CLINICAL PRACTICE GUIDELINES FOR THE PREVENTION, EARLY DETECTION AND MANAGEMENT OF COLORECTAL CANCER

SHORT FORM SUMMARY OF NHMRC APPROVED RECOMMENDATIONS

Cancer Council Australia

Last updated: January 2018

The Australian Government Department of Health commissioned and funded Cancer Council Australia to develop this guideline. This is a short-form summary of the recommendations.The complete guidelines and technical documentation can be accessed online: wiki.cancer.org.au/australia/Guidelines:Colorectal_cancer. Please also access the guidelines website for the latest version of the short-form summary.

The guidelines are a general guide to appropriate practice, to be followed subject to the clinician's judgment and the patient's preference in each individual case. The guidelines are designed to provide information to assist in decision-making.

The development of the *Clinical practice guidelines for the prevention, early detection and management of colorectal cancer* was undertaken by a non-remunerated Working Party. A membership list and disclosure of their interests is available in the long-form guidelines (online).

Suggested citation: Cancer Council Australia Colorectal Cancer Guidelines Working Party. Clinical practice guidelines for the prevention, early detection and management of colorectal cancer. Short form summary of NHMRC approved recommendations. Sydney (2017). Available from: https://wiki.cancer.org.au/australia/Guidelines:Colorectal_cancer.

Australian Government

National Health and Medical Research Council

The guideline recommendations on pages 5–44 of this document were approved by the Chief Executive Officer of the National Health and Medical Research Council (NHMRC) on 27 October 2017 under section 14A of the *National Health and Medical Research Council Act 1992*.

In approving the guideline recommendations, NHMRC considers that they meet the NHMRC standard for clinical practice guidelines. This approval is valid for a period of five years.

NHMRC is satisfied that the guideline recommendations are systematically derived, based on the identification and synthesis of the best available scientific evidence, and developed for health professionals practising in an Australian health care setting.

This publication reflects the views of the authors and not necessarily the views of the Australian Government.

INTRODUCTION

Colorectal cancer is a major cause of morbidity and mortality in Australia.

It is the second most common cancer diagnosed in both men and women, and is more common in those aged over 50 years. Colorectal cancer is also the second most common cause of cancer death and accounts for 9% of all cancer deaths.[1]

This profile of colorectal cancer in Australia highlights the need for guidelines to ensure clinical best practice in its prevention, detection and management.

The *Clinical practice guidelines for the prevention, early detection and management of colorectal cancer* aim to provide information and recommendations to guide practice across the continuum of cancer care including colorectal cancer prevention, screening and diagnosis, clinical aspects of surgery, radiotherapy and chemotherapy, follow-up and psychosocial care. The guidelines also provide an evidence base for the National Bowel Cancer Screening Program.

The clinical practice guidelines are a revision and update of the 2005 *Clinical practice guidelines for the prevention, early detection and management of colorectal cancer*. Australian guidelines were originally developed in 1999 and, since then, have been widely used as a reference and referred to by health practitioners, including general practitioners (GPs) and specialists, to guide clinical practice.

These guidelines do not cover surveillance colonoscopy in adenoma follow-up, surveillance colonoscopy following curative resection of colorectal cancer, or colonoscopic surveillance in inflammatory bowel disease. This is covered in the *Clinical Practice Guidelines for Surveillance Colonoscopy*.

Please note that this is a short-form summary document. To read the full guideline, including details about the development process, methodology and Working Party membership (chapter authorship), please see the online guidelines at: wiki.cancer.org.au/australia/Guidelines:Colorectal_cancer. The Working Party membership (authorship) is listed on pages 45–55 in this document.

1. Australian Institute of Health and Welfare. *Cancer in Australia: an overview 2014. [Version updated 16 April 2015] Cancer series No 90. Cat. no. CAN 88*. Canberra: AIHW; 2017 Nov 10.

Summary of recommendations

This guideline includes evidence-based recommendations (EBR), consensus-based recommendations (CBR) and practice points (PP) as defined in the table below.

Recommendations and practice points were developed by working party members and sub-committee members. Each EBR was assigned a grade by the expert working group, taking into account the volume, consistency, generalisability, applicability and clinical impact of the body of evidence according to *NHMRC Level and Grades for Recommendations for Guidelines Developers*.[1]

NHMRC APPROVED RECOMMENDATION TYPES AND DEFINITIONS

TYPE OF RECOMMENDATION	DEFINITION
Evidence-based recommendation	A recommendation formulated after a systematic review of the evidence, indicating supporting references
Consensus-based recommendation	A recommendation formulated in the absence of quality evidence, after a systematic review of the evidence was conducted and failed to identify admissible evidence on the clinical question
Practice point	A recommendation on a subject that is outside the scope of the search strategy for the systematic review, based on expert opinion and formulated by a consensus process

SOURCE: National Health and Medical Research Council. Procedures and requirements for meeting the NHMRC standard for clinical practice guidelines. Melbourne: National Health and Medical Research Council, 2011

EVIDENCE-BASED RECOMMENDATION GRADES

GRADE OF RECOMMENDATION	DESCRIPTION
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
D	Body of evidence is weak and recommendation must be applied with caution

SOURCE: National Health and Medical Research Council. NHMRC levels of evidence and grades for recommendations for developers of guidelines. Canberra: National Health and Medical Research Council; 2009. Available from: https://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/developers/nhmrc_levels_grades_evidence_120423.pdf.

PLEASE NOTE THAT SOME CHAPTERS DO NOT HAVE ASSOCIATED RECOMMENDATIONS.

1. National Health and Medical Research Council. *NHMRC levels of evidence and grades for recommendations for guideline developers*. Canberra: National Health and Medical Research Council; 2009 Available from: https://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/developers /nhmrc_levels_grades_evidence_120423.pdf.

Primary prevention

Dietary and lifestyle strategies

Practice point
Folic acid intake outside pregnancy should not exceed 1mg per day and those with a history of colorectal adenomas should not take more than 200mcg as a supplement.

Practice point
It is recommended to follow the primary prevention messages from the World Cancer Research Fund/American Institute for Cancer Research on tobacco smoking, alcohol, diet, body fatness, physical activity (see Table 2.3).

The use of aspirin for prevention of colorectal cancer

Evidence-based recommendation	Grade
For all people aged 50–70 years who are at average risk of colorectal cancer, aspirin should be actively considered to prevent colorectal cancer. A low dose (100–300 mg per day) is recommended for at least 2.5 years, commencing at age 50 to 70 years. The benefit may extend to older ages with longer duration of use. Benefit for cancer prevention (though shorter for cardiovascular risk) is evident only 10 years after initiation so a life expectancy of at least 10 years should be taken into consideration in the advice to use aspirin. The choice to take aspirin should be personalised based on age, sex and potential reduction in cardiovascular events, cerebrovascular events and thrombotic stroke. The individual should take into account the potential risks of taking aspirin. Aspirin should be avoided in patients with current dyspepsia, any history of peptic ulcer, aspirin allergy, bleeding diathesis, an increased risk of gastrointestinal haemorrhage (such as associated with use of oral anticoagulants or antiplatelet agents), or renal impairment. The benefit in colorectal cancer risk reduction in women over 65 is less clear cut. However, based on limited data available, older women with cardiovascular risk factors may derive a greater overall benefit than harm.	**B**

Practice point
Aspirin should be avoided in patients with uncontrolled hypertension.

Practice point
Breath testing for *Helicobacter pylori* (and treatment for those who test positive) can also be considered, as gastrointestinal toxicity from aspirin is enhanced in the presence of *Helicobacter pylori.*

Evidence-based recommendation	Grade
People who are at high risk of colorectal cancer due to Lynch Syndrome carrier status should be advised to begin aspirin from the commencement of their colonoscopy screening (usually at age 25 years).	**A**

RECOMMENDATIONS – PRIMARY PREVENTION

Evidence-based recommendation	Grade
Non-syndromic familial cancer patients should be actively considered for aspirin, bearing in mind the possibility of adverse events. 600 mg/day has been shown to be effective, but lower dose (100 mg /day) may be as effective and is recommended based on the data available at the time of the systematic review.	**B**

Practice point
Where surgery is inappropriate for people with familial adenomatous polyposis, an NSAID (e.g. sulindac) is recommended. (Kim B *et al* 2011)

Practice point
Without RCT evidence, metformin cannot be recommended for chemoprevention at this time.

Practice point
Bisphosphonates cannot be recommended for chemoprevention.

RECOMMENDATIONS – POPULATION SCREENING FOR COLORECTAL CANCER

Population screening for colorectal cancer

Evidence-based recommendation	Grade
OVERALL POPULATION SCREENING STRATEGY The recommended strategy for population screening in Australia, directed at those at average risk of colorectal cancer and without relevant symptoms, is immunochemical faecal occult blood testing every 2 years, starting at age 50 years and continuing to age 74 years.	C

Evidence-based recommendation	Grade
PRIMARY SCREENING TEST An immunochemical faecal occult blood test is recommended as the screening modality for the detection of colorectal cancer in the average-risk population.	C

Evidence-based recommendation	Grade
PRIMARY SCREENING TEST The emerging faecal, blood or serum tests for cancer-specific biomarkers such as DNA are not recommended as population screening modalities for colorectal cancer.	C

Evidence-based recommendation	Grade
PRIMARY SCREENING TEST The use of flexible sigmoidoscopy as a primary screening test is not recommended for population screening in the average-risk population.	C

Evidence-based recommendation	Grade
FREQUENCY OF TESTING Population screening for colorectal cancer using immunochemical faecal blood testing every 2 years is recommended. It is not recommended that the frequency of screening within the NBCSP be increased to yearly.	N/A

Evidence-based recommendation	Grade
TARGET AGE GROUP It is recommended that the age range for organised population screening continues to be 50–74 years.	N/A

Evidence-based recommendation	Grade
TARGET AGE GROUP Starting at age 40 is not recommended for population screening as it is unlikely to be cost-effective.	N/A

RECOMMENDATIONS – POPULATION SCREENING FOR COLORECTAL CANCER

Evidence-based recommendation	Grade
TARGET AGE GROUP Although modelling indicated that it may be cost-effective, starting screening at age 45 is not recommended for population screening because there is a much less favourable ratio of benefits to harms than for 50–74 years.	N/A

Evidence-based recommendation	Grade
TARGET AGE GROUP Extending the age range to 79 or 84 years is not recommended for population screening as it is unlikely to be cost-effective.	N/A

Consensus-based recommendation

Resources should be invested in increasing participation in the existing NBCSP target age group of 50– 74, rather than by lowering the starting age of screening, to optimise the balance of effectiveness, cost- effectiveness and ratio of benefits to harms.

Consensus-based recommendation

In people aged 45–49 years who request screening after being fully informed of the benefits and harms of testing, general practitioners (GPs) could offer an immunochemical faecal occult blood test every 2 years during the lead-up to the first routine invitation by the NBCSP at age 50 years.

Practice point

Encouragement by GPs and practice staff substantially boosts participation in colorectal cancer screening. Patient endorsement letters in advance of receiving a test kit, the use of GP reminder systems and practice audit are approaches likely to improve participation rates. Increased participation in the NBCSP will increase the program's effectiveness and cost-effectiveness.

Practice point

GPs have a critically important role in managing the interface between population screening and personalised care. This role includes identifying and advising those who should opt off the NBCSP because of the presence of major comorbidities and limited life expectancy and those who should defer participation for several months because of recent surgery or major illness.

Practice point

Participation in a population screening program is not recommended for people with symptoms such as rectal bleeding or persistent change in bowel habit or with iron-deficiency anaemia, nor for those who should be having regular surveillance or screening based on colonoscopy, e.g. for past colorectal canceror adenoma, chronic inflammatory bowel disease, a strong family history of colorectal cancer, or a high-risk genetic cancer syndrome (see *Risk and screening based on family history of colorectal cancer*).

RECOMMENDATIONS – POPULATION SCREENING FOR COLORECTAL CANCER

Practice point

Individuals who have had a high-quality colonoscopy performed within the previous two years should allow another two years to elapse (i.e. skip a round) before participating in their next round of iFOBT screening. Colorectal cancer will rarely be present within that interval.

High-quality colonoscopy is defined in the *Clinical Practice Guidelines for Surveillance Colonoscopy*.

Practice point

GPs have a key role in advising patients who are at average or slightly above average risk that iFOBT is the preferred method of screening. They should discuss the relative harms and benefits of colonoscopy and discourage inappropriate use of colonoscopy as a screening method.

Practice point

Participants with positive iFOBT results should have follow-up investigation unless there was a clear breach in protocol when samples were collected (e.g. menstrual blood loss close to the time of sample collection). Repeating the iFOBT test after a positive result carries the risk of a falsely negative test result on the second occasion because of low levels of bleeding from a cancer or adenoma, intermittent bleeding, or uneven distribution of blood in the stools.

Practice point

Colonoscopy should be performed as promptly as possible after a positive iFOBT to minimise the risk of psychological harm, although there is no evidence that prognosis is worsened within 120 days if cancer is present.

The symptomatic patient

Signs & symptoms predictive of colorectal cancer

Evidence-based recommendation	Grade
The urgency of colonoscopy to investigate symptoms suggestive of colorectal cancer should be based on an assessment of patient age, symptom profile and results of simple investigations including full blood count, iron studies and iFOBT (see Table 10.1 for consensus-based colonoscopy triage categories).	C

Consensus-based recommendation

In people with symptoms other than overt rectal bleeding, immunochemical faecal occult blood testing (iFOBT) can be used as part of the diagnostic assessment in primary care.

Practice point

Immunochemical faecal occult blood testing (iFOBT) is of particular use in the following circumstances to support diagnostic assessment and inform urgency of colonoscopy:

- people over 50 years with either unexplained weight loss or abdominal pain
- people under 60 years with either altered bowel habit or anaemia.

RECOMMENDATIONS – THE SYMPTOMATIC PATIENT

Optimal maximum time from referral to diagnosis and treatment (diagnostic interval)

Evidence-based recommendation	Grade
For patients with symptoms suggestive of colorectal cancer, the total time from first healthcare presentation† to diagnostic colonoscopy should be no more than 120 days. Diagnostic intervals greater than 120 days are associated with poorer clinical outcomes. † First healthcare presentation is defined as the date of presentation in general practice with symptoms suggestive of colorectal cancer or positive iFOBT for screening.	C

Evidence-based recommendation	Grade
A diagnostic interval of 120 days should be the maximum time from first healthcare presentation† to diagnostic colonoscopy for triage Categories 1 and 2, whether it is for a patient with symptoms or after a positive iFOBT used for colorectal cancer screening. Diagnostic intervals greater than 120 days are associated with poorer clinical outcomes. † First healthcare presentation is defined as the date of presentation in general practice with symptoms suggestive of colorectal cancer or positive iFOBT for screening.	D

Consensus-based recommendation

Triage category 1 patients, whether due to symptoms or positive iFOBT, should continue to be considered most urgent and prioritised for diagnostic colonoscopy, in any model of care at any jurisdictional level.

Practice point

Colonoscopy for symptomatic patients should be performed as promptly as possible after referral from general practice, especially for those meeting triage Category 1 criteria. If cancer is present, there is no evidence that prognosis is worsened within 120 days from first presentation to diagnostic colonoscopy. However, performing colonoscopy as promptly as possible after referral from general practice is to minimise the risk of psychological harm in symptomatic or iFOBT-positive patients who are potentially anxious while awaiting investigation. Prompt scheduling will also help to ensure that any unexpected delays between general practice referral and colonoscopy triaging do not flow on to exceed the 120-day threshold after which prognosis can worsen if cancer is present.

Risk and screening based on family history

Strength of association between family history and colorectal cancer risk

Evidence-based recommendation	Grade
CATEGORY 1 People who have one relative with colorectal cancer diagnosed at age 55 or older should be advised that their own risk of developing colorectal cancer could be up to twice the average risk, but is still not high enough to justify CRC screening by colonoscopy.	C

Evidence-based recommendation	Grade
CATEGORY 2 People should be advised that their risk of developing colorectal cancer is at least three times higher than average, but could be up to six times higher than average, if they have any of the following: • one first-degree relative with colorectal cancer diagnosed before age 55 years • two first-degree relatives with colorectal cancer diagnosed at any age • one first-degree relative and at least two second-degree relative diagnosed with colorectal cancer at any age.	C

Evidence-based recommendation	Grade
CATEGORY 3 People should be advised that their risk of colorectal cancer is at least seven times higher than average, but could be up to 10 times higher than average, if they have either of the following: • at least three first-degree or second-degree relatives with colorectal cancer, with at least one diagnosed before age 55 years • at least three first-degree relatives with colorectal cancer diagnosed at any age.	C

Practice point

Approximately 95–98% of the population are in Category 1 (near average risk of developing colorectal cancer).

Practice point

Approximately 65% of those with a family history of colorectal cancer only have a weak family history which means they are category 1 risk.

Practice point

Medical information that patients provide about their relatives is often inaccurate. (St John *et al* 1993, Love *et al*} 1985, Douglas *et al* 1999, Ruo *et al* 2001, Mitchell *et al* 2004) The percentage of colorectal cancer reports that are correct (positive predictive value) is 86% meaning that reports by relatives are usually true. However, a high proportion of people appear to be unaware that their relatives have had colorectal cancer, with the percentage of all colorectal cancers in first-degree relatives that are reported (sensitivity) being 27%. (Mai 2011)

RECOMMENDATIONS – RISK AND SCREENING BASED ON FAMILY HISTORY

Practice point

Given the potential importance of an accurate risk prediction for an individual, every effort should be made to collect reliable information.

Practice point

When there is uncertainty on family history, people should be encouraged to seek clarification within their family including details on which relatives have had colorectal cancer and their ages of diagnoses.

Practice point

If a family medical history appears to be significant but diagnoses prove difficult to confirm, it may be appropriate to seek expert help from a familial cancer clinic who have resources available to confirm cancer diagnoses.

Screening strategies for people with a family history of colorectal cancer

Practice point

For people with category 1 risk of colorectal cancer with one relative with colorectal cancer, iFOBT should be considered every 2 years from age 45, given the risk of colorectal cancer at this age is approximately equivalent to the population risk at age 50.

Practice point

For people with category 2 risk of colorectal cancer:

- iFOBT should be performed every 2 years from age 40 up to age 50, and colonoscopy should be performed every 5 years from age 50 to age 74.
- low-dose (100 mg) aspirin daily should be considered (see *Aspirin*).

Practice point

For people in category 2, CT colonography can be offered if colonoscopy is contraindicated (Dachman 2003).

Practice point

Because of the possibility of Lynch syndrome, a complete family history should be taken and updated regularly, and the accuracy of the cancer diagnoses and polyp pathology should be checked carefully.

Practice point

Genetic testing is not appropriate at present for people with category 2 risk. Tumour testing for Lynch syndrome-related changes, using immunohistochemistry and microsatellite instability, should be considered when any of the revised Bethesda criteria are met (see *Lynch syndrome*).

RECOMMENDATIONS – RISK AND SCREENING BASED ON FAMILY HISTORY

Practice point

As with all forms of screening, those at risk should be carefully checked for the presence of symptoms that might be due to colorectal neoplasia. Where symptoms are present, appropriate diagnostic steps should be taken before entry into a screening program.

Practice point

For people with category 3 risk of colorectal cancer:

- iFOBT should be performed every 2 years from age 35 up to age 45, then 5-yearly colonoscopy from age 45 to age 74.
- Low-dose (100 mg) aspirin daily should be considered (see *Aspirin*).
- Referral to a genetic centre for hereditary cancer syndromes should be considered. Those carrying their family-specific mutation or having uncertain genetic status require careful cancer screening (see *High-risk familial syndromes*).

Practice point

Category 3 can now be met by inclusion of relatives from both sides of the family. This is expected to increase the numbers in this category by approximately 50%. Referral to a genetic centre for hereditary cancer syndromes should be prioritised to those with family members with colorectal cancer from the same side of the family.

Practice point

Screening recommendations no longer specify that screening should begin at 10 years younger than the age of first diagnosis of colorectal cancer in the family, as there is no published evidence to support this strategy.

Evidence-based recommendation	Grade
CATEGORY 1 For people with a family history of colorectal cancer who are assessed as having category 1 risk, iFOBT should be performed every 2 years from age 50 to age 74. See *Population screening for colorectal cancer*. For those with one first-degree relative with colorectal cancer, iFOBT every two years from age 45 should be considered.	C

Evidence-based recommendation	Grade
CATEGORY 2 For category 2 patients, offer iFOBT every 2 years starting at age 40, then colonoscopy every 5 years starting at age 50. CT colonography may be offered if colonoscopy is contraindicated.	C

Evidence-based recommendation	Grade
CATEGORY 3 For category 3 patients, offer iFOBT every two years starting at age 35, then colonoscopy every five years starting at age 45. CT colonography may be offered if colonoscopy is contraindicated.	C

High-risk familial syndromes

Familial adenomatous polyposis (FAP)

Practice point

Colonic surveillance should be offered to:

- individuals found on genetic testing to carry a pathogenic APC mutation
- first-degree relatives of patients with FAP or AFAP in whom genetic testing has been declined or is not possible because the family mutation has not been identified.

Surveillance should commence from age 10 to 15 years or earlier if there are gastrointestinal symptoms (Robays and Poppe, 2014). In families with classical FAP, flexible sigmoidoscopy is adequate since adenomas occur simultaneously throughout the colorectum (Syngal et al., 2015; Stoffel *et al*., 2015; Robays and Poppe, 2014). Once an adenoma is identified, annual colonoscopy should be performed until colectomy is undertaken. In AFAP, surveillance should be by colonoscopy since the first adenomas may only be present in the proximal colon but surveillance can be delayed until 18 years of age (Syngal *et al*., 2015; Cancer Institute NSW 2016; Robays and Poppe, 2014).

Practice point

- Total colectomy and ileorectal anastomosis should be reserved for patients with rectal adenomas considered easily controllable by endoscopy and < 1000 colonic adenomas. Proctocolectomy with a permanent ileostomy is rarely needed (Syngal *et al*., 2015). Annual surveillance of the residual rectum or ileal pouch is required following colectomy (Cancer Institute NSW 2016).
- Some patients with AFAP can be managed with colonoscopic polypectomy at one- to two-yearly intervals (Syngal *et al*., 2015; Balmaña *et al*., 2013). If surgery is required due to a high number of adenomas, colectomy with ileorectal anastomosis can nearly always be performed, because of the small number of adenomas in the rectum (Syngal *et al*., 2015; Balmaña *et al*., 2013)

MUTYH-associated polyposis

Practice point

Referral to a genetics service for germline genetic testing for mutations in MUTYH is indicated for persons with a cumulative count of ≥ 20 colorectal adenomas at any age (Syngal *et al*., 2015). It is also indicated for siblings of a MUTYH biallelic mutation carrier (Syngal *et al*., 2015).

Testing may also be considered in patients with ≥ 10 adenomas and any of the following (Syngal *et al*., 2015):

- age under 50
- synchronous colorectal cancer
- both adenomatous and serrated polyps where the adenomatous polyps dominate
- family history suggestive of recessive inheritance (e.g. consanguinity in parents or siblings with documented adenomatous polyposis or colorectal cancer).

Clinical practice in some familial cancer clinics would accept patients in these categories even if there are no synchronous adenomas in the proband.

RECOMMENDATIONS – HIGH-RISK FAMILIAL SYNDROMES

Practice point

Biallelic mutation carriers should have colonoscopy every 2 years starting at age 18 to 20 years (Cancer Institute NSW, 2016; Robays and Poppe, 2014; Balmaña *et al*., 2013). If polyps are detected, annual colonoscopy may be required to control the polyp burden (Cancer Institute NSW, 2016). If polyps cannot be easily managed colonoscopically, a colectomy with ileorectal anastomosis should be considered and discussed with the patient (Cancer Institute NSW, 2016; Balmaña *et al*., 2013) The residual rectum requires annual surveillance.

Lynch syndrome

Practice point

All colorectal cancers should be tested for mismatch repair deficiency as a means to subsequently identify Lynch syndrome (Robays and Poppe, 2014; Ladabaum *et al*., 2015; Giardiello *et al*., 2014; Rubenstein *et al*., 2015).

Juvenile polyposis syndrome

Practice point

In patients with a diagnosis of juvenile polyposis syndrome, colonoscopy should commence at age 12–15 or earlier if symptoms occur (Syngal *et a*l., 2015; Cancer Institute NSW, 2016). It should be repeated every 1 to 3 years depending on polyp burden. Colectomy is indicated if polyps cannot be managed endoscopically (Syngal *et al*., 2015; Cancer Institute NSW, 2016).

Serrated polyposis syndrome

Practice point

Expert opinion is that colonoscopy should be performed every 1 to 3 years with the aim to remove all polyps ≥ 5mm. If the number and size of polyps make it impossible to achieve this, colectomy and ileorectal anastomosis should be considered. (Syngal S, Brand RE, Church JM, Giardiello FM, Hampel HL, Burt RW, *et al* 2015) (Cancer Institute NSW 2016).

Imaging a patient with a diagnosis of colon/rectal adenocarcinoma

Imaging for colon cancer

Practice point

CT colonoscopy should be considered for a patient with colon cancer if it has not been possible to view the entire colon by colonoscopy due to the risk of synchronous tumours. (New Zealand Guidelines Group 2011.)

Practice point

If CT shows metastatic disease confined to the liver, MRI of the liver can be considered to assess for resectability, particularly if the background liver parenchyma is abnormal, the patient has recently received chemotherapy, or when a patient cannot have iodinated contrast.

Practice point

For patients with colorectal cancer who have potentially resectable metastatic disease, PET-CT is recommended to detect additional metastases.

Practice point

For patients with stage II and III disease who have undergone initial surgery and/or adjuvant treatment, a suitable approach to imaging surveillance may involve 12-monthly CT of chest, abdomen and pelvis.

Practice point

For patients with stage IV disease who have undergone a resection procedure with curative intent, a suitable approach to imaging surveillance may involve CT of chest, abdomen and pelvis every 6 months.

RECOMMENDATIONS – IMAGING A PATIENT WITH A DIAGNOSIS OF COLON/RECTAL ADENOCARCINOMA

Imaging for rectal cancer

Practice point

MRI of the rectum is the recommended staging investigation for rectal cancer.

Practice point

High-resolution sequences must be performed and must meet accepted criteria.

Practice point

Additional sequences coronal to the anal canal are required for low tumours (see Table 7.2).

Practice point

Template reports are recommended, which include all of:

- Distance from anal verge (and puborectalis sling for low tumours)
- Relationship to the peritoneal reflection
- T stage including spread in mm beyond muscularis
- N stage and pelvic lymph nodes using morphological criteria
- EMVI status
- CRM status using 1mm as a cut-off distance.

Pathology and staging

Selection of a clinicopathological staging system

Practice point
TNM staging, ACPS/Concord staging and the data required to stage the patient should all be recorded to allow national and international comparisons.

Additional information on pathology reporting

Practice point
DNA mismatch repair status studies should be performed on all cases of colorectal cancer for the detection of Lynch syndrome.

Practice point
BRAF mutation studies should be performed in conjunction with DNA mismatch repair status studies to differentiate between sporadic and familial (Lynch syndrome) cases of DNA mismatch repair status-deficient colorectal cancer.

Practice point
Extended RAS mutation testing should be carried out on all patients at the time of diagnosis of metastatic colorectal cancer. **Note:** RAS testing is not currently pathologist-determinable and therefore can only be performed for metastatic colorectal cancer following a request from a specialist (surgeon or oncologist).

Practice point
Synoptic reporting is strongly recommended to capture the key variables to enable translation between major internationally recognised staging systems and facilitate multidisciplinary patient management.

Optimal molecular profiling of colorectal cancer

Practice point
A suitable tissue block with a high proportion of tumour tissue (preferably over 70%) should be designated for the purpose of further molecular testing if required.

Evidence-based recommendation	Grade
RAS mutation studies should be performed on patients with advanced (metastatic) colorectal cancer in whom anti-EGFR treatment is being considered. Cetuximab and panitumumab should only be considered for the treatment of patients with RAS wild-type metastatic colorectal cancer.	D

Evidence-based recommendation	Grade
There is emerging evidence suggesting that BRAF mutation may be associated with poor response to anti-EGFR treatment, and that BRAF mutation studies should therefore be performed on patients with advanced (metastatic) colorectal cancer.	D

Preparation for surgery and peri-operative optimisation

Multidisciplinary meetings

Practice point

Ideally, all patients with newly diagnosed colorectal cancer should be discussed at a multidisciplinary team meeting.

Practice point

Discussion at a multidisciplinary team meeting is mandatory for high-risk and complex cases such as patients with preoperative rectal cancers, metastatic disease or recurrent disease.

Perioperative anaemia management

Practice point

Patients undergoing elective surgery for colorectal cancer should be assessed for anaemia and iron deficiency and any deficiencies should be addressed preoperatively.

Practice point

Intravenous iron should be considered in preference to oral iron preoperatively given its quicker therapeutic effect.

Practice point

Consideration should also be given to treating postoperative functional iron deficiency anaemia with intravenous iron.

Thromboembolic prophylaxis

Practice point

All patients undergoing surgery for colorectal cancer should have standard thromboprophylaxis in hospital with compression stockings, unfractionated or low molecular-weight heparin and sequential compression devices. Extended prophylaxis for 28 days can be considered in high risk patients following colorectal cancer surgery.

Nutritional interventions

Practice point

Patients undergoing elective surgery for colorectal cancer should be screened for malnutrition.

Practice point

If patients are found to be malnourished, nutritional interventions should be put in place.

RECOMMENDATIONS – PREPARATION FOR SURGERY AND PERI-OPERATIVE OPTIMISATION

Stomal therapy

Practice point
Patients undergoing colorectal cancer surgery who may, or will, require a stoma should be seen prior to surgery by a stomal therapist.

Practice point
Patients with stomas should be given postoperative education.

Body temperature

Practice point
Perioperative normothermia should ideally be maintained at or above 36.0 ˚C.

Practice point
The use of warmed IV fluids and forced-air warming can be used to minimise perioperative hypothermia.

Enhanced recovery after surgery

Practice point
Patients having elective surgery for colorectal cancer should be managed within an appropriately resourced enhanced recovery after surgery (ERAS) program.

Can peri operative management be optimised?

Evidence-based recommendation	Grade
Mechanical bowel preparation should not be used routinely in colonic surgery. It can be used selectively according to individual patient and tumour characteristics, at the surgeon's discretion.	D

Elective and emergency surgery for colon and rectal cancer

Optimal approach to resection of colon cancers

Evidence-based recommendation	Grade
Either an open approach or a laparoscopic approach can be used for the resection of colon cancer.	D

Evidence-based recommendation	Grade
Laparoscopic colectomy has post-operative advantages over open colectomy and should be performed when the surgical expertise and hospital infrastructure are available.	D

Practice point

Laparoscopic colectomy requires significant additional skills. Surgeons should ensure that they have mastered the necessary techniques before performing laparoscopic colectomy as an independent operator.

Practice point

Laparoscopic colorectal surgery is complex minimally invasive surgery that requires high-resolution video imaging and up-to-date equipment, including instrumentation and energy sources. It should only be undertaken in facilities that provide this infrastructure.

Optimal approach to resection of rectal cancers

Evidence-based recommendation	Grade
Open surgery is the standard approach for resection of rectal cancer. Laparoscopic resection can be considered in selected cases if the surgical expertise (including advanced laparoscopic skills) and hospital infrastructure are available noting that it is a technique that has yet to be proven safe and efficacious in all patients for rectal cancer.	C

Practice point

Regardless of the approach utilised, rectal cancer resection must be undertaken by surgeons who have been appropriately trained in surgical resection of rectal cancer, utilising the principles of total mesorectal resection as proposed by *Heald*. This should include sharp dissection undertaken along the mesorectal plane. Surgical resection undertaken by inadequately trained surgeons is likely to result in inferior oncological outcomes.

Practice point

Case selection is important, as it is suboptimal to generalise the surgical approach for rectal cancer to all patients. Factors such as patient body mass index, tumour stage, and surgeon experience are important considerations when determining whether a laparoscopic or open approach is optimal for the patient.

RECOMMENDATIONS – ELECTIVE AND EMERGENCY SURGERY FOR COLON AND RECTAL CANCER

Practice point

The laparoscopic approach may have a higher potential for an inferior quality TME specimen, as demonstrated by two recent multicentre RCTs, though long-term outcome data are not yet available on these studies (Fleshman *et al* 2015, Stevenson *et al* 2015). Two other large multicentre RCTs have reported long-term outcomes with no difference in local recurrence or survival (Jeong et al 2014, Bonjer *et al* 2015). The surgeon should discuss with the patient the potential impact on oncological outcome of the laparoscopic approach along with the potential improvements on short term recovery.

Effective treatment for early rectal cancer

Evidence-based recommendation	Grade
For patients with stage 1 rectal cancer (T1/2, N0, M0), cases should be discussed by a multidisciplinary team to determine optimal management with respect to risk of local recurrence, avoidance of a permanent stoma, and fitness for surgery.	C

Evidence-based recommendation	Grade
For patients with T1 tumours local excision can be considered, provided that the tumour can be removed with clear margins and that the treating clinician counsels the patient that: • the risk of local recurrence increases as the T1 tumour stage progresses (from T1sm1 to T1sm2, or from T1sm2 to T1sm3) • radical resection may be required after histopathological review of the local excision specimen.	D

Evidence-based recommendation	Grade
For patients with T2 tumours, consider radical resection as the first option if they are fit for surgery.	C

Practice point

When determining the optimal management strategy for each patient, the multidisciplinary team, treating clinician and patient should discuss the balance of risks (e.g. local recurrence) and benefits (e.g. avoidance of a permanent stoma), with consideration of the individual's fitness for surgery. The treating clinician should explain to the patient that local excision carries a lower risk of perioperative mortality and a lower permanent stoma rate, but is associated with a higher local recurrence rate, which increases as the depth of tumour invasion increases from T1sm1 to T1sm2 to T1sm3 to T2.

Practice point

Radical resection is recommended for patients with T1sm3 tumours, and for those with T2 tumours who are considered fit for radical surgery.

Practice point

The use of transanal endoscopic microsurgery or transanal minimally invasive surgery has not shown any significant advantages over transanal local excision, however it is essential to obtain clear resection margins and the choice of approach to local resection should be determined by the individual surgeon with this factor in mind.

Practice point

Application of radiotherapy before or after local excision of rectal cancer may reduce the risk of local recurrence. However, it may have an adverse effect on bowel function.

RECOMMENDATIONS – ELECTIVE AND EMERGENCY SURGERY FOR COLON AND RECTAL CANCER

Stenting or colostomy vs. acute resection with primary anastomosis in acute obstruction due to left-sided colon or rectal carcinoma

Evidence-based recommendation	Grade
In patients with acute obstruction due to left-sided colorectal cancer who are potentially curative, the use of stenting as a bridge to surgery is not recommended as standard treatment, due to the potential risk of tumour perforation and conversion of a curative case to a palliative case.	D

Consensus-based recommendation
The insertion of an intraluminal colonic stent can be considered in large bowel obstruction secondary to colorectal cancer as palliation to relieve large bowel obstruction in patients with incurable metastatic colorectal cancer.

Consensus-based recommendation
For patients with potentially curable left-sided obstructing colonic cancer who are considered to be at increased risk of post-operative mortality, stent placement may be considered as an alternative to emergency surgery.

Consensus-based recommendation
If stenting is considered, it should be discussed by the multidisciplinary team and implications for anti-VEGF systemic therapy should be assessed.

The role for peritonectomy in the treatment of recurrent and primary colorectal cancer with peritoneal involvement

Evidence-based recommendation	Grade
For patients with colorectal peritoneal metastases (either synchronous or metachronous to the primary), consider cytoreduction with perioperative intraperitoneal chemotherapy. Where this procedure is suitable, offer referral to a centre with the necessary expertise and infrastructure to perform this procedure.	D

Evidence-based recommendation	Grade
Cytoreduction surgery and perioperative intraperitoneal chemotherapy should only be offered after due consideration of, and discussion with the patient about, the potential treatment-related mortality and morbidity.	D

Practice point

Patients with peritoneal carcinomatosis should be referred to a centre with expertise in the management of peritoneal surface malignancies and should be offered enrolment in a prospective trial, so as to allow further evaluation of cytoreduction and intraperitoneal chemotherapy.

Practice point

Prior to referral, treating clinicians should have an in-depth discussion with every patient about the potential survival advantage and potential treatment-related mortality or morbidity.

Practice point

All patients' cases should be discussed at a multidisciplinary team meeting with clinicians who have expertise in the management of peritoneal metastases, to review the relevant clinical information, previous histology (if applicable) and relevant imaging prior to offering patients cytoreductive surgery and intraperitoneal chemotherapy.

Practice point

All patients offered this procedure in established cytoreduction centres should be asked to give their consent for their patient records to be available for ongoing auditing of clinical outcomes. Patients should also be invited and encouraged to participate in research to enable collection of prospective longitudinal data for clinical and quality-of-life outcomes.

Adjuvant therapy for colon cancer

Adjuvant therapy for stage III colon cancer

Practice point

Oxaliplatin in combination with a fluoropyrimidine is standard therapy for young patients (< 70 years) with stage III colon cancer.

Practice point

Capecitabine plus oxaliplatin (XELOX) can be considered as an alternative to FOLFOX for adjuvant treatment for patients with stage III colon cancer.

Efficacy of adjuvant combination chemotherapy in elderly patients with colon cancer

Consensus-based recommendation

Elderly patients (≥ 70 years) with stage III colon cancer who are fit for adjuvant chemotherapy should receive 6 months of a single-agent fluoropyrimidine (either 5FU or capecitabine).

Practice point

The addition of oxaliplatin to adjuvant fluoropyrimidine-based therapy in elderly patients (≥ 70 years) with stage III colon cancer did not improve survival outcomes.

Practice point

The combination of oxaliplatin and fluoropyrimidine-based therapy in the metastatic setting provides a similar benefit in elderly patients and younger patients. The discordance between the adjuvant and metastatic setting remain unexplained.

Adjuvant therapy for stage II colon cancer

Practice point

The optimal approach to adjuvant therapy in stage II colon cancer remains uncertain. Adjuvant therapy can be considered in high-risk patients on a case-by-case basis.

Irinotecan and targeted (biological) agents in adjuvant therapy for stage II and stage III colon cancer

Practice point

Neither Irinotecan nor a biological agent (either bevacizumab or cetuximab) should be used as adjuvant therapy for patients with stage II or III colon cancer.

Neoadjuvant and adjuvant therapy for rectal cancer

Neoadjuvant therapy for rectal cancer

Practice point

Accurate determination of suitability for neoadjuvant therapy is based on careful preoperative location and staging assessments, and requires optimal quality of care from each aspect of the multidisciplinary team's assessment.

Practice point

'Early' cT3N0 rectal cancer (<1mm extension) is considered potentially suitable for surgery without neoadjuvant treatment in some international guidelines; but requires a high level of confidence in staging investigations and interpretation.

Short-course radiation treatment

Practice point

Preoperative (neoadjuvant) radiation treatment (either short-course radiation treatment alone or long-course chemoradiation) is recommended for most patients with stage II and III rectal cancers, to reduce risk of local recurrence.

Practice point

Short-course radiation treatment should be considered if there are clear concerns regarding a patient's physical or psychosocial ability to tolerate long-course chemoradiation.

Practice point

MRI imaging, patient and clinical factors including comorbidity status should be carefully reviewed by the multidisciplinary team. If clinical T4 primary or nodal disease is seen, or tumour extends close to the mesorectal fascia, then long-course chemoradiation is preferable where possible.

RECOMMENDATIONS – NEOADJUVANT AND ADJUVANT THERAPY FOR RECTAL CANCER

Which patients with rectal cancer stage I-II could be considered for definitive chemoradiotherapy (no surgery), neo-adjuvant chemoradiotherapy or surgery alone?

Evidence-based recommendation	Grade
Consider neoadjuvant chemoradiation for patients with stage II-III rectal cancer where appropriate.	C

Practice point

The current standard dose of neoadjuvant chemoradiation is 50–50.4 Gy (boost volume after 45 Gy) with either continuous infusional 5FU or capecitabine.

Practice point

'Early' cT3N0 rectal cancer (<1mm extension) is considered potentially suitable for surgery without neoadjuvant treatment in some international guidelines; but requires a high level of confidence in staging investigations and interpretation.

Evidence-based recommendation	Grade
For patients with rectal cancer who have had a clinical complete response to neoadjuvant chemoradiation, and planned resection according to the standard recommendation is either not possible or the patient declines it, a 'watch and wait' approach can be considered, provided that: • the risks and benefits have been discussed with the multidisciplinary team and the patient • the patient is monitored closely for local recurrence • the patient is offered an appropriate surgical resection procedure if local recurrence is detected.	D

Practice point

A 'watch and wait' approach for patients with clinical complete response following chemoradiation is not considered standard practice. Clinicians and patients who select this option must be aware of increased risk of recurrence necessitating surgical intervention, and the importance of close follow-up.

Practice point

Follow-up and surveillance guidelines for a 'watch and wait' approach, in particular the frequency of follow-up tests, are not established. Testing may include serial CEA measurements, clinical examination, radiological surveillance, and sigmoidoscopy/colonoscopy.

RECOMMENDATIONS – NEOADJUVANT AND ADJUVANT THERAPY FOR RECTAL CANCER

Neoadjuvant chemotherapy regimen

Practice point

Infusional fluoropyrimidine is preferable to bolus fluoropyrimidine for use in combination with radiation treatment for rectal cancer.

Practice point

Oral capecitabine or intravenous infusional 5FU are both acceptable agents to combine with radiation treatment for rectal cancer.

Practice point

If capecitabine is considered, patients should be carefully selected to minimise risk of non-compliance or overdosing.

Practice point

Neoadjuvant oxaliplatin with radiation treatment for rectal cancer is not currently regarded as standard therapy. Data for local control or survival benefit are mixed and oxaliplatin is associated with higher toxicity than fluoropyrimidine alone.

Practice point

The role of neoadjuvant systemic chemotherapy is still under investigation and is not regarded as routine.

Practice point

The roles of bevacizumab, panitumumab and cetuximab in the neoadjuvant setting for rectal cancer are uncertain, based on available evidence. These are not currently available for the treatment of non-metastatic rectal cancer, and they are not indicated in this setting.

Optimal timing surgery after neoadjuvant therapy

Practice point

Available data for the optimal timing between completion of neoadjuvant C-RT and surgery indicate that surgery at least 6 weeks but by 12 weeks appears to be appropriate, until results from further studies become available.

Practice point

Waiting longer within the 6-12 week time frame to allow optimal pathological downstaging may be selected preferentially, for example for patients with T4 tumours, where maximal downstaging is desirable.

RECOMMENDATIONS – NEOADJUVANT AND ADJUVANT THERAPY FOR RECTAL CANCER

Postoperative chemotherapy

Practice point

Strong evidence for benefit of adjuvant chemotherapy for rectal cancer is lacking, even in patients with node positive disease. In disease regarded as high risk, the uncertain benefits of adjuvant chemotherapy should be acknowledged.

Practice point

Patients with upper third rectal tumours (10–15cm from the anal verge) with either cN+ or pN+ findings, are possibly those who may derive any/most benefit from adjuvant chemotherapy.

Practice point

For patients with pathological stage II/III rectal cancer, adjuvant oxaliplatin-based chemotherapy is associated with increased toxicities. Benefits, if any, may be confined to those with stage III disease; but not all data concur.

Practice point

The uncertain benefits of oxaliplatin as adjuvant therapy in rectal cancer should be acknowledged.

Practice point

There are no randomised trials for adjuvant chemotherapy for patients with pathological complete response after chemoradiation followed by surgery. Available evidence suggests that these patients have a very good prognosis and any absolute benefits are likely to be small.

Postoperative radiation treatment

Practice point

Patients with higher risk disease post-operatively who did not receive neoadjuvant treatment should be considered for adjuvant pelvic radiotherapy concurrent with 5 fluorouracil chemotherapy.

Management of resectable locally recurrent disease and metastatic disease

Investigation of recurrent cancer

Practice point

Initial assessment of patients with suspected local or systematic recurrence should include serum CEA, contrast CT scan of the chest, abdomen and pelvis (unless contraindicated) and PET.

Practice point

Depending on the type of recurrence, additional investigations are likely to be necessary. A high-quality pelvic MRI is recommended for patients with locally recurrent rectal cancer. Additional local investigations may also need to be considered depending on patient and disease factors such as CT or MRA if mesenteric or iliac vessel involvement is suspected, or cystoscopy if bladder involvement is suspected.

Practice point

If possible, local recurrence should be histologically confirmed before surgery. If this is not possible because of the extraluminal location of the disease, a transvaginal biopsy may be feasible where the recurrence abuts the vagina. Alternatively, CT-guided percutaneous biopsies can be considered after assessing the need for biopsy at a multidisciplinary team meeting.

Practice point

In patients with liver metastases, an MRI of the liver is usually also necessary if surgery is being considered. The use of disodium gadoxetate (*Primovist*) contrast can increase the sensitivity and specificity of MRI for detecting liver metastases. Colonoscopy may be needed if further resection is planned.

Practice point

In patients with suspected lung metastases, CT chest and PET are usually sufficient to confirm diagnosis. In patients where there is diagnostic uncertainty or concerns for mediastinal nodal involvement, an endobronchial ultrasound or bronchoscopy may be needed.

Practice point

All patients with locally recurrent disease or metastatic disease should be discussed in a multidisciplinary team meeting taking into consideration patient's previous surgical history, current imaging, fitness and desire for further treatment.

RECOMMENDATIONS – MANAGEMENT OF RESECTABLE LOCALLY RECURRENT DISEASE AND METASTATIC DISEASE

Patients with locally recurrent colon or rectal cancer suitable for curative surgery

Evidence-based recommendation	Grade
For patients with isolated local recurrence of rectal cancer, consider referral to a centre with the necessary expertise to perform curative surgery (also known as pelvic exenteration).	D

Evidence-based recommendation	Grade
Re-operative surgery for locally recurrent rectal cancer should only be offered after due consideration of, and discussion with the patient about, the potential survival advantage, quality-of-life outcomes, and potential treatment-related morbidity.	D

Consensus-based recommendation
Patients who have not previously received radiotherapy should be considered for neoadjuvant chemoradiation prior to re-operative surgery.

Practice point
Patients with locally recurrent colorectal cancer should be referred to a centre with the expertise in the management of these cancers.

Practice point
All patients with locally recurrent colorectal cancer should be discussed at a multi-disciplinary team meeting with clinicians who have the expertise in the management of such malignancies. These meetings should review the patient's previous histology and relevant imaging prior to making an appropriate clinical recommendation.

Practice point
Re-operative surgery for locally recurrent colorectal cancer can be associated with significant morbidity. As such, all re-resections should only be offered when cure is considered possible.

Practice point
The key factor in achieving long-term survival in patients with locally recurrent colorectal cancer is a complete resection with clear resection margins (R0 margins), which is an important consideration when making clinical decision about disease resectability.

Patients with resectable synchronous or metachronous metastatic colon or rectal cancer suitable for curative surgery

Evidence-based recommendation	Grade
In patients with resectable liver metastases, liver resection should be offered, as this improves overall and progression free survival.	D

Evidence-based recommendation	Grade
Patients referred for liver resection should be counselled about the potential complications associated with liver resection in comparison with non-curative treatments.	D

RECOMMENDATIONS – MANAGEMENT OF RESECTABLE LOCALLY RECURRENT DISEASE AND METASTATIC DISEASE

Consensus-based recommendation

Patients at higher risk of recurrence should receive adjuvant therapy following liver resection, so as to reduce the likelihood of further local or systemic recurrences.

Consensus-based recommendation

For patients with liver metastases that are considered 'borderline' resectable, neoadjuvant chemotherapy should be considered and the case should be discussed by a multidisciplinary team that includes an experienced liver surgeon.

Consensus-based recommendation

In patients with pulmonary metastases, pulmonary resection improves locoregional control and may improve survival.

Consensus-based recommendation

Systemic adjuvant chemotherapy following complete resection of pulmonary metastases may reduce the likelihood of further systemic or local recurrences.

Consensus-based recommendation

In patients with liver and lung metastases, curative treatment may still be feasible. Combined or staged resection of the metastases may be possible provided both the liver and lung metastases can be completely resected and after taking into account the anatomic as well as functional considerations of the remnant liver and lung. Furthermore, lung resection may be considered in patients who have previously undergone a liver resection and vice versa. The use of neoadjuvant chemotherapy with subsequent restaging may also be considered in patients with synchronous liver and lung metastases prior to offering definitive resection.

Consensus-based recommendation

In patients with other isolated metastases, metasectomy may be appropriate in a well-informed patient after appropriate investigations and discussion in a multi-disciplinary team meeting.

Practice point

Patients with liver metastases should be referred to a centre with expertise in the management of these malignancies, for consideration of liver resection, if appropriate.

Practice point

Following curative treatment of liver metastases, patients need ongoing regular follow-up so as to permit early detection of further recurrences that may be amendable to further therapy.

Management of non-resectable locally recurrent disease and metastatic disease

Liver directed therapies in patients with incurable metastatic colorectal cancer

Evidence-based recommendation	Grade
For patients with non-resectable liver metastases of colorectal cancer, liver-directed therapies (selective internal radiation treatment, radiofrequency ablation, hepatic arterial infusion of chemotherapy agents or transarterial chemoembolisation) can be considered in centres with expertise in the specific technique after multidisciplinary team discussion, or in the context of a clinical trial.	D

Consensus-based recommendation

In patients with non-resectable liver metastases only (or oligometastatic disease) liver directed techniques can be considered by the MDT based on local experience, patient preference and tumour characteristics. Treating clinicians should have an in-depth discussion with every patient regarding technical complexity, potential outcomes and complications in addition to other therapies available for that patient.

Practice point

All patients with metastatic colorectal cancer should be discussed at a multidisciplinary team meeting with clinicians who have expertise in management of metastatic colorectal cancer.

Practice point

For patients who could be considered surgical candidates if their metastases were smaller, we suggest initial systemic chemotherapy followed by re-evaluation for surgery.

Practice point

Wherever possible, patients considering liver-directed therapies should be enrolled into clinical trials examining these treatments in comparison to standard therapies.

Practice point

SIRT in combination with systemic chemotherapy can be used to prolong the time to liver progression but not improve colorectal cancer survival with most evidence currently in the chemo-refractory patients. At present there is insufficient data to recommend SIRT in the first line setting for patients with non-resectable mCRC.

Management synchronous primary in metastatic CRC

Practice point

Routine palliative resection of asymptomatic synchronous primary lesion in patients with unresectable metastatic colorectal cancer remains controversial and there are no prospective randomised studies to guide treatment. Recruitment into such trials has been difficult.

Practice point

All patients with an asymptomatic primary and unresectable metastatic colorectal cancer should be discussed in a multi-disciplinary team meeting and the risks and benefits of a palliative resection for an individual patient be carefully discussed bearing in mind the volume of metastatic disease, degree of stenosis/risk of impending obstruction, comorbidities and patient preferences.

Practice point

Patients with an asymptomatic primary and good medium to long term disease control after initial systemic therapy could be re-evaluated for potential resection of both the primary tumour and metastases in the absence of widespread disease progression.

Practice point

For patients with a symptomatic primary tumour (obstruction, bleeding or perforation) and synchronous metastatic disease, resection of the primary tumour should be considered before initiation of systemic therapy. For candidates not suitable for primary tumour resection other palliative options to control symptoms including surgical bypass, radiotherapy, stents, laser ablation in addition to systemic treatment should be considered.

Practice point

For patients with unresectable metastatic rectal cancer with symptomatic primary tumour, irradiation (+/- chemotherapy) of the primary tumour should be considered after multidisciplinary discussion in order to obtain optimal symptom control and reduce patient morbidity.

The role of systemic therapies in non-resectable metastatic disease

Molecular pathology and biomarkers – implications for systemic therapy

Practice point

RAS testing should be carried out on all patients at the time of diagnosis of metastatic colorectal cancer.

Practice point

RAS mutational status is a negative predictive biomarker for therapeutic choices involving EGFR antibody therapies in metastatic colorectal cancer.

Practice point

Cetuximab and panitumumab should only be considered for the treatment of patients with RAS wild-type metastatic colorectal cancer.

Practice point

The BRAF mutation status should ideally be performed at the time of diagnosis of metastatic colorectal cancer, as this represents a distinct biologic subtype.

Practice point

The presence of a BRAF mutation in metastatic colorectal cancer is considered a poor prognostic marker.

Practice point

BRAF mutation status in combination with testing for DNA mismatch repair deficiency can assist in the identification of a germline versus somatic cause of DNA mismatch repair deficiency.

Practice point

The preponderance of the available evidence is that response to EGFR-targeted agents is less likely in patients whose tumours harbour a BRAF mutation.

Practice point

Metastatic colorectal cancer patients with a BRAF mutation should be considered for a clinical trial where available or triplet chemotherapy if suitable.

Practice point

MSI testing in the metastatic setting can be useful to help identify patients who require referral for further genetic testing and counselling.

RECOMMENDATIONS – THE ROLE OF SYSTEMIC THERAPIES IN NON-RESECTABLE METASTATIC DISEASE

Practice point

BRAF V600 mutational analysis should be done in conjunction with MSI testing for prognostic stratification.

Practice point

MSI testing may be a predictive marker for the use of immune checkpoint inhibitors in the treatment of patients with metastatic colorectal cancer.

Practice point

Emerging biomarkers are not recommended for routine patient management outside of the clinical trial setting.

Practice point

The location of the primary tumour is a strong prognostic factor. Patients with left sided primary tumours have a favourable outcome compared with those with right sided tumours regardless of treatment type received.

Practice point

Left sided colorectal cancer should be considered for initial doublet chemotherapy and anti-EGFR therapy where appropriate. Alternate options remain appropriate based on patient preference and comorbidity.

Practice point

Right sided colorectal cancer should be considered for initial doublet chemotherapy plus or minus anti-VEGF. There may be a role for initial chemotherapy with anti-EGFR in right sided colon cancer where the aim of treatment is down staging for resection given the improved response with anti-EGFR. However, this should be done with caution given the lack of benefit on overall survival or progression free survival.

Practice point

Sequential use of all available therapies should continue to be utilised in patients with colorectal cancer regardless of the side of the primary tumour, provided it is appropriate for the individual patient.

Practice point

Future trials for colon cancer should stratify patients by ‘sidedness,’ to better understand this issue.

RECOMMENDATIONS – THE ROLE OF SYSTEMIC THERAPIES IN NON-RESECTABLE METASTATIC DISEASE

Systemic chemotherapy treatment options for first-line treatment

Practice point

For patients who are able to tolerate it, combination chemotherapy with a doublet (FOLFOX, XELOX [CAPOX], or FOLFIRI) rather than a single agent sequential therapy for initial treatment of metastatic colorectal cancer, is preferred.

Practice point

Patients with potentially resectable metastatic disease should be discussed at a multidisciplinary meeting, and treatment plans should consider patient comorbidity and suitability for an aggressive treatment strategy.

Practice point

Monotherapy is not appropriate and combination chemotherapy with a doublet (FOLFOX, XELOX [CAPOX], or FOLRIR) should be used where the aim of therapy is significant cytoreduction. For those with RAS wild-type tumours, an anti-EGFR antibody in conjunction with combination chemotherapy can be considered especially in those with left sided primaries.

Practice point

For those with good performance status and without significant comorbidities, intensive triplet chemotherapy with FOLFIRINOX can be considered.

Practice point

Patient comorbidities, ECOG performance status, and location and burden of metastatic disease should be considered in treatment decisions.

Practice point

For patients who are medically unfit with poor performance status, a supportive care approach may be appropriate.

Practice point

In patients with poor performance status or significant comorbidities palliative treatment with single agent fluoropyrimidine (with or without bevacizumab) may be preferred to doublet chemotherapy. Fluoropyrimidine-based therapy alone (or in combination with bevacizumab) can be considered in patients with low-volume unresectable disease.

RECOMMENDATIONS – THE ROLE OF SYSTEMIC THERAPIES IN NON-RESECTABLE METASTATIC DISEASE

Role of biological agents in first-line treatment of metastatic colorectal cancer

Practice point

Biological agents targeting EGFR or VEGF in combination with chemotherapy are recommended in the first-line treatment of most patients unless contraindicated.

Practice point

EGFR antibodies should:

- be used in patients with RAS wild-type tumours
- be used in combination with FOLFIRI or FOLFOX
- not be combined with capecitabine-based and bolus 5FU-based regimen.

Practice point

Patients with left sided colorectal cancer should be considered for initial doublet chemotherapy and anti-EGFR therapy where appropriate. Alternate options remain appropriate based on patient preference and comorbidity. See left vs. right section.

Practice point

EGFR antibodies may be less efficacious in patients with BRAF mutations.

Practice point

VEGF antibody (bevacizumab):

- should be used in combination with cytotoxic doublets including FOLFOX, XELOX and FOLFIRI
- can be used in combination with the triplet cytotoxic regimen FOLFOXIRI in select fit patients where tumour shrinkage is the goal, and potentially in fit patients with a BRAF mutation
- can be used in combination with fluoropyrimidine monotherapy in less fit patients unlikely to be suitable for a doublet cytotoxic regimen.

Practice point

Patients with right sided colorectal cancer should be considered for initial doublet chemotherapy plus or minus anti-VEGF. See left vs. right section.

RECOMMENDATIONS – THE ROLE OF SYSTEMIC THERAPIES IN NON-RESECTABLE METASTATIC DISEASE

Subsequent treatment and the continuum-of-care model

Practice point

Individualisation and discussion with the patient is essential when planning treatment breaks and or de-escalation/ maintenance schedules.

Practice point

When the combination of leucovorin calcium (folinic acid), 5-fluorouracil (5FU) and oxaliplatin (FOLFOX), with or without bevacizumab, is used for first-line therapy, the available data suggest that it is reasonable to discontinue oxaliplatin temporarily while maintaining a fluoropyrimidine with or without bevacizumab.

Practice point

When the combination of folinic acid, 5FU and irinotecan hydrochloride (FOLFIRI), with or without bevacizumab, is used for first-line therapy, patients can continue on induction therapy for as long as tumour shrinkage continues and the treatment is tolerable.

Practice point

For patients receiving initial therapy with folinic acid, 5FU, oxaliplatin and irinotecan hydrochloride (FOLFOXIRI), with or without bevacizumab, a fluoropyrimidine plus bevacizumab may be considered as maintenance therapy (as was done in the pivotal trials examining FOLFOXIRI).

Practice point

For patients receiving initial therapy with a single-agent fluoropyrimidine (plus bevacizumab), induction therapy should be maintained.

Practice point

Initial induction therapy or a second-line therapy should be reintroduced at radiological or first signs of symptomatic progression.

Practice point

If a second-line therapy is chosen, re-introduction of the initial induction treatment should be a part of the entire treatment strategy as long as no relevant residual toxicity is present.

RECOMMENDATIONS – THE ROLE OF SYSTEMIC THERAPIES IN NON-RESECTABLE METASTATIC DISEASE

Systemic options for second-line treatment

Practice point

Patients who did not receive bevacizumab as part of first-line therapy should be considered for bevacizumab in second-line therapy, in combination with a second-line cytotoxic regimen.

Practice point

Patients who received bevacizumab as part of the first-line regimen and have RAS wild-type (BRAF wild-type) metastatic colorectal cancer should be considered for combination EGFR monoclonal antibodies with FOLFIRI/irinotecan.

Practice point

Patients who received a first-line oxaliplatin-containing regimen should be switched to an irinotecan-containing regimen, and vice versa.

Practice point

Patients who experience disease progression during first-line 5FU monotherapy should be offered an irinotecan or oxaliplatin-containing regimen if they have adequate performance status.

Systemic options for third-line treatment

Practice point

Patients with mCRC considering treatment in the third-line setting have limited therapeutic options and typically have reduced quality of life; therefore physicians must carefully balance any efficacy benefit associated with therapy with its toxicity profile.

Practice point

Cetuximab or panitumumab treatment should be considered in patients with RAS wild-type and BRAF wild-type metastatic colorectal cancer not previously treated with these agents, taking into account the following:

- Cetuximab and Panitumumab are equally effective as single agents.
- Cetuximab in combination with irinotecan is more active than cetuximab alone in patients refractory to irinotecan with adequate performance status to receive combination therapy.

Practice point

If available, regorafenib or trifluridine/tipiracil can be considered for patients with metastatic colorectal cancer refractory to all standard available therapies.

Practice point

Patients receiving third-line therapy should be offered participation in clinical trials, wherever available.

Practice point

Symptom burden is often high in patients with mCRC especially as the disease progresses. Early palliative care intervention should be considered for all patients with mCRC as they can improve the quality of life of patients with cancer.

Follow-up after curative resection for colorectal cancer

Rationale for follow-up

Practice point

As there are no reliable indicators of an individual's risk of synchronous or metachronous lesions, nor of treatable recurrence, all patients who have undergone curative surgery should be offered follow-up if they are fit for further intervention should disease be detected.

Practice point

Patients who are unfit for further surgery or who have advanced disease require appropriate follow-up directed at psychological support and symptom relief.

Optimal intensity of follow up post curative resection of colorectal cancer

Evidence-based recommendation	Grade
Intensive follow-up after curative surgery for colorectal cancer should include CEA and CT scan, with the aim of early detection of recurrence or residual disease where there is the possibility for curative resection. PET/CT scan can be used as an effective adjunct for detection of recurrence, especially when the CEA and/or CT scans are suggestive of recurrence.	D

Practice point

These recommendations apply only to asymptomatic patients. All patients who develop symptoms should be investigated rigorously.

Practice point

Colonoscopy should be performed at 12 months after surgery to exclude missed lesions. If the initial colonoscopy was incomplete then a colonoscopy should be performed at the latest 6 months after surgery. If the colonoscopy is normal, refer to the *Clinical Practice Guidelines for Surveillance Colonoscopy* for subsequent colonoscopies.

Practice point

Intensive follow-up for colorectal cancer should be considered for patients who have had potentially curable disease, although optimal modality and frequency are yet to be firmly established.

Practice point

Intensive follow-up can detect recurrences earlier, thus surgical resection for curative intent is possible. However, this is not associated with improved survival.

RECOMMENDATIONS – FOLLOW-UP AFTER CURATIVE RESECTION FOR COLORECTAL CANCER

Practice point

CEA and CT scans are readily accessible and relatively sensitive investigations.

Health professionals performing follow-up and suggested follow-up schedule

Practice point

Follow-up can be delivered as a combination of visits to the surgeon or associated gasteroenterologist, with ongoing care by the GP and clinical nurse consultant.

RECOMMENDATIONS – PSYCHOSOCIAL CARE

Psychosocial care

Practice point

Patients with colorectal cancer should be screened for psychological distress at diagnosis and key points in their disease trajectory.

Practice point

Psychological interventions should be a component of colorectal cancer care, as they can improve the quality of life for patients with cancer.

Practice point

The use of decision aids should be considered for preference-sensitive decisions about treatment for colorectal cancer.

COLORECTAL CANCER GUIDELINES WORKING PARTY MEMBERS AND CONTRIBUTORS

Working Party members and contributors

Management committee

NAME	AFFILIATION
Professor Timothy Price (Chair)	Chair, Management Committee and Colorectal Cancer Guidelines Revision Working Party Medical Oncologist, The Queen Elizabeth Hospital, Adelaide
Professor Sanchia Aranda	CEO, Cancer Council Australia
Dr Cameron Bell	Gastroenterologist, Royal North Shore Hospital, Sydney
Professor Alexander (Sandy) Heriot	Consultant Colorectal Surgeon, Director Cancer Surgery, Peter MacCallum Cancer Centre Director, Lower GI Tumour Stream, Victorian Comprehensive Cancer Centre
Professor Finlay Macrae AO	Gastroenterologist, Royal Melbourne Hospital, Melbourne
Dr Elizabeth Murphy	Head, Colorectal Surgical Unit, Lyell McEwin Hospital Adelaide
Professor Michael Solomon	Colorectal Surgeon, Royal Prince Alfred Hospital, Sydney
Professor James St John AO	Emeritus Consultant Gastroenterologist, The Royal Melbourne Hospital; Honorary Senior Associate, Cancer Council Victoria; Honorary Clinical Professorial Fellow, The University of Melbourne
Dr Bernie Towler	Principal Medical Adviser, Population Health Division, Department of Health, Canberra
Ms Jutta Thwaites	Head, Clinical Guidelines Network (maternity leave from November 2016 – November 2017)
Ms Laura Wuellner	Acting Head, Clinical Guidelines Network (from November 2016 – January 2018)
Professor John R Zalcberg	Head of Cancer at the School of Public Health and Preventive Medicine, Monash University, Melbourne

COLORECTAL CANCER GUIDELINES WORKING PARTY MEMBERS AND CONTRIBUTORS

Guideline section leaders

NAME	SPECIALTY	SECTION
Professor Finlay Macrae AO	Gastroenterology	Primary prevention
Professor James St John AO	Gastroenterology	Population screening for colorectal cancer (co-lead)
Dr Hooi Ee	Gastroenterology	Population screening for colorectal cancer (co-lead)
Professor Mark Jenkins	Genetic epidemiology, cancer epidemiology (colorectal cancer, Lynch syndrome, genetic epidemiology)	Risk and screening based on family history
Professor Jon Emery	General practice	The symptomatic patient
Professor Phyllis Butow	Psycho-oncology	Psychosocial care
Professor Barbara Leggett	Gastroenterology	High-risk familial syndromes
Dr Kirsten Gormly	Radiology	Imaging a patient with a diagnosis of colon/rectal adenocarcinoma
Dr Andrew Luck OAM	Colorectal surgery	Elective and emergency surgery colon
Professor Alexander (Sandy) Heriot	Colorectal surgery	Elective and emergency surgery for colon and rectal cancer
Dr Elizabeth Murphy	Colorectal surgery	Preparation for surgery and peri-operative optimisation
Professor Pierre Chapuis	Colorectal surgery	Pathology and staging (co-lead)
A/Professor Charles Chan	Pathology	Pathology and staging (co-lead)
A/Professor Peter Gibbs	Medical oncology	Adjuvant therapy for colon cancer
Professor Desmond Yip	Medical oncology	Neoadjuvant and adjuvant therapy for rectal cancer (co-lead)
Dr Kathryn Field	Medical oncology	Neoadjuvant and adjuvant therapy for rectal cancer (co-lead)
Dr Peter J. Lee	Colorectal surgery	Follow up after curative resection for colorectal cancer
Dr Cherry Koh	Colorectal surgery	Management of resectable locally recurrent disease and metastatic disease
Dr Louise Nott	Medical oncology	Management of non-resectable locally recurrent disease and metastatic disease; The role of systemic therapies in non-resectable metastatic disease

COLORECTAL CANCER GUIDELINES WORKING PARTY MEMBERS AND CONTRIBUTORS

Additional working party members

NAME	SPECIALTY
Jeff Cuff	Consumer representative
Jillian Arnott	Consumer representative
Professor Karen Canfell	Director, Cancer Research Division, Cancer Council NSW (Epidemiology expert)
Professor Dianne O'Connell	Senior Epidemiologist, Manager, Cancer Research Division, Cancer Council NSW (Epidemiology expert)

Cancer Council Australia project team contributions

NAME	AFFILIATION
Jutta Thwaites	Head, Clinical Guidelines Network, Cancer Council Australia (maternity leave from November 2016 – November 2017)
Laura Wuellner	Project Manager, Clinical Guidelines Network (until November 2016), Acting Head, Clinical Guidelines Network, Cancer Council Australia (from November 2016 – January 2018)
Katrina Anderson	Project Manager, Clinical Guidelines Network (from November 2016 – December 2017)
Dr Albert Chetcuti	Project Officer, Systematic Literature Reviews, Colorectal Cancer Guidelines
Ben Lee-Bates	Research Assistant, Colorectal Cancer Guidelines
Victoria Freeman	Research Assistant, Colorectal Cancer Guidelines
Melissa Chow	Research Assistant, Colorectal Cancer Guidelines
Cecilia Taing	Research Assistant, Colorectal Cancer Guidelines

COLORECTAL CANCER GUIDELINES WORKING PARTY MEMBERS AND CONTRIBUTORS

Chapter details

Colorectal cancer in Australia

NAME	AFFILIATION
Dr Prema Thavaneswaran*	Manager, Public Health Policy, Cancer Council Australia
Professor Jane Young	Executive Director, Research, Institute of Academic Surgery, Executive Director, Surgical Outcomes Research Centre (SOuRCe) Royal Prince Alfred Hospital and University of Sydney, Professor in Cancer Epidemiology, School of Public Health, University of Sydney
Professor Michael Solomon	Colorectal Surgeon, Royal Prince Alfred Hospital, Sydney

*Section lead author

Primary prevention

NAME	AFFILIATION
Professor Finlay Macrae AO*	Gastroenterologist, Royal Melbourne Hospital, VIC
Dr Julie Clarke	Senior Research Scientist, CSIRO Health and Biosecurity, Adelaide
Professor Jon Emery	General Practitioner
Professor Mark Jenkins	Risk and screening based on family history
Dr Trevor Lockett	Group Leader Personalised Health, CSIRO, Adelaide
Professor John McNeil	Head, Monash University School of Public Health & Preventive Medicine, Melbourne
Professor Allan Spigelman	Professor of Surgery, UNSW St Vincent's Clinical School, Sydney; Director, Cancer Genetics, St Vincent's Hospital, Sydney and Hunter Family Cancer Service, Newcastle & Regional NSW
Dr Nicholas Pachter	Clinical Geneticist, Genetic Services of Western Australia, King Edward Memorial Hospital for Women, Perth, Western Australia.
Dr Aung Ko Win	Senior Research Fellow, Centre for Epidemiology & Biostatistics, The University of Melbourne
A/Professor Robyn Woods	Associate Professor, Monash University
Professor Graeme Young AM	Matthew Flinders Distinguished Professor, Professor of Global Gastrointestinal Health, Flinders Centre for Innovation in Cancer, College of Medicine and Public Health, Flinders University
Professor John R Zalcberg	Head of Cancer at the School of Public Health and Preventive Medicine, Monash University, Melbourne

*Section lead author

COLORECTAL CANCER GUIDELINES WORKING PARTY MEMBERS AND CONTRIBUTORS

Population screening for colorectal cancer

NAME	AFFILIATION
Professor James St John AO*	Emeritus Consultant Gastroenterologist, The Royal Melbourne Hospital; Honorary Senior Associate, Cancer Council Victoria; Honorary Clinical Professorial Fellow, The University of Melbourne
Dr Hooi Ee*	Gastroenterologist, Sir Charles Gairdner Hospital, Perth
Professor Jon Emery	Honorary Senior Visiting Research Fellow, Winthrop Professor of General Practice at the Western University of Australia and Professor of Primary Care Cancer Research at the University of Melbourne (also practising GP)
Professor Finlay Macrae AO	Gastroenterologist, Royal Melbourne Hospital, Melbourne
Professor Mark Jenkins	Director of the Centre for Epidemiology & Biostatistics, University of Melbourne
Paul Grogan	Director, Public Policy & Knowledge Management, Cancer Council Australia
Professor Karen Canfell	Director, Cancer Research Division, Cancer Council NSW
Ms Jie-Bin Lew	Senior Research Programmer, Cancer Council NSW
Ms Rachel Mulqueeney	Cancer Screening Project Coordinator Prevention Division Cancer Council Victoria
Dr Albert Chetcuti	Senior Project Officer, Cancer Council Australia

*Section lead author

The symptomatic patient

NAME	AFFILIATION
Professor Jon Emery*	General Practitioner
Dr Cameron Bell	Gastroenterologist – Royal North Shore Hospital, Sydney
A/Professor Gregor Brown	Head of Endoscopy, The Alfred Hospital, Melbourne
Professor Finlay Macrae AO	Gastroenterologist, Royal Melbourne Hospital, VIC
Dr Iain Skinner	Colorectal surgeon
A/Professor Justin Tse	Director of Medical Student Education (Clinical Dean) St Vincent's Clinical School, The University of Melbourne

*Section lead author

COLORECTAL CANCER GUIDELINES WORKING PARTY MEMBERS AND CONTRIBUTORS

Risk and screening based on family history

NAME	AFFILIATION
Professor Mark Jenkins*	Director of the Centre for Epidemiology & Biostatistics, University of Melbourne, Melbourne.
Professor Alex Boussioutas	GE at University of Melbourne, Peter MacCallum Cancer Centre and Royal Melbourne Hospital, Melbourne
Dr Driss Ait Quakrim	Research Fellow – Epidemiologist, Centre for Epidemiology and Biostatistics, University of Melbourne, Melbourne
Professor John Hopper AM	Academic, School of Population and Global Health, The University of Melbourne
Professor James St John AO	Emeritus Consultant Gastroenterologist, The Royal Melbourne Hospital; Honorary Senior Associate, Cancer Council Victoria; Honorary Clinical Professorial Fellow, The University of Melbourne
Dr Hooi Ee	Gastroenterologist, Sir Charles Gairdner Hospital, Perth
Professor Jon Emery	Honorary Senior Visiting Research Fellow, Winthrop Professor of General Practice at the Western University of Australia and Professor of Primary Care Cancer Research at the University of Melbourne (also practising GP)
Professor Finlay Macrae AO	Gastroenterologist, Royal Melbourne Hospital, Melbourne

*Section lead author

High-risk familial syndromes

NAME	AFFILIATION
Professor Barbara Leggett*	Gastroenterologist, Royal Brisbane and Womens Hospital; Professor of Medicine, School of Medicine, University of Queensland; Honorary Group Leader, Queensland Institute of Medical Research Berghofer
Dr Nicola Poplawski	Clinical Geneticist, SA Pathology, South Australia
Dr Nicholas Pachter	Clinical Geneticist, Genetic Services of Western Australia, King Edward Memorial Hospital for Women, Perth, Western Australia.
Dr Christophe Rosty	Anatomical Pathologist at Envoi Specialist Pathologist; Associate Professor, Molecular and Cellular Pathology, University of Queensland; Associate Professor, Department of Pathology, The University of Melbourne
A/Prof Ian Norton	Head, Department of Gastroenterology, Royal North Shore Hospital
Professor Finlay Macrae AO	Gastroenterologist, Royal Melbourne Hospital, Melbourne
A/Professor Caroline Wright	Colorectal Surgeon, Royal Prince Alfred Hospital, Sydney
Dr Aung Ko Win	Senior Research Fellow, Centre for Epidemiology & Biostatistics, The University of Melbourne

*Section lead author

COLORECTAL CANCER GUIDELINES WORKING PARTY MEMBERS AND CONTRIBUTORS

Imaging a patient with a diagnosis of colon/rectal adenocarcinoma

NAME	AFFILIATION
Dr Kirsten Gormly*	Radiologist, Dr Jones and Partners, SA
Dr Wendy Brown	Senior Staff Specialist, Radiology Department, Royal Prince Alfred Hospital, Camperdown, NSW
Dr Damien Stella	Director of CT, Department of Radiology, University of Melbourne, Royal Melbourne Hospital, VIC
Professor Eva Segelov	Professor/Director of Oncology, Monash Health and Monash University, VIC
Dr Elizabeth (Liz) Murphy*	Head, Colorectal Surgical Unit, Lyell McEwin Hospital Adelaide, SA
Professor Timothy (Tim) Price	Chair, Management Committee and Colorectal Cancer Guidelines Revision Working Party. Medical Oncologist, The Queen Elizabeth Hospital, SA

*Section lead author

Pathology and staging

NAME	AFFILIATION
Professor Pierre Chapuis*	Head, Academic Surgery, the Concord Clinical School and Director of Postgraduate Surgical Education, Discipline of Surgery, the University of Sydney
Associate Professor Charles Chan*	Senior Staff Specialist, Anatomical Pathology Department, Concord Repatriation General Hospital; Clinical Associate Professor, Concord Clinical School, Discipline of Medicine; School of Medical Sciences, Discipline of Biomedical Science, University of Sydney
Dr Louise Nott	Medical Oncologist, Royal Hobart Hospital and St John's Hospital
A/Professor Muhammad Khattak	Consultant Medical Oncologist, Fiona Stanley Hospital
Professor Timothy (Tim) Price	Chair, Management Committee and Colorectal Cancer Guidelines Revision Working Party Medical Oncologist, The Queen Elizabeth Hospital, Adelaide, SA
Dr Amanda Townsend	Oncologist, The Queen Elizabeth Hospital, Adelaide, SA
Dr Albert Chetcuti	Senior Project Officer, Cancer Council Australia

*Section lead author

COLORECTAL CANCER GUIDELINES WORKING PARTY MEMBERS AND CONTRIBUTORS

Preparation for surgery and peri-operative optimisation

NAME	AFFILIATION
Dr Elizabeth (Liz) Murphy*	Head, Colorectal Surgical Unit, Lyell McEwin Hospital Adelaide, SA
Dr Karen Barclay	Colorectal Surgeon and Senior Lecturer in Surgery, Acting Head of the Academic Surgical Unit, NCHER, The Northern Hospital and the University of Melbourne, VIC
Dr Kate Burbury	Lead Haematologist for Haemostasis and Thrombosis, Peter MacCallum Cancer Centre, Melbourne, VIC
Dr Bernd Froessler	Staff Specialist, Anaesthesia, Lyell McEwin Hospital; Clinical Senior Lecturer, University of Adelaide
Professor Alexander (Sandy) Heriot*	Colorectal Surgeon, Peter MacCallum Cancer Centre, Melbourne, VIC
Dr Cherry Koh	Colorectal surgeon, Royal Prince Alfred Hospital, Sydney
Professor Timothy (Tim) Price	Medical Oncologist, The Queen Elizabeth Hospital, Adelaide, SA
Dr Kathryn Robinson	Transfusion medicine specialist, Australian Red Cross Blood Service, Haematologist, The Queen Elizabeth Hospital, Adelaide, SA

*Section lead author

Elective and emergency surgery for colon and rectal cancer

NAME	AFFILIATION
Professor Alexander (Sandy) Heriot*	Colorectal Surgeon, Peter MacCallum Cancer Centre, Melbourne, VIC
Dr Andrew Luck OAM*	Colorectal Surgeon, Lyell McEwin Hospital, Adelaide, SA
Dr Cherry Koh*	Colorectal surgeon, Royal Prince Alfred Hospital, Sydney
Dr Carina Chow	Colorectal Surgeon , Royal Brisbane Hospital, QLD
Dr Chip Farmer	Colorectal Surgeon, The Alfred Hospital, Melbourne, VIC
Dr Henry Hicks	General Surgeon, Wagga Wagga Specialist Medical Centre, NSW
Professor Cameron Platell	Director of Colorectal Cancer Research, St John of God Subiaco Hospital, WA
Dr Bruce Stewart	Colorectal Surgeon, The Specialist Centre, Ballarat; Consultant Medical Oncologist, Peter MacCallum Cancer Centre & Western Health Senior Research Fellow, Walter and Eliza Hall Institute of Medical Research, VIC
Dr Andrew Stevenson	Specialist Colorectal Surgeon, Head of Colorectal Surgery at Royal Brisbane and Womens Hospital, Associate Professor, The University of Queensland, QLD

*Section lead author

COLORECTAL CANCER GUIDELINES WORKING PARTY MEMBERS AND CONTRIBUTORS

Adjuvant therapy for colon cancer

NAME	AFFILIATION
Professor Peter Gibbs*	Laboratory Head, Walter & Eliza Hall, Institute of Medical Research, Melbourne, VIC
Dr Margaret Lee	Medical Oncologist, Department of Medical Oncology, Eastern Health and Western Health
Dr Jeanne Tie	Consultant Medical Oncologist, Peter MacCallum Cancer Centre & Western Health Senior Research Fellow, Walter and Eliza Hall Institute of Medical Research
Professor Timothy (Tim) Price	Medical Oncologist, The Queen Elizabeth Hospital, Adelaide, SA

*Section lead Author

Neoadjuvant and adjuvant therapy for rectal cancer

NAME	AFFILIATION
Professor Desmond Yip*	Medical Oncologist and Clinical Director, The Canberra Hospital, Australian National University; Honorary Associate, Sydney Medical School, The University of Sydney, ACT
Dr Kathryn Field*	Medical Oncologist, Peter MacCallum Cancer Centre
Professor Les Bokey	Colorectal Surgeon, Liverpool Hospital, Sydney, NSW
Associate Professor George Hruby	Senior Staff Specialist Royal North Shore Hospital and Genesis Cancer Care
Professor Ian Jones	Colorectal Surgeon, Royal Melbourne Hospital, VIC
Professor Christos Karapetis	Medical Oncologist, Flinders Medical Centre, Adelaide, SA
Dr Elizabeth (Liz) Murphy	Head, Colorectal Surgical Unit, Lyell McEwin Hospital, Adelaide, SA
A/Professor Sam Ngan	Head of the GI Unit of the Department of Radiation Oncology, Peter MacCallum Cancer Centre, Melbourne, VIC
Dr Kirsten Gormly*	Radiologist, Dr Jones and Partners Medical Imaging, Adelaide, SA
Professor Alexander (Sandy) Heriot	Colorectal Surgeon, Peter MacCallum Cancer Centre, Melbourne, VIC

*Section lead author

COLORECTAL CANCER GUIDELINES WORKING PARTY MEMBERS AND CONTRIBUTORS

Management of resectable locally recurrent disease and metastatic disease

NAME	AFFILIATION
Dr Cherry Koh*	Surgical Outcomes Research Centre (SOuRCe), Sydney, NSW
Dr Andrew Luck OAM	Colorectal Surgeon, Lyell McEwin Hospital Adelaide
Dr Nicholas O'Rourke	Surgeon (laparoscopic and hepatobiliary), Wesley Hospital, Brisbane, QLD
Dr Kirsten Gormly	Radiologist, Dr Jones and Partners Medical Imaging, Adelaide
Professor Tristan Yan	Consultant Cardiothoracic Surgeon, Professor of Cardiovascular and Thoracic Surgery at the Macquarie University Hospital and Associate Clinical Professor at the University of Sydney, Department of Cardiothoracic Surgery, Royal Prince Alfred Hospital, Sydney, NSW
Dr Peter Lee	Colorectal surgeon (visiting), Colorectal, Royal Prince Alfred Hospital, Chris O'Brien Lifehouse, St Luke's Hospital, Sydney, NSW
Professor Alexander (Sandy) Heriot	Colorectal Surgeon, Peter MacCallum Cancer Centre, Melbourne, VIC

*Section lead author

Management of non-resectable locally recurrent disease and metastatic disease

NAME	AFFILIATION
Dr Louise Nott*	Medical Oncologist, Royal Hobart Hospital and St John's Hospital, TAS
A/Prof Muhammad Khattak	Consultant Medical Oncologist, Fiona Stanley Hospital
Dr Amanda Townsend	Senior Medical Oncologist the Queen Elizabeth Hospital
Professor Timothy (Tim) Price	Medical Oncologist, The Queen Elizabeth Hospital, Adelaide, SA

* Section lead author

The role of systemic therapies in non-resectable metastatic disease

NAME	AFFILIATION
Dr Louise Nott*	Medical Oncologist, Royal Hobart Hospital and St John's Hospital, TAS
A/Prof Muhammad Khattak	Consultant Medical Oncologist, Fiona Stanley Hospital
Dr Amanda Townsend	Senior Medical Oncologist the Queen Elizabeth Hospital
Professor Timothy (Tim) Price	Medical Oncologist, The Queen Elizabeth Hospital, Adelaide, SA

* Section lead author

COLORECTAL CANCER GUIDELINES WORKING PARTY MEMBERS AND CONTRIBUTORS

Follow up after curative resection for colorectal cancer

NAME	AFFILIATION
Dr Peter J. Lee*	Colorectal surgeon (visiting), Colorectal, Royal Prince Alfred Hospital, Chris O'Brien Lifehouse, St Luke's Hospital, Sydney, NSW
Dr Andrew Gilmore	Head: Colorectal Unit Liverpool Hospital; Chairman: Complex Pelvic Surgery Liverpool Hospital
Professor Phillip Beale	Director, Cancer Services and Palliative Care, SLHD; Director Concord Cancer Centre; Head of Medical Oncology, CRGH; University of Sydney

*Section lead author

Psychosocial care

NAME	AFFILIATION
Professor Phyllis Butow*	Chair Psycho-Oncology Co-operative Research Group (PoCoG), and Co Director of the Centre for Medical Psychology and Evidence-based Medicine (CeMPED) and of the Surgical Outcomes Research Centre (SoURCe), University of Sydney
Professor Afaf Girgis	Director, Psycho-Oncology Research Group, Centre for Oncology Education and Research Translation, Ingham Institute for Applied Medical Research, South Western Sydney Clinical School, University of NSW

*Section lead author

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