



Complete Summary

GUIDELINE TITLE

Colorectal cancer.

BIBLIOGRAPHIC SOURCE(S)

Singapore Ministry of Health. Colorectal cancer. Singapore: Singapore Ministry of Health; 2004 Feb. 85 p. [245 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [February 28, 2008, Heparin Sodium Injection](#): The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.

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** REGULATORY ALERT **

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

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SCOPE

DISEASE/CONDITION(S)

Colorectal cancer

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Geriatrics
Internal Medicine
Oncology
Preventive Medicine
Radiation Oncology
Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide extensive evidence-based recommendations on diagnosis, risk factors, surgery, chemotherapy, radiotherapy, and prevention of colorectal cancer
- To complement the recommendations on colorectal cancer screening in the Ministry of Health (MOH) Health Screening Clinical Practice Guidelines
- To maintain the positive trend towards better survival of patients with colorectal cancer in Singapore

TARGET POPULATION

Men and women in Singapore with or at risk for colorectal cancer

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation/Risk Assessment

1. Investigation of signs and symptoms
2. Proctoscopy
3. Colonoscopy
4. Double contrast barium enema together with sigmoidoscopy
5. Assessment and stratification of risk
6. Selected screening for colorectal cancer (faecal occult blood testing)
7. Post-polypectomy surveillance programme
8. Surveillance in selected populations
9. Screening for familial adenomatous polyposis coli (FAP) (flexible sigmoidoscopy)
10. Genetic counseling/genetic testing
11. Surveillance colonoscopy with systematic biopsies in selected high risk individuals

Treatment/Management/Prevention

1. Surgery (bowel resection; colectomy; no-touch isolation technique; reconstruction, stomas, other related surgeries)
 - Perioperative antibiotics
 - Prophylaxis for deep vein thrombosis (DVT)
 - Counselling, stoma nurse
2. Use of tumour markers (carcinoembryonic antigen [CEA])
3. Follow-up after primary surgery (surveillance colonoscopy)
4. Adjuvant therapy for colon cancer (chemotherapy), including 5-fluorouracil-based chemotherapy
5. Adjuvant therapy for rectal cancer (radiotherapy, chemotherapy)
6. Chemotherapy for advanced rectal cancer, including 5-fluorouracil and newer agents (irinotecan, oxaliplatin, capecitabine, raltitrexed)
7. Preventive measures (diet, calcium supplementation, physical activity, smoking cessation)

MAJOR OUTCOMES CONSIDERED

- Disease free survival and overall survival of patients with colorectal cancer
- Rates of cure
- Functional outcome
- Recurrence rates
- Quality of life
- Risk of developing colorectal cancer

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level Ia: Evidence obtained from meta-analysis of randomised controlled trials

Level Ib: Evidence obtained from at least one randomised controlled trial

Level IIa: Evidence obtained from at least one well-designed controlled study without randomisation

Level IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

Level III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies

Level IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

Grade A (evidence levels Ia, Ib): Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation

Grade B (evidence levels IIa, IIb, III): Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation

Grade C (evidence level IV): Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates absence of directly applicable clinical studies of good quality

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

COST ANALYSIS

The guideline developers reviewed published cost analyses. Some of the findings were as follows:

- A single dose of appropriate antibiotics administered perioperatively is as effective as long term post-operative use in the prophylaxis against wound infection following colorectal cancer surgery. Inappropriate postoperative use of antibiotics is associated with increased costs.
- Due to the low sensitivity and specificity, carcinoembryonic antigen (CEA) cannot be recommended as a screening test for colorectal cancer. There are no data that CEA screening provides better survival, quality of life or lower costs in the population compared to no screening.
- CEA is the most sensitive test for the detection of recurrence and has been found to be the most cost-effective approach to detecting potentially resectable metastases.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations that follow are those from the guideline's executive summary; detailed recommendations can be found in the original guideline document. Each recommendation is rated based on the level of the evidence and the grade of recommendation. Definitions of the grades of the recommendations (A, B, C, Good Practice Points) and level of the evidence (Level I-Level IV) are presented at the end of the Major Recommendations field.

Diagnosis of Colorectal Cancer in a Patient with Symptoms

B - In the presence of symptoms and signs suggestive of colorectal cancer or in the presence of unexplained iron deficiency anaemia, proctoscopy should be performed to identify an anorectal cause for symptoms. In the absence of an obvious cause, colonoscopy should be performed and is the investigation of choice. (Goulston, Cook, & Dent, 1986; Fitjen et al., 1995; Young, 2003; Cook, Pavli, & Riley, 1986) (**Grade B, Level III**)

B - Double contrast barium enema together with sigmoidoscopy is an alternative to colonoscopy in investigating patients with colorectal cancer. Barium enema should be performed if colonoscopy is incomplete. (Goulston, Cook, & Dent, 1986; Fitjen et al., 1995; Young, 2003; Cook, Pavli, & Riley, 1986) (**Grade B, Level III**)

B - Colonoscopy should be performed for persistent symptoms despite initial treatment for a presumptive diagnosis of a benign condition. (Goulston, Cook, & Dent, 1986; Fitjen et al., 1995; Young, 2003; Cook, Pavli, & Riley, 1986) (**Grade B, Level III**)

Risk Factors for Colorectal Cancer

A - Asymptomatic individuals above the age of 50 years should undergo screening for colorectal cancer. (Ministry of Health, 2003) (**Grade A, Level Ib**)

A - A post-polypectomy surveillance programme is recommended for patients with a personal history of colorectal adenoma. (Zauber & Winawer, 1997; Winawer, 1999) (**Grade A, Level Ia**)

A - Asymptomatic individuals above the age of 50 years should undergo screening for colorectal cancer. This would include asymptomatic individuals with a family history limited to non-first degree relatives. The screening options would be faecal occult blood testing annually. (Ministry of Health, 2003) (**Grade A, Level Ia**)

B - It is recommended that people at high risk of colorectal cancer be referred for colonoscopy at three-yearly intervals from age 45, or 10 years younger than the age of earliest diagnosis of colorectal cancer in the family, whichever is the younger age. (Luchtefeld et al., 1991; Hunt et al., 1998; Winawer, Fletcher, & Miller, 1997) (**Grade B, Level Iib**)

B - The first step in the management of familial adenomatous polyposis (FAP) is the identification of the affected patient and his kindred. Detailed family history of individuals having colorectal cancer or polyps should be obtained. Genetic testing if available may be informative. (Church, Lowry, & Simmang, 2001) (**Grade B, Level Iib**)

B - Screening of familial adenomatous polyposis kindred begins at the age of puberty with flexible sigmoidoscopy. Genetic testing should be considered and, if the individual carries the mutation, these patients should be followed-up closely from puberty with possible proctocolectomy or total colectomy. (American Cancer Society, 2001; "Colorectal cancer screening," 2001) (**Grade B, Level Iib**)

B - Colonoscopy rather than flexible sigmoidoscopy is recommended in kindred with a history of hereditary non-polyposis colorectal cancer as they are predisposed to right-sided colon cancer. (**Grade B, Level IIb**)

B - Surveillance colonoscopy with systematic biopsies should be considered for patients with extensive, longstanding ulcerative colitis. (Choi et al., 1993) (**Grade B, Level IIa**)

Surgery for Colorectal Cancer

A - A single dose of appropriate antibiotics administered perioperatively is as effective as long-term postoperative use in the prophylaxis against wound infection following colorectal cancer surgery. Inappropriate postoperative use of antibiotics is associated with increased costs. (Wong-Beringer et al., 1995; Wasey, Baughan, & de Gara, 2003) (**Grade A, Level Ib**)

A - Randomized trials both locally and overseas have shown reduction in the risk of deep venous thrombosis with heparin prophylaxis. (Ho et al., 1999; McLeod et al., 2001) (**Grade A, Level Ib**)

B - Optimal care of patients undergoing stoma creation surgery would include preoperative counselling and stoma siting. (**Grade B, Level III**)

B - The length of bowel resected for colon cancer will be dictated by the removal of the arterial supply of the colon which parallels the lymphatic drainage. At least 5 cm of normal bowel on either side of the tumour appears to be a minimum length to remove the paracolic lymph nodes and to minimize anastomotic recurrences. (Devereux & Deckers, 1985) (**Grade B, Level III**)

C - Patients with multiple (i.e., two or more) colon cancers or those with hereditary nonpolyposis colorectal cancer should be considered for a total abdominal colectomy with ileorectal anastomosis. (Nelson et al., 2001; Easson et al., 2002) (**Grade C, Level IV**)

C - Patients with ulcerative colitis who develop a colorectal cancer should have a panproctocolectomy with or without restoration. (Nelson et al., 2001) (**Grade C, Level IV**)

B - The ideal bowel margin is 2 cm or more distally and 5 cm or more proximally, measured in the fresh, anatomically restored ex vivo condition from the transected full-thickness edge and does not include the tissue donuts from the endoluminal stapler. The minimal acceptable distal margin for tumours of the lower rectum (<5 cm from the anal verge) where sphincter preservation is an issue is 1cm. A 1-cm margin is not advised in cases of large, bulky tumours or poorly differentiated tumours with lymphovascular or perineural invasion. (Pollett & Nicholls, 1983; Vernava et al., 1992; Andreola et al., 1997) (**Grade B, Level III**)

B - Total mesorectal excision (TME) is not required for tumours located in the upper rectum (10-15 cm from the anal verge), which can be resected including 5

cm of distal mesorectum. (Lopez-Kostner et al., 1998; Leong, 2000) (**Grade B, Level III**)

B - 5-year survival in excess of 50 to 60% can be obtained by pelvic exenteration for selected patients with locally advanced rectal cancer operated with curative intent. The operative mortality should be less than 10%, but morbidity of 25 to 50% can be expected. (Hida et al., 1998; Luna-Perez et al., 1995; Yamada et al., 2002) (**Grade B, Level III**)

B - Distal rectal washout (after distal occlusion) may have a benefit in reducing anastomotic recurrence in rectal cancer surgery. (Jenner et al., 1998) (**Grade B, Level III**)

B - En bloc resection of adjacent organs locally invaded by colorectal cancers can achieve survival rates similar to those of tumours that do not invade an adjacent organ. To achieve this, the tumour must not be transected at the site of adherence, and negative resection margins are required. (Lopez & Monafu, 1993; Talamonti et al., 1993) (**Grade B, Level III**)

B - Metastatic tumor burden limited to one site and less extensive liver involvement select out a group of patients with stage IV colorectal cancer who can have resection of the asymptomatic colorectal primary tumour and expect substantial survival benefit over those never having resection. (Ruo et al., 2003) (**Grade B, Level IIb**)

B - Transanal excision of ultrasound staged T1 and ultrasound staged T2 rectal cancers together with adjuvant therapy may be an acceptable alternative in those not suitable for major resection surgery. (**Grade B, Level IIa**)

A - Synchronous liver metastases are those diagnosed within 6 months from diagnosis of the primary. The treatment of choice in this setting is resection of the metastases if there is no extrahepatic disease. (Steele & Ravikumar, 1989; Scheele, Stangl, & Altendorf-Hofmann, 1990) (**Grade A, Level Ib**)

Use of Tumour Markers

C - Due to the low sensitivity and specificity, carcinoembryonic antigen (CEA) cannot be recommended as a screening test for colorectal cancer. There are no data that CEA screening provides better survival or quality of life or lower costs in the population compared to no screening. (Bast et al., 2001) (**Grade C, Level IV**)

A - It is recommended that CEA levels be monitored every 2 to 3 months in patients with stage II or III disease for at least 2 years after diagnosis. The benefit of monitoring decreases after 2 years. (**Grade A, Level Ia**)

Follow-up after Primary Surgery

B - The frequency of surveillance colonoscopy is not clear but has been recommended to between 3 to 5 yearly after an initial complete colonoscopic examination (without synchronous polyps or cancers) either preoperatively or within 6 weeks after surgery. Metachronous lesions and polyps are believed to

occur less frequently than extraluminal recurrence. More frequent examination is suggested for certain high-risk factors such as high grade dysplasia, multiplicity, flat rather than polypoid morphology, and the size of greater than 1 cm in the resected polyp. (Schoen, 2003; Bruinvels et al., 1994; McFall, Woods, & Miles, 2003) (**Grade B, Level IIb**)

Adjuvant Therapy for Colon Cancer

A - 5-fluorouracil-based chemotherapy is recommended after surgery as it improves disease-free survival and overall survival for stage III (Tumour, Node, Metastasis [TNM] staging system) colon cancer. Postoperative chemotherapy with 5-fluorouracil/folinic acid (leucovorin) for 6 months is equivalent to 5-fluorouracil/levamisole for 12 months. (Moertel et al., 1990; Moertel et al., 1995; National Institutes of Health [NIH] consensus conference, 1990; O'Connell et al., 1997; "Efficacy of adjuvant fluorouracil," 1995) (**Grade A, Level Ib**)

Adjuvant Therapy for Rectal Cancer

A - If total mesorectal excision is not performed, postoperative radiotherapy can be recommended for improved local control and also recommended for improved survival when combined with chemotherapy. (**Grade A, Level Ib**)

A - Neoadjuvant, preoperative, short course radiotherapy improves local control and survival. Surgical complications may be increased, but not substantially. (Camma et al., 2000; Cedermark et al., 1995; "Improved survival," 1997; Kapiteijn et al., 2001; Marijnen et al., 2002) (**Grade A, Level Ia**)

Chemotherapy for Advanced Colorectal Cancer

A - Chemotherapy prolongs survival and improves quality of life for patients with metastatic colorectal cancers. Even when there is no radiologically demonstrable shrinkage of tumour, stabilization of disease is often associated with prolongation of survival and decrease in tumour-related symptoms. (Simmonds, 2000; Ragnhammer et al., 2001; Zalcborg et al., 1998) (**Grade A, Level Ia**)

B - While studies have shown age-dependent toxicity associated with the use of cytotoxic agents, advanced age is not a reason to withhold chemotherapy. (Rothenberg et al., 1999; Zalcborg et al., 1998; "Modulation of fluorouracil," 1992) (**Grade B, Level IIa**)

C - Raltitrexed can be used when 5-fluorouracil is either not tolerated or inappropriate. (National Institute for Clinical Excellence [NICE], 2002) (**Grade C, Level IV**)

A - Capecitabine or uracil plus tegafur (UFT) plus folinic acid are acceptable as a first-line chemotherapy for advanced colorectal cancer. (**Grade A, Level Ib**)

Prevention of Colorectal Cancer

B - Case-control studies show a positive correlation between energy intake and colorectal cancer risk. Although fat intake may be a confounding factor in this

relationship, it has been concluded that replacing fat with other energy sources is unlikely to reduce colorectal cancer risk. There is sufficient evidence to recommend reducing energy intake to prevent colorectal cancer. (Mao et al., 2003; Howe et al., 1997) (**Grade B, Level III**)

B - It is reasonable to recommend a high fibre intake as a possible measure to prevent colorectal cancer. (**Grade B, Level III**)

B - Calcium supplementation on current evidence may be beneficial in the prevention of colorectal cancer. (**Grade B, Level III**)

B - Physical activity is recommended as a preventive measure against colorectal cancer. (**Grade B, Level IIa**)

B - Stop smoking to avoid development of colorectal cancer. (**Grade B, Level IIa**)

Definitions:

Grades of Recommendations

Grade A (evidence levels Ia, Ib): Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation

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Level IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

- Appropriate diagnosis, risk assessment, treatment, and prevention of colorectal cancer
- Better survival and improved quality of life of patients with colorectal cancer in Singapore

Specific Benefits

- *Adjuvant therapy for colon cancer:* 5-fluorouracil-based chemotherapy is recommended after surgery as it improves disease-free survival and overall survival for stage III colon cancer.
- *Adjuvant therapy for rectal cancer.* Neoadjuvant, preoperative, short course radiotherapy improves local control and survival.
- *Chemotherapy for advanced colorectal cancer.* Chemotherapy prolongs survival and improves quality of life for patients with metastatic colorectal cancers. Even when there is no radiologically demonstrable shrinkage of tumour, stabilization of disease is often associated with prolongation of survival and decrease in tumour-related symptoms.

POTENTIAL HARMS

- Surgical complications
- Adverse effects of treatment, such as toxicity associated with cytotoxic agents
- Side effects of aspirin for chemoprevention include gastrointestinal haemorrhage and haemorrhagic stroke

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines are not intended to serve as a standard of medical care. Standards of medical care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge advances and patterns of care evolve.
- The contents of this publication are guidelines to clinical practice, based on the best available evidence at the time of development. Adherence to these guidelines may not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care. Each physician is ultimately responsible for the management of his/her unique patient in the light of the clinical data presented by the patient and the diagnostic and treatment options available.
- Users must keep in mind that new evidence could supersede recommendations in these guidelines.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The following clinical audit parameters, based on recommendations in these guidelines are proposed:

1. Percentage of patients at average risk undergoing faecal occult blood testing annually from age 50 years
2. Percentage of patients with single dose of appropriate perioperative antibiotics administered
3. Percentage of patients receiving prophylaxis for deep vein thrombosis (DVT) prior to any surgery for colorectal cancer
4. Percentage of patients undergoing stoma creation surgery who receive preoperative counselling and advice on stoma siting
5. Percentage of patients with Stage II or III colorectal cancer with carcinoembryonic antigen (CEA) levels being monitored every 2 to 3 months for a period of no less than 2 years after diagnosis

IMPLEMENTATION TOOLS

Patient Resources

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Singapore Ministry of Health. Colorectal cancer. Singapore: Singapore Ministry of Health; 2004 Feb. 85 p. [245 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Feb

GUIDELINE DEVELOPER(S)

Singapore Ministry of Health - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Singapore Ministry of Health (MOH)

GUIDELINE COMMITTEE

Workgroup on Colorectal Cancer

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Singapore Ministry of Health Web site](#).

Print copies: Available from the Singapore Ministry of Health, College of Medicine Building, Mezzanine Floor 16 College Rd, Singapore 169854.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Colorectal cancer. Singapore: Singapore Ministry of Health; 2004. 3 p.

Electronic copies: Available in Portable Document Format (PDF) from the [Singapore Ministry of Health Web site](#).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on May 17, 2004. This summary was updated by ECRI Institute on June 22, 2007 following the U.S. Food and Drug Administration (FDA) advisory on heparin sodium injection. This summary was updated by ECRI Institute on March 13, 2008 following the updated FDA advisory on heparin sodium injection.

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