ColonCancerCheck

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Centre for Effective Practice

Nurse Practitioners' Association of Ontario

RNAO

- The lifetime risk of developing Colorectal Cancer (CRC) is about 1 in 14 (7.1%) in men and 1 in 16 (6.3%) in women.
- CRC risk increases over age 50 - only 6.3% of cases in Canada occur under age 50.
- Ten to 15% of colorectal cancers occur in people with a family history of CRC.
- ColonCancerCheck aims to reduce mortality from CRC through an organized population-based screening program and to improve the capacity for primary care to participate in comprehensive CRC screening. The screening method will be determined by assessing risk.

Risk Assessment

Assess risk in individuals who have never had colorectal cancer.

1 Assess for Colorectal Cancer Signs and Symptoms

Patients should be referred for diagnostic work-up if they have one or more of the following:

- Rectal mass
- Abdominal mass
- Unexplained weight loss
- Unexplained change in bowel habits
- Rectal bleeding
- Unexplained anemia
- Persistent urge to evacuate the rectum
- Unexplained stool incontinence

FOBT is NOT appropriate for symptomatic patients.

2 Assess for Increased Risk of Colorectal Cancer

No CRC signs or symptoms
One or more first degree relatives with CRC (parent, sibling or child) [1,2]

→ Refer for Colonoscopy [3]
Begin at age 50 or 10 years younger than earliest age of diagnosis of relative, whichever comes first

→ If negative, repeat colonoscopy every 5 - 10 years

→ See reverse 'Surveillance after Colonoscopy' for abnormal results

3 Average Risk - Asymptomatic Age 50 Years and Older [4]

No CRC signs or symptoms
No affected first degree family member [5]

→ Fecal Occult Blood Test (FOBT) [6,7,8]

→ **Positive:** [9,10] refer for colonoscopy

→ **Incomplete:** [11] CCC will recall

→ **Negative:** repeat two years

1 Lifetime risk of CRC:

One first degree relative with CRC	= 9%
One first degree relative < 45 years with CRC	= 15%
Two first degree relatives with CRC	= 16%

2 For other patients at increased risk for CRC including familial and hereditary syndromes refer to www.mtsinai.on.ca/FamMedGen

3 For a list of participating hospitals in your area to refer patients for colonoscopy who have a positive FOBT or one or more first degree relatives with CRC please visit: www.ColonCancerCheck.ca

4 The upper age limit to initiate or continue CRC screening is at the discretion of the clinician and should be based on the individual patient's health status, anticipated life expectancy and risk of CRC.

5 Lifetime risk of CRC for average risk asymptomatic individuals = 4%.

6 There are no restrictions on oral intake of any prescribed medications, including aspirin, NSAIDs or iron supplements or specific foods except for Vitamin C, citrus fruits or juices, which should be discontinued 3 days prior to and during stool collection.

7 Hema Screen kits are provided by ColonCancerCheck. FOBT screening involves 3 stool cards with 2 windows each. A total of 6 stool samples are submitted. A single stool specimen obtained during rectal examination is NOT an adequate screen.

8 Other CRC screening tests are not funded by the ColonCancerCheck program but will still be available and funded by the MOHLTC.

9 If one or more of the 6 samples are positive, the patient should be referred for colonoscopy.

10 Research shows that 2% will have a positive FOBT, of whom ~10% will be found to have cancer at a follow-up colonoscopy.

11 ColonCancerCheck will send a letter to participants when a retest is needed due to incomplete results.

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Repeat Screening After Negative FOBT

- ColonCancerCheck will send a letter to participants with negative results.
- Every two years participants will be sent a letter from ColonCancerCheck to repeat the FOBT.

Surveillance After Colonoscopy

- Over 90% of CRC are adenocarcinomas. Most CRCs (>95%) arise from adenomatous polyps (AP).
- ~2/3 of polyps are adenomas. The remaining third are hyperplastic (none to minimal malignancy risk).
- Prevalence of AP increases with age. Prevalence is ~ 25% by age 50 and 50% by age 80.
- ~1-5% of APs will progress to invasive cancer especially if they are larger (>1cm), have villous features or high grade dysplasia. Progression from normal mucosa to invasive cancer takes ~10-15 years.

Colonoscopy Result	Surveillance Recommendation[1]
Normal Colonoscopy or Hyperplastic Polyps ■ Asymptomatic Average Risk ■ Increased Risk of CRC	■ Colonoscopy or average risk screening in 10 years ■ Colonoscopy in 5-10 years (depending on prior colonoscopy findings, family history, etc.)
1 or 2 small (≤1 cm) tubular adenomas with low-grade dysplasia	Colonoscopy in 5-10 years (depending on prior colonoscopy findings, family history, etc.)
• 3-10 adenomas, or • Any adenoma ≥ 1 cm, or • Adenoma with villous features, or • Adenoma with high-grade dysplasia	• Colonoscopy in 3 years (if adenomas were completely removed, not removed piecemeal) • If follow-up colonoscopy normal or 1-2 small tubular adenomas with low-grade dysplasia, then next colonoscopy in 5 years
> 10 adenomas	Endoscopist discretion for more intense follow-up
Sessile adenomas removed piecemeal	Endoscopy in 2-6 months to verify complete removal Then individualized surveillance

[1]Note that other CRC screening modalities including FOBT are not recommended in the interim

Winawer SJ et al. Gastroenterology 2006;130:1872-1885.
The US Multi-Society Task Force on Colorectal Cancer and the American Cancer Society

Why is ColonCancerCheck Funding Population-Based Biennial CRC Screening Using FOBT for Average Risk Adults?

- Biennial FOBT (followed by colonoscopy for those with a positive FOBT) is the only CRC screening modality with the highest level of evidence (Level 1) from randomized controlled trials (RCTs) in average risk adults demonstrating a reduction in CRC mortality.
- Based on this evidence, FOBT has been recommended by the Canadian Task Force on Preventive Health Care, the Canadian Association of Gastroenterology and the Ontario Guidelines Advisory Committee.
- FOBT is safe – there are no risks of perforation or death.
- FOBT can be easily completed at home – no bowel preparation, no dietary or medication restrictions except Vitamin C and no time off work is required.
- FOBT is not perfect. There may be false negatives in which case cancer or polyps with advanced neoplasia can be missed, or false positives which lead to colonoscopy with its associated risks.
- All recommended screening strategies for CRC, including biennial screening with FOBT, are cost-effective compared to no screening.
- Using FOBT in average risk individuals and colonoscopies in increased risk individuals is economically feasible, and allows for greater use of colonoscopies for patients with symptoms and for those at increased risk.
- Other jurisdictions in Canada and around the world are implementing population-based FOBT Colorectal Cancer Screening Programs.

Your local ColonCancerCheck centre and fax number: _____

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Colorectal Cancer Screening – Asymptomatic Average Risk Adults 50 Years of Age and Above

	Guaiac Fecal Occult Blood Testing (gFOBT)[1]	Colonoscopy (CS)	Flexible Sigmoidoscopy (FS)	Double Contrast Barium Enema (DCBE)	CT Colonography (CTC)
Recommended Frequency	• CTFPHC: Annual or biennial; good evidence to support (A recommendation) • CAG-CDHF: Biennial • GAC endorsed: At least biennial strongly recommended	• CTFPHC and GAC endorsed: Insufficient direct evidence to include or exclude as initial screen (C recommendation) • CAG-CDHF: Every 10 years	• CTFPHC: Fair evidence to support (B recommendation). Insufficient evidence to recommend only 1 or both of gFOBT and FS (C recommendation) • CAG-CDHF: Every 5 years (alone or combined with gFOBT) • GAC endorsed: Every 5 years (evidence is inconclusive)	• CAG-CDHF: Every 5 years • Not commonly used for screening. Often used when colonoscopy cannot be completed	• Not currently recommended by Canadian guidelines • Clinical efficacy is currently being evaluated • In some centres used when colonoscopy cannot be completed
Patient Preparation	• There are no restrictions on oral intake of any prescribed medications, including aspirin, NSAIDs or iron supplements or specific foods except for Vitamin C, citrus fruits or juices, which should be discontinued 3 days prior to and during stool collection	• One day prior to procedure patients must only consume clear liquids and then take a purgative • Patient generally spends the day and evening before very close to, if not on a toilet	• At least 1-2 saline enemas administered the morning of the examination • A stool softener or stool motility agent may also be advised the night before	• Same preparation as colonoscopy	• Same preparation as colonoscopy
Patient Convenience	• Patients can complete at home • Does not require any time off work • Can be mailed to lab for processing	• Patient must take up to 1-2 days off work • Sedation is administered intravenously • Patients cannot drive and must be accompanied by another individual to escort them home	• Patient takes time off work • Patient may experience some abdominal discomfort • Sedation is not administered • Patient may drive and return to work immediately following the procedure • Colonoscopy is required if polyps detected	• Patient takes time off work • Patient may experience discomfort • Colonoscopy is required if abnormality is detected	• Patient takes time off work • Patient may experience slight discomfort from the air insufflation • No sedation is required • Colonoscopy is required if abnormality is detected
Evidence of Clinical Efficacy	• 2 large population based RCTs (UK and Denmark) showed biennial screening with nonrehydrated gFOBT after 10 years reduced CRC mortality by 15-18% • CRC mortality was reduced by 43% among participants who completed all nine rounds of biennial gFOBT (Denmark)	• No available RCTs of CS that evaluate CRC mortality • Indirect evidence of incidence reduction from observational studies including a 76-90% reduction in CRC incidence in 2 large cohort studies (US, Italy) • Indirect evidence of benefit from RCTs of gFOBT using CS for follow up of positive tests	• Four current large RCTs (US, UK, Italy, Norway) examining CRC mortality reduction are underway • Case control studies of FS showed a 59-79% reduction in distal CRC mortality but no mortality reduction for proximal CRC • Indirect evidence from small RCT showed 80% reduction in CRC incidence • FS plus gFOBT: small non-RCT showed non significant 43% CRC mortality reduction ; 1 RCT showed 3-5 times more large polyps and cancers detected compared to gFOBT alone	• No published RCTs have examined effectiveness of DCBE in reducing CRC mortality	• Population-based evaluation for CRC screening underway • No current data on incidence or mortality reduction
Performance Characteristics Note: Sensitivity = proportion with CRC or adenomatous polyps who test positive Specificity = proportion with no cancer who test negative	• Sensitivity for CRC - Single Test: 13-25% - Repeated Testing: 50% • Specificity for CRC - Single Test: 80-95% - Repeated Testing: 96-98% • gFOBT does not detect APs	• Sensitivity for CRC - 95% • Specificity - 99-100% • Sensitivity for polyps - AP >1cm: 94% - AP 6-9 mm: 87% - AP ≤5 mm: 73%	• Sensitivity for CRC and advanced adenomas: - estimated 50-60% • Sensitivity for CRC and advanced adenomas: if detection of adenoma by FS screening followed by complete colonoscopy: - estimated 70-80% • Prevalence of advanced proximal adenomas without distal adenomas is 2-5% • Specificity difficult to determine	• Sensitivity for CRC - 80-85% • Specificity for CRC - Difficult to determine • Sensitivity for polyps - AP >1cm: 48% - AP 6-9 mm: 53% - AP ≤ 5 mm: 32%	• Sensitivity for CRC - 96% • Sensitivity for polyps - AP >1cm: 85% - AP 6-9 mm: 70% - AP ≤ 5 mm: 48% • Specificity for polyps - 91% (< 6mm) - 97% (> 1cm)
Risks	• False sense of reassurance with false negatives • Risks associated with colonoscopy for positive gFOBT	• Perforation: 1/1000 • Death: 1/15 000	• Perforation: less than 1/20 000 • Death: not well documented	• Perforation: 1/25 000 • Exposure to radiation	• No documented perforations or death with screening • Exposure to radiation
Cost Effectiveness	Although the up-front costs vary by screening modality, all CRC screening strategies are cost effective compared with no screening and are well within accepted guidelines in terms of cost per year of life saved				

[1] Two new CRC screening tests not yet evaluated in Canada include: Fecal Immunochemical Testing and tests for altered DNA in stool.
CTFPHC = Canadian Task Force on Preventive Health Care (2001), CAG-CDHF = Canadian Association of Gastroenterology and the Canadian Digestive Health Foundation (2004), GAC = Ontario Guidelines Advisory Committee (2003), CS = Colonoscopy, AP = Adenomatous Polyp