inder Mainie Mr A Armstrong Mr J Lee Dr W Loan Dr Mark McLoughlin Mr T Irwin Mr K Khosraviani Mr R Maxwell Mr K Gardiner Dr N Patterson Dr G Turner Ms. C Rodgers Dr A Collins Dr P Kennedy Dr P Ellis	Consultant Gastroenterologist, BCH Consultant Gastroenterologist, BCH Consultant Surgeon, BCH Consultant Surgeon, BCH Consultant Radiologist, BCH Consultant Gastroenterologist, MIH Consultant Surgeon, RVH Consultant Surgeon, RVH Consultant Surgeon, RVH Consultant Surgeon, RVH Consultant Gastroenterologist, RVH Consultant Gastroenterologist, RVH Nurse endoscopist, RVH Consultant Radiologist, RVH Consultant Radiologist, RVH Consultant Radiologist, RVH
Northern HSC Trust	Dr Lynch Dr Jacob Dr Rodgers	Consultant Gastroenterologist, Causeway Hospital Consultant Gastroenterologist, Antrim Area Hospital Consultant Gastroenterologist, Antrim Area Hospital
Southern HSC Trust	Dr Paul Rice Dr Richard McConville	Consultant Radiologist, Craigavon Area Hospital Consultant Radiologist, Craigavon Area Hospital

South Eastern HSC Trust	Dr Grant Caddy Dr Tony Tham Mr Jeffery Campbell	Gastroenterologist/Colonoscopist , Ulster Hopsital Gastroenterologist/Colonoscopist , Ulster Hospital Surgeon/ Colonoscopist , Ulster Hospital
Western HSC Trust	Dr W Dickey Dr Andre Murdock Dr N Mukherji Dr E Campbell Mr Essam Ghareeb	Gastroenterologist, Altnagelvin Hospital Gastroenterologist, Altnagelvin Hospital Gastroenterologist, Altnagelvin Hospital Gastroenterologist, Erne Hospital Consultant Surgeon, Erne Hospital

11.0 Systemic Therapies Colorectal Cancer (N08-2D-230)

Note: this section may change subject to the development of the clinical management guideline for systemic therapies that will be developed by the NICaN Regional Chemotherapy Project.

11.1 Radiotherapy

In general all patients with Rectal Carcinoma should be considered, depending on individual circumstances, for preoperative radiotherapy either with the goal of reducing local recurrence or to down stage.

Following the pathology report on the resected sample, a decision should be made at the MDM regarding the benefits of post-operative oncological therapies.

11.2 Adjuvant treatments

Colon

Node positive, colon - Capox (Oxaliplatin/Capecitabine); 5FU/FA; Capecitabine
Node neagative colon (selected cases i.e. under 70, fit for treatment and wishes to proceed when aware of the 2-3% 5-year survival advantage) - 5FU/FA, Capecitabine

Rectum

Node positive, rectum - 5FU/FA; Capecitabine
Node negative, rectum - 5FU/FA; Capecitabine

11.3 Palliative treatments

IMDG (Irinotecan, infusional 5FU/FA)
OMDG (Oxaliplatin, infusional 5FU/FA), or Oxaliplatin/Capecitabine
Capecitabine

These would account for the vast majority of treatments outside Clinical Trials.

GI therapeutic trials will still account for <5% of treatments delivered.

These do not account for the small number of private patients who have access to the licensed but unfunded treatments such as Bevacizumab ("Avastin") and Cetuximab ("Erbix").

12.0 Guidelines For The Management Of Patients With Anal Cancer (08-2D-231 & 08-2D-233)

12.1 Introduction

Anal cancer is a rare disease, accounting for 1 – 2 % of gastrointestinal malignancies. The annual incidence is 1 per 100,000, or approximately 500 new cases in the UK per year (ACPBGI 2007); around 17 cases per annum in Northern Ireland.

Surgery is typically only used as a first-line treatment for small anal cancers that do not involve the anal sphincter muscles. In these cases, local resection can be curative. If the tumour involves the anal sphincter or is too extensive to be cured by local resection, the recommended treatment is [chemoradiotherapy](#). Chemoradiotherapy often avoids the need for radical excisional surgery.

There are around 10-20 new cases of invasive squamous cell carcinoma of the anal canal and margin are diagnosed in Northern Ireland each year (mean 17; NI Cancer Registry 2009).

12.2 Referral for specialist treatment

Chemoradiotherapy

Following the detection of an abnormal mass either on the perianal skin or within the anal canal the diagnosis will be confirmed by a biopsy demonstrating squamous carcinoma (less common variants include basaloid and cloacogenic type but are managed in the same way), patients should be referred directly to the site-specific oncologist via the MDM.

Surgery

Patients with recurrent or persistent anal cancer following chemoradiotherapy should be considered for salvage surgery. Salvage surgery is specialised and requires input from plastic surgery. There are currently two designated MDTs undertaking salvage surgery, Belfast Trust and SE Trust. Patients requiring salvage surgery should be referred for discussion to the Belfast or SE Trust CRC MDM.

12.3 Diagnosis & staging

Initial consultation

- Full history and examination
- Assessment of suitability for primary chemoradiotherapy (ensuring no prior pelvic radiotherapy)
- Clinical staging and completion of radiological staging of anal carcinoma.
- Explanation of proposed treatment
- Written patient information available on PPM

Staging investigations

- Clinical examination
- Full blood count
- Urea and electrolytes
- Liver function tests
- CT Chest, Abdomen and Pelvis
- MRI pelvis

*In HIV positive cases advice from GUM clinic on current status/medication

TNM staging

The UICC 1990 staging system will be used

- Tx Primary tumour cannot be assessed
- Tis Carcinoma in situ
- T1 Tumour 2cm or less
- T2 Tumour >2cm – 5cm
- T3 Tumour >5cm
- T4 Tumour invades other organ (vagina, urethra, bladder, sacrum) – anal canal
- Tumour invades deeper structures (skeletal muscle or cartilage) – anal margin

Anal canal (regional nodes are perirectal, internal iliac and inguinal)

- Regional nodes are perirectal, internal iliac and inguinal.
- Nx Regional nodes cannot be assessed
- N0 No regional node metastases
- N1 Metastasis in perirectal nodes
- N2 Metastasis in unilateral internal iliac and/or inguinal nodes
- N3 Metastasis in perirectal and inguinal nodes and/or bilateral internal iliac or inguinal
- Nodes

Anal margin

Regional nodes are inguinal nodes on both sides

N0 No metastasis

N1 Metastasis present (unilateral or bilateral)

Assessment of clinically involved nodes

This is difficult and is a clinical decision. Formal biopsy of nodes is not normally recommended. FNA of nodes that are of uncertain significance can sometimes be useful, but only if the FNA is positive. If the FNA is negative it does not exclude malignancy because of the problem of a sampling error.

The final decision is based on clinical suspicion and must be documented.

12.4 MDM

The anal cancer patients will be discussed at the local CRC MDMs which are held weekly.

All cases will be registered by the local MDT via the CaPPs system.

It is anticipated that the majority of newly diagnosed cases will require limited discussion.

More detailed discussion will be required for patients with:-

- Difficult histology
- Small anal margin tumours less than 2cm where complete local excision with clear margins can/have been obtained
- Patients who have received previous high dose radiotherapy to the pelvis.
- Preservation of fertility
- Previous renal transplant
- HIV positive patients (especially in the presence of a high viral load or low CD4 count)
- Significant pre-existing bowel disease
- Recurrent disease

12.5 Management

- Chemo – radiotherapy is the treatment of choice for the majority of patients with anal cancer
- Small (T1 and some T2) tumours of the anal may be treated by local excision.
- Salvage AP resection should be considered for residual or recurrent local disease subject to re–staging confirmation that there is no distant metastatic disease
- Defunctioning ileostomy/colostomy may be required
- Block dissection of inguinal nodes may be needed in addition to other treatment
- Perineal reconstruction with myocutaneous flaps can be performed for extensive local disease.

The standard of care for patients with squamous cell carcinoma of the anal canal and margin is primary chemoradiotherapy (CRT) with anorectal excision reserved for patients with persistent or locally recurrent disease.

A minority of patients will not be suitable for primary CRT. This includes patients with:

- Small anal margin tumours less than 2cm where complete local excision with clear margins can be obtained. **Anal canal tumours should not be locally excised (poor function outcome – additional CRT usually required)**
- Patients who have received previous high dose radiotherapy to the pelvis
- Where preservation of fertility is essential

There are also a small group of patients where discussion will be needed with regards to the most appropriate treatment and the CRT might need to be modified. This includes patients with:

- Previous renal transplant
- HIV positive patients (especially in the presence of a high viral load or low CD4 count)
- Significant pre-existing bowel disease

12.6 Summary of chemo radiation treatment protocols

Anal Canal T1 and all T2/3/4 NO/N1/N2 M0 -

AN1 T2-T4 Clinically Node -ve tumours

RT phase I - 30Gy in 15F large parallel opposed fields

RT phase II - 20 Gy in 10F planned volume to GTV + margin

Chemotherapy MMC D1, 5FU days 1-4, 29-32

AN2 Tany Clinically Node +ve tumours

RT phase I - 30Gy in 15F large parallel opposed fields

RT phase II - 20 Gy in 10F parallel opposed fields to cover GTV + margin

Chemotherapy MMC D1, 5FU days 1-4, 29-32

AN3 T1N0 (tumour in situ)

Residual or high risk of microscopic disease after local excision

RT single phase 30Gy in 15F to GTV + margin

Chemotherapy MMC D1, 5FU days 1-4

AN4 TanyNany elderly, frail

Considered fit for three week course of CRT only

RT single phase 30Gy in 15F to GTV + margin

Chemotherapy 5FU only D1-4

Palliative radiotherapy

Patients of very poor performance status with significant symptoms from the primary eg bleeding/ pain who would not tolerate AN4 protocol or patients with metastatic disease eg bone metastases. Single fraction of 8-10Gy

Neoadjuvant chemotherapy

Patients with extensive bulky primary disease or extensive nodal disease prior to radical CRT. Combination 5FU and cisplatin 3 weekly reassessed after 2-3 cycles.

Palliative chemotherapy

TanyNany M1

Depends on hepatorenal function and performance status but treatment options include either Mitomycin Modified deGramont, Mitomycin Capecitabine, Cisplatin 5FU, Cisplatin Capecitabine

12.7 Follow up

Post chemoradiotherapy follow up

Patients will be seen in the radiotherapy review clinic on a weekly basis until the moist desquamation and any other severe acute toxicity has settled.

Post treatment assessment will take place in the Oncology out patient clinic 4-6 weeks after the end of chemoradiotherapy treatment. When clinical examination is too uncomfortable for the patient an examination under anaesthetic will be arranged.

Biopsy following chemoradiotherapy is only advised where there is a residual mass and the clinical suspicion is of persistent or recurrent disease. Biopsies should be taken - the risk of necrosis because of prior CRT is minimised by taking small biopsies.

Routine out patient follow up

Following assessment at 4-6 weeks after CRT approximately 80-90% of patients will be in clinical remission. There is no indication for routine investigations to detect recurrence during follow-up. Clinical examination is performed on each clinic visit. The rationale for the below follow up policy is to:-

- Detect local recurrence amenable to salvage surgery (greatest risk period 12-36 months)
- Allow audit of outcome of current protocols
- Allow detection and appropriate management of severe treatment related morbidity

Routine follow up:-

3 monthly year 1 and 2

6 monthly year 3,

Yearly years 4 and 5

12.8 Management of recurrent local disease / distant metastases

Following detection of biopsy proven persisting or recurrent local disease or metastases, patients should be discussed by the local MDT. The following investigations would usually be indicated:-

- CT scan chest and abdomen
- MRI pelvis

Review of the above investigations, review of prior definitive treatment and multi-disciplinary team discussion is required to formulate an appropriate management plan.

The options are likely to include:-

- Salvage anorectal excision with vascularised flap (because of prior CRT) for isolated local recurrence
- Palliative chemotherapy – for multifocal locoregional or metastases recurrence
- Block dissection of the groin - for isolated inguinal node recurrence
- Chemoradiotherapy – for a small minority of patients treated by primary surgical excision

References

Anonymous (1996a) Epidermoid anal cancer: results from the UKCCCR randomised trial of radiotherapy alone versus radiotherapy, 5-fluorouracil, and mitomycin. UKCCCR Anal Cancer Trial Working Party. UK Co-ordinating Committee on Cancer Research [see comments]. *Lancet* 348, 1049-1054.

Bartelink, H., Roelofsen, F., Eschwege, F., Rougier, P., Bosset, J.F., Gonzalez, D.G., Peiffert, D., van Glabbeke, M. and Pierart, M. (1997) Concomitant radiotherapy and chemotherapy is superior to radiotherapy alone in the treatment of locally advanced anal cancer: results of a phase III randomized trial of the European Organization for Research

and Treatment of Cancer Radiotherapy and Gastrointestinal Cooperative Groups [see comments]. *Journal of Clinical Oncology* 15, 2040-2049.

Cummings, B.J., Keane, T.J., O'Sullivan, B., Wong, C.S. and Catton, C.N. (1991) Epidermoid anal cancer: treatment by radiation alone or by radiation and 5-fluorouracil with and without mitomycin C [see comments]. *International Journal of Radiation Oncology, Biology, Physics* 21, 1115-1125.

Flam, M., John, M., Pajak, T.F., Petrelli, N., Myerson, R., Doggett, S., Quivey, J., Rotman, M., Kerman, H., Coia, L. and Murray, K. (1996) Role of mitomycin in combination with fluorouracil and radiotherapy, and of salvage chemoradiation in the definitive nonsurgical treatment of epidermoid carcinoma of the anal canal: results of a phase III randomized intergroup study. *Journal of Clinical Oncology* 14, 2527-2539.

Leichman, L., Nigro, N., Vaitkevicius, V.K., Considine, B., Buroker, T., Bradley, G., Seydel, H.G., Olchowski, S., Cummings, G. and Leichman, C. (1985) Cancer of the anal canal. Model for preoperative adjuvant combined modality therapy. *American Journal of Medicine* 78, 211-215.

Melcher A, Sebag-Montefiore D. (2003) Concurrent chemoradiotherapy for squamous cell carcinoma of the anus using a shrinking field radiotherapy technique without a boost. *British Journal of Cancer* 88, 1352-7

Sebag-Montefiore D, Cooper R, Chesser P Network wide pattern of care of anal cancer: implications of COG guidelines *Colorectal disease* 7(Suppl 1) abstract P135 p88,2005

Gunderson LL, Winter KA, Ajani JA, Pedersen JE, Benson AB, Thomas CR, Mayer RJ, Haddock MG, Willett CG, Rich TA. (2006) Intergroup RTOG 9811 Phase III comparison of chemoradiation with 5-FU and Mitomycin Vs 5-FU and cisplatin for anal carcinoma: Impact on disease-free, overall and colostomy-free survival. *International Journal of Radiation Oncology, Biology & Physics*, 66 Suppl 1, 524.

13.0 Management Of Patients With Colorectal Metastases (N08-2D-232 & N08-2D-234)

13.1 Introduction

It has been known for many years that patients with operable metastases in the liver or lung may benefit from resection, and with careful patient selection, hepatectomy for colorectal metastases is associated with a 5 year survival of around 33%.

It is currently unclear whether patients with operable metastatic disease benefit from pre-operative chemotherapy, and if the temporal development of metastases (synchronous or metachronous) has any influence on the role of systemic therapy. The results of a UK-led international phase III trial investigating the magnitude of benefit for pre- and post-operative chemotherapy in this setting are awaited with interest (EORTC/GITCCG 40983). There is also some evidence to support the use of the same approach for patients with resectable pulmonary metastases, but there is no evidence that resection of nodal metastatic disease is beneficial.

Non-randomised evidence exists to support the use of pre-operative combination chemotherapy prior to resection in patients with potentially operable liver metastases (Giacchetti et al 2000 III). Such patients should be discussed at the HPB MDM. If appropriate following radiological and surgical review, pre-operative combination chemotherapy should be delivered for at least 8 weeks prior to re-imaging.

13.2 Referral and management

Fit patients with resectable or potentially resectable liver or lung metastases should be referred immediately to the HPB MDT⁸ to evaluate operability and to decide on a plan of management to optimise the chance of achieving complete resection of all metastatic disease.

Criteria for liver resection:

Patients who are fit to for major surgery and in whom all disease sites can be treated with curative intent should be considered for resection.

The ability to achieve clear margins should be discussed by the radiologist and the surgeon at the specialist HPB MDM.

The surgeon should define the acceptable residual volume of the liver.

Synchronous metastases

- Lesions discovered at the primary operation should not be biopsied.
- Patients should be referred for consideration of liver resection after recovery from the primary surgery (within 8 weeks)
- Patients should be considered for liver resection before consideration of chemotherapy.

⁸ The HPB MDT meets weekly at the Royal Victoria Hospital, Belfast trust.

The following patients should be considered for resection:

- Solitary liver metastases
- Multiple unilobar liver metastases
- Provided that 30% of disease free parenchyma can be spared we also consider patients with:
 - Bilobar resectable liver metastases
 - Multiple bilobar liver metastases amenable to down-staging
 - Such patients are also considered for staged hepatectomies.

Patients with extrahepatic liver metastases that should be considered for resection would include:

- Resectable isolated extrahepatic sites (e.g. spleen, adrenal, local recurrence)
- Local direct extension of the liver metastases that can be resected (e.g. diaphragm or adrenal).
- Resectable pulmonary metastases (up to 6 in number)

Patients with synchronous liver metastases and those with metachronous metastases arising within the first 2 years after resection of the primary colorectal cancer should be considered for chemotherapy before liver resection. Patients with metachronous liver metastases arising more than 2 years after their primary colorectal cancer has been removed may proceed directly to resection.

Criteria that exclude patients from liver resection:

- Unfit for major surgery – borderline cases assessed by an HPB anaesthetist
- Unresectable primary disease (that had failed down-staging chemotherapy)
- Positive pelvic CRM leaving local residual disease
- Peritoneal / Omental metastases
- Bony or unresectable lung metastases
- Widespread pulmonary disease
- CNS metastases
- Locoregional recurrence

Patients that are unsuitable for resection should if appropriate be referred to an oncologist for consideration of palliative chemotherapy or inclusion in clinical trials. They should also be referred to the palliative care team.

13.3 Staging protocol

All staging should be done locally.

Staging should include the following:

- Spiral CT of the chest, abdomen and pelvis – contemporary scan
- TESLA MRI scan of the liver
- Colonoscopy (before or after resection of the primary)
- PET scanning in patients with high risk primary disease (T4(perforated); C2 (apical node))

13.4 Multi Disciplinary Team Involvement

All patients to be discussed at the Specialist HPB MDM (which meets each Friday at the Royal Victoria Hospital) and a management plan made for treatment with chemotherapy

and / or surgery.

All patients considered for resection will be seen in Belfast Trust by a consultant HPB surgeon together with the HPB CNS to provide a contact point and treatment details.

13.5 Following surgery

Following surgery a letter is sent to the referring clinicians providing all operative details. All patients are followed up for one post-operative visit at the centre 4 to 6 weeks after surgery.

Histology once available is reviewed at the Regional weekly HPB MDM and further adjuvant therapy plans discussed.

All patients liver resection are referred back to the local oncology team who are provided with a full discharge summary and the specialist cancer MDT opinion on adjuvant therapy.

13.6 Chemotherapy and neo-adjuvant chemotherapy

There is evidence from two systemic reviews that chemotherapy for metastatic colorectal cancer can improve survival and should be considered in all patients not suitable for surgery.

In some cases tumours may be considered for downsizing if they are initially unsuitable for resection.

There is no evidence to support pre-treatment with neo-adjuvant chemotherapy in patients with resectable diseases. This may be influenced when the results of EPOC are available.

13.7 Follow-up

There are no definite national guidelines for follow up of these patients. However recurrent disease in the liver is still amenable to curative resection.

An intensive follow up protocol of 6 monthly CT and CEA marker is advised for the first 2 years and annually thereafter for a further 3 years.

Patients with recurrent disease will be reviewed in the same way as before to discuss further resection or non surgical options.

References

Adam R, Avisar E, Ariche A et al 5 year survival following hepatic resection after neoadjuvant therapy for non-resectable colorectal (liver) metastases. *Ann Surg Oncol* 2001;**8**:347-53.

Bismuth H, Adam R, Levi F et al Resection of non-resectable liver metastases from colorectal cancer after neoadjuvant chemotherapy. *Ann Surg* 1996;**224**:509-20.

Choti MA, Bulkley GB. Management of hepatic metastases *Liver Transpl Surg* 1999;**5**:65-80.

Garden OJ, Rees M, Poston GJ et al Guidelines for resection of colorectal cancer liver metastases. *gut.bmjournals.com* 2006 (4th August).

Giachettie S, Perpoint B, Zidani R et al Phase 111 multicenter randomised trial of oxaliplatin added to chronomodulated fluorouracil-leucovorin as first line metastatic treatment of colorectal cancer. *J Clin Oncol* 2000;**18**:136-47.

Hughes KS. Resection of the liver for colorectal metastases: a multi-institutional study of indications for resection. Registry of Hepatic Metastases. *Gut* 1988;**103**:278-88.

Jonker DJ, Maroun JA, Kocha W. Survival benefit of chemotherapy in metastatic colorectal cancer: a meta-analysis of randomised controlled trials. *Br J Cancer* 2000;**137**:1789-94.

Oshowo A, Gilliams AR, Lees WR et al Radiofrequency ablation extends the scope of surgery in colorectal liver metastases. *Eur J Oncol* 2003;**29**:244-47.

Simmonds PC, Primrose JN, Colquitt et al Surgical resection of hepatic metastases from colorectal cancer: A systematic review of published studies. *British Journal of Cancer* 2006;**94**:982-99.

Tournigand C, Andre T, Achille E et al. FOLFIRI followed by FOLFOX6 or the reverse sequence in advanced colorectal cancer: a randomised GERCOR Study *J Clin Oncol* 2004;**22**:229-37.

14.0 Colorectal Nursing

From the time of diagnosis, each patient should have access to a named nurse or Clinical Nurse Specialist (CNS). In emergency The role of the CNS for colorectal cancer encompasses more than stoma care and is similar to that of breast care nurses. A CNS should be available to provide support, assistance, information and advice to every patient. She/he should ensure that patients' non-clinical needs – for example, for information and support – are met. (ACPGBI, 2007)

Patients who may require stomas - whether temporary or permanent - should be counselled as early as possible before surgery by a specialist nurse on the siting and implications of a stoma (ACPGBI, 2007). In emergency cases where a specialist nurse is not available, the stoma site should be marked pre-operatively by the operating surgeon and the patient seen as soon as possible after the operation by a stomatherapist. After surgery, the same nurse should be available to assist patients in managing the stoma and to advise for as long as required on physical, social, sexual and emotional problems associated with the stoma (NHS Executive, 1997)

References

NHS Executive (1997) Guidance on Commissioning Cancer Services
Improving Outcomes in Colorectal Cancer the Manual

ACPGBI Guidelines for the Management of Colorectal Cancer
3rd edition (2007)

15.0 Supportive and Palliative Care

Supportive care is available to people with cancer and their carers throughout the patient pathway, from pre-diagnosis onwards and is a term used to describe all services that may be required to support people with cancer and their carers(NICE,2004). It is identified by NICE (2004) that patients and carers may have a series of problems preceding diagnosis (when cancer is suspected) which may include physical and anxiety related symptoms which require appropriate management, and information should be available for patients at this stage if they require it. As recognised by NICE (2004) supportive care is the responsibility of all health and social care professionals involved in delivering care and effective communication within teams will enable a seamless transition from one service to another if and when required.

Patients with advanced colorectal cancer may benefit from treatment of the cancer and from palliative care (NICE, 2004). Palliative care is defined by the World Health Organization (W.H.O., 2003) as an approach that improves the quality of life of patients and their families, dealing with the problems associated with life threatening illness. Uncontrolled symptoms can adversely affect quality of life and a patient's ability to cope with their illness, therefore, early identification, thorough assessment and treatment of pain and other problems, physical, psychological and spiritual, is essential (WHO 2003). The overall goal of palliative care is to help manage the symptoms and difficulties that may arise with disease progression, through appropriate support and intervention.

Palliative Care is an integral part of the activities of the multidisciplinary team and patients may require palliative care at different stages of the patient pathway (NICE, 2004). Referral to Palliative Care may be made at any time in the course of the disease when the patient wishes and would benefit from it.

References

National Institute for Clinical excellence (2004) Improving Outcomes in Colorectal Cancer. www.nice.org.uk

World Health Organisation (2003)<http://www.who.int./cancer/palliative/definition/en/>

National Institute for Clinical Excellence (NICE) (2004) Guidance on Cancer Services. Improving Supportive and Palliative Care for Adults with Cancer. London: NICE.

16.0 Psychosocial Support and Access to Financial Advice

Assessment and discussion of patient's needs for physical, psychological, social, spiritual and financial support should be undertaken at key points (such as diagnosis; at commencement, during and at the end of treatment, at relapse, and when death is approaching). Patients should be appropriately referred / signposted to any required support services.

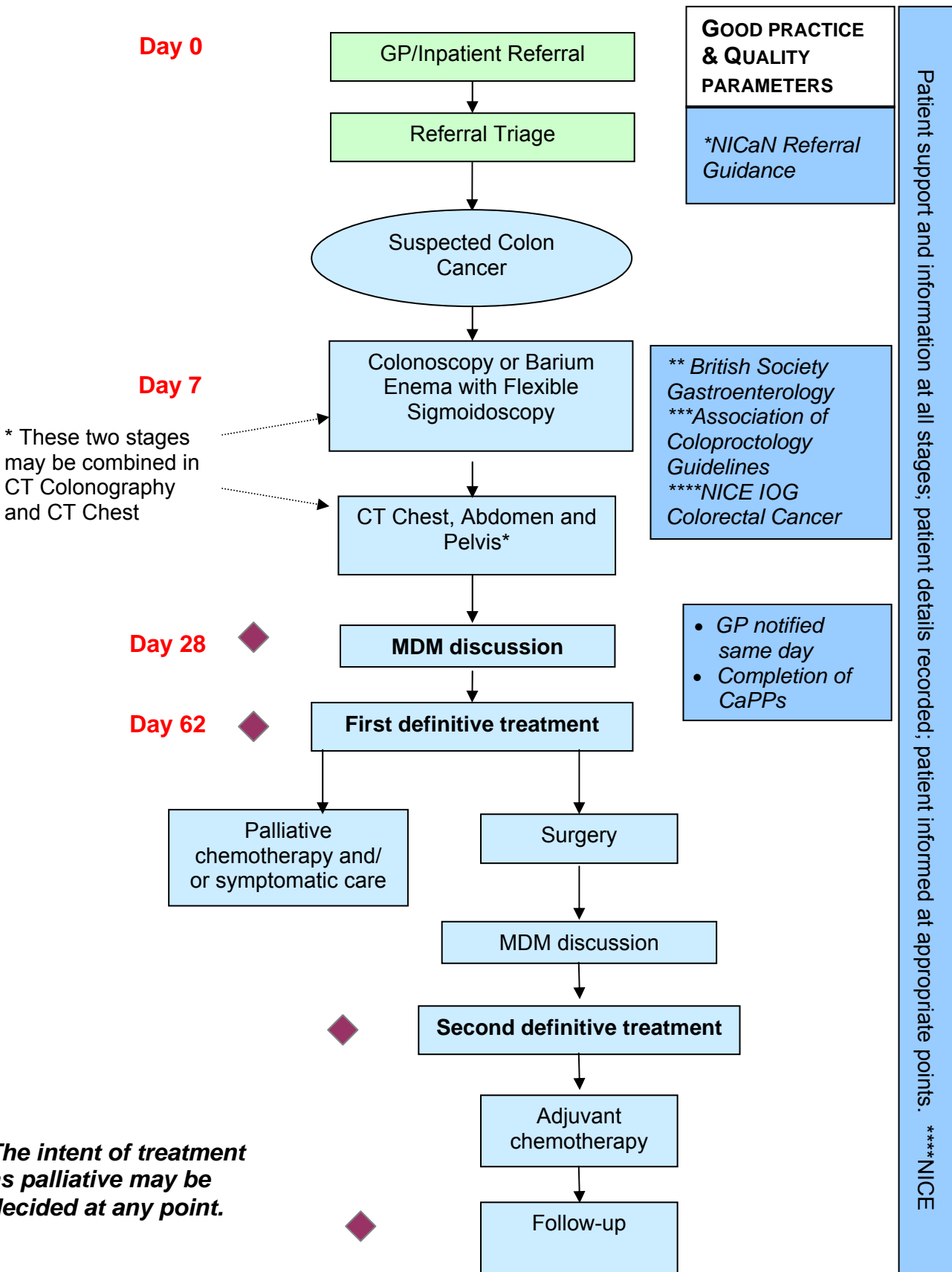
Reference

National Institute for Clinical Excellence (NICE) (2004) Guidance on Cancer Services. Improving Supportive and Palliative Care for Adults with Cancer. London: NICE.

Appendix 1: Regional care pathways

(Version 10: Amendments ratified at NICaN CRC Regional Group meeting on the 12th December 2009 – see Appendix 2)

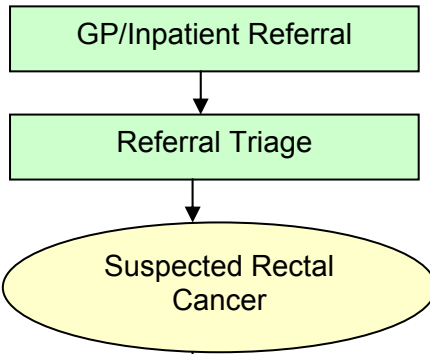
Colon Cancer



◆ Referral for holistic assessment should be made at key points in the patient pathway or whenever the patient requests it. Where it is required, inter-trust transfer must take place by day 28 on the pathway.

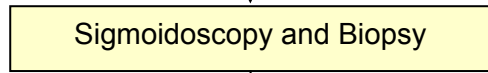
Rectal cancer pathway

Day 0

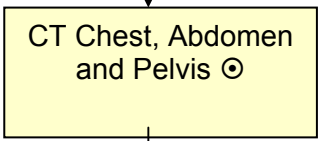
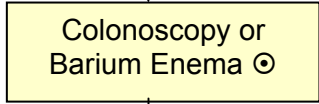


GOOD PRACTICE & QUALITY PARAMETERS
 *NICE Referral Guidance

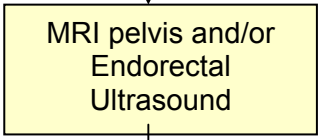
Patient support and information at all stages; patient details recorded; patient informed at appropriate points. ****NICE



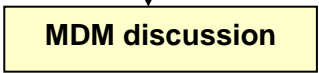
⊙ These two stages may be combined in CT Colonography and CT Chest



** British Society Gastroenterology
 *** Association of Coloproctology Guidelines
 **** NICE IOG Colorectal Cancer.

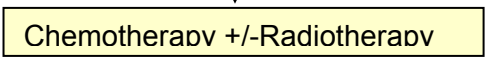
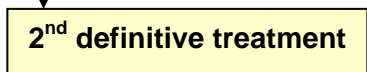
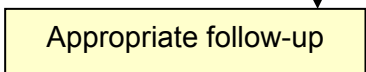
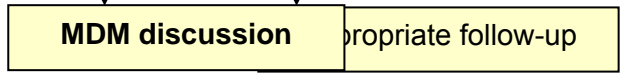
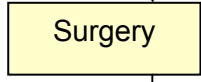
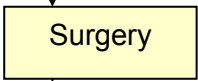
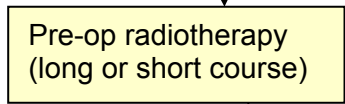
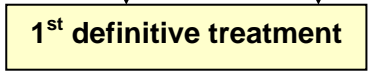


Day 28



- GP notified same day
- Completion of CaPPs

Day 62



The intent of treatment as palliative may be decided at any point

◆ Referral for holistic assessment should be made at key points in the patient pathway or whenever the patient requests it. Where it is required, inter-trust transfer must take place by day 28 on the pathway.

Anal Cancer Pathway

Day 0

GP/Inpatient Referral

Referral Triage

Suspected Anal Cancer

Day 7

Biopsy
(usually under general anaesthetic)

CT Chest, Abdomen
and Pelvis

MRI (Optional)

Day 28

MDM discussion

Day 62

1st definitive treatment

Chemo-
radiation
(Usually)

Surgery

MDM discussion

2nd definitive treatment

Salvage
Surgery

Adjuvant
Chemotherapy /
Radiotherapy

Appropriate follow-up

**GOOD PRACTICE
& QUALITY
PARAMETERS**

**NICE Referral
Guidance*

*** British Society
Gastroenterology
*** Association of
Coloproctology
Guidelines
**** NICE IOG
Colorectal*

- GP notified same day
- Completion of CaPPs

- GP notified same day
- Completion of CaPPs

Patient support and information at all stages; patient details recorded; patient informed at appropriate points. ****NICE

Salvage surgery and chemoradiation to be undertaken by named personnel designated by the NSSG.

The intent of treatment as palliative may be decided at any point.

◆ Referral for holistic assessment should be made at key points in the patient pathway or whenever the patient requests it. Where it is required, inter-trust transfer must take place by day 28 on the pathway.

Purpose of the pathway

This pathway has been developed by the NICaN Regional Colorectal Cancer Group to:

- Support quality service provision by outlining an evidence based patient pathway for those with colorectal cancers;
- Enable clinical, managerial and lay people to see an outline of what patients with colorectal cancer can expect across the patient pathway at different stages of the cancer journey;
- Enable key staff at all levels throughout Health and Social Care Services to identify where patients should be in their journey at a certain time point, to assist in monitoring performance against the cancer access standards (31/62 day targets).

While this pathway is applicable in the majority of cases, the primary concern must always be to ensure that care is provided according to the wishes and needs of each patient.

Service Optimisation

There are a number of practical steps that could be taken to improve patients' experience of care and reduce cancer waiting times. Such steps may include:

- Streamlining the referral route – one route, single queue, one point of contact
- Pooling referrals
- Straight to test
- Combining tests/visits
- Agreed protocols for diagnosis/staging
- Robust booking/scheduling systems
- Competency based workforce development with skill mix and extended roles

The Belfry Plan provides a pragmatic evidence-based approach to improving the quality and timeliness of care for patients with gastrointestinal problems due to cancer and other conditions.

2007/2008 PFA Cancer Access Standards

- 98% of patients diagnosed with cancer (decision to treat) should begin their treatment within a maximum of 31 days.

This standard applies to all new diagnoses of cancer regardless of the route of referral and will include: urgent GP referrals; routine GP referrals; screen-detected cancers; referrals from another consultant and incidental findings.

- 95% of patients urgently referred with a suspected cancer should begin their first definitive treatment within a maximum of 62 days.

This standard refer to all patients referred as a suspect cancer using the NICaN Referral Guidance for Suspected Cancer.

Timed Schedule

'Day 0' and 'Day 62' on the pathway mark the stage of the pathway the patient should have reached by this stage in their journey and are included to support the proactive management of the patient from point of receipt of referral to first definitive treatment.

◆ **Referral for holistic assessment** should be made at key points in the patient pathway or whenever the patient requests it. Where it is required, **inter-trust transfer must take place by day 28 on the pathway.**

It is recognised that there may be different service pressures in each Trust. Clinical Teams working with Executive Leads should resolve these internally to ensure the Cancer Access Standards (above) are met.

Inter Trust Transfer

Where it is required, inter trust transfer should take place by day 28 on the patient pathway.

Management of referrals

Consideration needs to be given to the management of the symptomatic patient referred, but not suspected of, having cancer.

'Red Flag' referrals for patients suspected of having cancer should meet the guidelines set out in the NICA guidelines for the referral of suspected cancer (2007). Referrals which do not meet these guidelines may be downgraded by the consultant if agreement is reached with the referring GP.

Selecting a diagnostic test

The British Society of Gastroenterology published guidelines in GUT "Guidelines for colorectal cancer screening and surveillance in high risk groups" [Gut 2002; 51 (Suppl V):v28] and recommends that in most cases colonoscopy is the recommended diagnostic test.

The Association of Coloproctology of Great Britain and Northern Ireland, in its Guidelines for the management of colorectal cancer (2007), recommends that Patients referred with suspected colorectal cancers should be investigated with sigmoidoscopy (flexible or rigid) plus a high quality double contrast barium enema, or colonoscopy, or CT colonography.

NICE guidance 'Improving Outcomes in Colorectal Cancers' (May 2004) acknowledges that each type of investigation has specific advantages and disadvantages which make it more or less appropriate for particular patients. It also notes that the local availability of facilities, equipment and skilled staff will inevitably influence the choice of investigation used, and that as diagnostic services are upgraded the impact of these service variables should diminish.

The selected method of investigation is dependent upon clinical judgement based on patient need and choice. Available service capacity to provide colonoscopy and CT Colonography will increase as services modernise.

Clinical Trials

All patients should be considered for entry into clinical trial where appropriate.

Evidence and Rationale

The evidence base and rationale for this document is set out in the following documents:

- Manual of Cancer Services Standards, Colorectal Cancer Update July 2004, DH (http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_4090080)
- Association of Coloproctology of Great Britain and Ireland Guidelines 2007 (<http://www.acpghi.org.uk/documents/COLO%20guides.pdf>)
- Improving Outcomes in Colorectal Cancers – Manual Update NICE 2004 (<http://www.nice.org.uk/nicemedia/pdf/CSGCCfullguidance.pdf>)
- Improving Supportive and Palliative Care for Adults with Cancer: The Manual NICE 2004 (<http://www.nice.org.uk/nicemedia/pdf/csgspmanual.pdf>)
- Guidelines for colorectal cancer screening and surveillance in high risk groups, BSG in GUT.BMJ 2002; 51 (Suppl V):28

◆ **Referral for holistic assessment** should be made at key points in the patient pathway or whenever the patient requests it. Where it is required, **inter-trust transfer must take place by day 28 on the pathway.**

- (http://gut.bmj.com/cgi/reprint/51/suppl_5/v28.pdf)
- Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with Cancer, Kings College London, January 2007
(http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_076928)
- Priorities for Action 2007-08, DHSSPS, 2007
(http://www.dhsspsni.gov.uk/pfa_2007-08.pdf)
- The Belfry Plan, Cancer Services Collaborative, 2005
(http://www.cancerimprovement.nhs.uk/%5Cdocuments%5Cbowel%5CBelfry_Plan.pdf)
- Improving Endoscopy Services – meeting the challenges' (National Endoscopy Team for ACPGBI Conference, 2006)
(http://www.endoscopy.nhs.uk/%5Cresources%5Cpublications%5CNHS_MTC.pdf)
- Referral Guidance for Suspected Cancer (NICaN 2007)
(www.nican.n-i.nhs.uk)

◆ **Referral for holistic assessment** should be made at key points in the patient pathway or whenever the patient requests it. Where it is required, **inter-trust transfer must take place by day 28** on the pathway.



Group	Regional Colorectal Cancer Group
Date and Time	Tuesday 8 th December 2009, 2.00pm – 4.00pm
Venue	Lecture Room, Fern House

Attendees

Mrs Cara Anderson	NICaN
Mr Victor Blease	NICaN
Ms Karen Boyd	Belfast Trust
Mr Manos Epanimeritakis	Southern Trust
Dr Robert Harte	Belfast Trust
Mr Geoff Hill	Belfast Trust
Dr Dermot Hughes	NICaN
Mr Kourosh Khosraviani	Belfast Trust
Mr Roger Lawther	Western Trust
Dr Maurice Loughrey	Belfast Trust
Ms Caroline Lynas	SEHSCT
Ms Gail Malmo	NICaN
Mr Roy Maxwell (Chair)	Belfast Trust
Mr Michael Megaw	NICaN
Mr Kevin McCallion	South Eastern Trust
Mr David McCrory	NHSCT
Dr C. Ozo	NHSCT
Dr Richard Park	Belfast Trust
Ms Sarah Williamson	BHSCT
Dr Richard Wilson	Belfast Trust & QUB
Mr Chris Thomas	Belfast Trust

Apologies

Ms Wilma Boyd Carson	SEHSCT
Dr Simon Johnston	Belfast Trust
Dr Kiran Kuar	Belfast Trust
Mrs Sarah Liddle	NICaN
Dr Paul Lynch	Northern Trust
Dr Myles Nelson	Northern Trust
Dr Tracy Owen	Public Health Agency
Dr Colin Rodgers	Northern Trust
Ms Mary Jo Thompson	Southern Trust

1.0 Welcome

- 1.1 Mr Roy Maxwell welcomed everyone to the meeting and a round of introductions took place.

2.0 Minutes of previous meeting

- 2.1 The minutes of the previous meeting were agreed as a true and accurate reflection.

3.0 Matters arising

- 3.1 **Regional Health and Social Care Board (RHSCB) representative** – Mrs Cara Anderson noted that a letter had been sent to Mr John Compton seeking commissioner representation on the group. Mr Compton has intimated that as there is a close link between the RHSCB and Public Health Agency (PHA) the commissioner representative may be drawn from the PHA or the HSCB. Cara indicated that it is possible that they will nominate Dr Tracy Owen who is already a member of the group.
- 3.2 **Outcome of NICaN Board meeting** – Dr Dermot Hughes outlined that the purpose of the NICaN board meeting was to discuss the future of the network post RPA. Mr John Compton attended the meeting in order to inform decisions yet to be taken regarding the future role and accountability of the Network. Dr Hughes noted that the majority view was that NICaN should network should move towards a commissioner-led governed partnership in order to strengthen its links with the commissioner. However, there was a strong view that to move too far down the continuum towards commissioning was to ignore the strength of the Network which lies with its clinician and provider engagement. To this end, it was felt to be important for the Board to continue to be chaired by a Trust Chief Executive but with a more direct line of accountability to the commissioner. Mr Compton is to consider this feedback and will inform the Network as to his decision. Cara Anderson will then establish a small working group to redraft the Network's constitution accordingly.
- 3.3 Mr Maxwell felt that there was no clear definition of roles or lines of communication, and felt that further work needed to be done to improve clinician engagement.
- 3.4 Dr Robert Harte outlined that the final outcome of the meeting was satisfactory from a clinical point of view and stated that the challenge lay in engaging those clinicians who did not participate in regional group meetings.
- 3.5 **Confirmed contacts for patients with metastatic disease** – Mr Maxwell outlined that Mr McGuigan (lung), Mr Diamond (hepatic) and Mr Fogarty (plastics) have been identified as leads for patients with metastatic disease or requiring plastics input.

4.0 Clinical Management Guidelines

- 4.1 Mr Maxwell indicated that the CMGs would have to be signed off at today's meeting subject to amendments agreed during the meeting.
- 4.2 Mr Kevin McCallion outlined that the use of peri-anal throughout the document should be replaced with trans-anal.
- 4.3 Section 3.3 – 'The vast majority of early rectal cancers' should be replaced with 'selected early rectal cancers' and it will be the purpose of the MDT to decide who this applies to.
- 4.4 Mr Chris Thomas highlighted that note 8 should be removed.
- 4.5 Section 5.2 – The abbreviation DRTT should be clarified in the document. Mrs Anderson to clarify with Dr Myles Nelson.
- 4.6 Section 5.4 – Surveillance / follow – up – Mr Kevin McCallion outlined that available research shows a minimal difference between scheduled CT and aggressive follow up and CEA's. Mr McCallion felt it would be beneficial to leave this section more open as it will be difficult to establish mandatory surveillance. Dr Harte emphasised the need for agreement on a unified approach and a high standard of care. Mr Blease, agreed and stated that a variable standard of service would create anxiety for patients.
- 4.7 Dr Richard Wilson noted that if CT's are not used it is possible to miss something in patients that are potentially curable. Mr Epanimeritakis agreed and felt it essential to have a CT 15 month's post colorectal surgery.
- 4.8 It was agreed that while the evidence base is not clear that the group should agree a statement around a minimum standard of follow-up but would also allow for more intensive follow-up in those patients where a clinician identifies a clear need / benefit. This is likely to be informed by a number of considerations including: the stage and location of the tumour; risk of recurrence; co-morbidity; and patient wishes. It was agreed that the ACP guidelines should form the minimum standard with the Oncology Association guidelines providing stretch in those cases where more aggressive follow-up is deemed necessary or beneficial.
- 4.9 Section 6 – Pathology – Mr McCallion highlighted that there is no pathologist at the SE Trust MDM and this will result in a failing MDT. Dr Hughes outlined that this had been raised with commissioners following the first round of pre-visits but there are resource issues. Ms Sarah Williamson noted that the Belfast Trust have just reconfigured their MDM's so this may be a good time to raise the issue with them. It was agreed that the group should write formally to Dr Hughes to follow this up.
- 4.10 **Anal Cancer** – Mr Maxwell outlined that the peer review team were concerned about the large number of people in Northern Ireland performing small numbers of anal cancer surgery, and suggested a need to create a central anal cancer MDT with two named oncologists and two named surgeons.
- 4.11 It was suggested that, based on data of current practice, there could be local diagnostic and staging with input from the surgeon and oncologist. If there is a

clear course of treatment this should be initiated and brought to the central MDM for approval. If there are any difficult issues the central MDT decide on an appropriate management plan. Mr David McCrory queried if a central MDM would meet once a week, as if not it would delay patient care. Dr Harte outlined that there would be rapid access referral to a central MDM through the oncologist who will then start preparation for treatment. Mr McCrory emphasised the need for clear pathways of responsibility to ensure that it works function effectively.

4.12 Dr Parke presented audit data which demonstrated that anal cancer outcomes overall in Northern Ireland (i.e. looking at all treatment modalities combined) compare well with those of ACT II data reports. This led to a debate about whether or not it was necessary to seek to reconfigure the current system. After some discussion it was agreed that there should be two named colorectal surgeons, one at RVH and one at the Ulster. After further discussion it was deemed reasonable that for reasons of cross-cover and succession planning two named surgeons would be identified in each trust, operating on a buddy system. A named plastic surgeon would also be identified at each site. It was also agreed that the number of oncologists should be reduced to three. It was agreed that the group should present their outcome data together with a proposed structure for the service to the next meeting of the NICaN Board so that commissioners could consider what was being proposed.

4.12 Stenting Policy – It was agreed that stenting should not be confined to the left side of the colon.

4.13 Involvement of interventional radiologist – It was agreed that this should be amended to 'interventional radiologist or colonoscopist'.

4.14 Exclusion criteria – It was agreed that this section should be changed to 'relative exclusion criteria' and caution should be exercised with closed loop or sharp angulations.

4.15 Mrs Anderson stated that once the amendments agreed at today's meetings had been made, the CMG document will be forwarded to each individual MDT who will be expected to hold a business meeting where they agree to sign up to implementation of the CMG.

5.0 Care Pathway for Colorectal Cancer

5.1 Mr Maxwell highlighted that cases of colonic cancer should be discussed at MDM prior to treatment unless the situation dictates otherwise (e.g. emergency or informed patient choice). Mrs Anderson emphasised that pathway applies to elective patients only and not to patients with urgent clinical need. It was agreed that the pathway should be amended accordingly. Mrs Anderson agreed to amend the document and re-circulate.

6.0 Clinical Trials Update

- 6.1 Mr Maxwell confirmed that all MDTs had confirmed their nominated trials lead with the exception of SE Trust. Mr. McCallion confirmed the SE lead as Mr. Ian McAllister.
- 6.2 Dr Wilson, NSSG trials lead, presented the updated NSSG agreed list of open clinical trials dated December 2009). Dr. Wilson acknowledged that the portfolio was currently limited to non-surgical trails but stated that the trials unit hoped to extend and broaden the portfolio in the coming year.
- 6.3 Mrs Anderson presented slides clarifying how each MDT has to address the clinical trials peer review aspect at the end of the year.

7.0 Regional Audit

- 7.1 There are two regional audits currently underway. Mr Maxwell outlined that Clare Jones has been in communication to say that the hepatic colorectal metastases study discussed at a previous meeting is now underway and to thank those MDTs who have already agreed to participate (Northern, Southern and Western). Mr Maxwell encouraged the remaining MDTs to make contact with Clare. While the audit will take up to two years to complete it was agreed that it would be useful to have Clare present initial findings at the group's next meeting in order to identify any early practice implications. Mrs. Anderson is to contact Clare to arrange.
- 7.2 Cara Anderson indicated that the results of the regional patient information audit would also be ready to present at the next meeting.
- 7.3 Dr Hughes highlighted that the Cancer Registry has produced a draft colorectal audit and stated that it might be useful to invite Dr Gavin along to present the initial findings and to see if there is any additional analysis that the group would like to see included. He also felt it might provide an opportunity to discuss how we can make best use of CaPPs data on an ongoing basis. It was agreed that Dr Gavin should be invited to present at the next meeting. Mrs Anderson to write to Mrs Gavin.

8.0 Peer Review

- 8.1 Ms Gail Malmo gave a presentation outlining key areas of feedback from the peer review pre visits. Ms Malmo outlined that the operational policy should clarify local detail, include achievements and challenges, and the annual report should be based on 2009 data. Ms Malmo added that the annual work plan should be based on key challenges and service/team development for 2010 and should include things such as remedial actions in relation to trails accrual, planned audit activity etc.
- 8.2 Ms Malmo outlined the next steps for the peer review process. Revisions need to be made to evidence documents and practice changes such as key worker policy and patient survey need to be implemented. Mrs Anderson added that each MDT is required to review and approve the CMG's and this should be minuted in the evidence folder.

8.3 Ms Malmo highlighted that the final deadline for documents to be submitted to CQUINS is 12th February 2010. Formal peer review visits will start on 20th April 2010.