Title: Screening Guidelines for Colorectal Cancer

Date: 04 October, 2007

Context and policy issues:

Colorectal cancer is the second leading cause of death from cancer in Canada and the fourth most common cancer diagnosed in men and women, accounting for 12% of all cancer deaths and 13% of new cancer cases in Canada in 2007. According to the National Cancer Institute of Canada, population-based screening is intended to detect cancer or precancerous conditions in asymptomatic individuals. The primary objectives of population-based screening are to reduce the cancer death rate and to increase the likelihood of successful treatment, if detected early.

Policy decisions facing jurisdictions across Canada include determining which of the currently available interventions are acceptable for population-based screening for colorectal cancer. In addition, jurisdictions require information on the significance and impact of newer technologies including Computed Tomography (CT) imaging for Colonoscopy to support decision-making within their respective programs.

Research questions:

1. What screening guidelines exist for stratifying risk in Canadians or populations with roughly the same risk of colorectal cancer as a Canadian population?
2. Do any current guidelines incorporate CT colonoscopy?
3. Are any Canadian guidelines currently in development?
Methods:

A literature search was conducted in Medline and EMBASE databases; search terms included virtual colonoscopy and synonyms. Results were restricted by a literature type filter for guidelines. In addition, an extensive gray literature search of major health technology assessment and guideline organizations was conducted; these organizations included but were not limited to NICE (National Institute for Health and Clinical Excellence), National Guideline Clearinghouse, and CMA (Canadian Medical Association) Infobase.

An environmental scan was also conducted of provincial cancer agencies in Canada. Communication was initiated within each of the respective agencies via electronic mail and a review of the agencies’ websites was undertaken. The following questions were asked of the respective agencies:

1. Are there guidelines available or currently in development?
2. What screening guidelines exist for stratifying risk in Canadians or populations with roughly the same risk of colorectal cancer as a Canadian population?
3. Is your cancer care agency aware of any current guidelines that incorporate CT colonoscopy?

Summary of findings:

1. What screening guidelines exist for stratifying risk in Canadians or populations with roughly the same risk of colorectal cancer as a Canadian population?

Recommendations for colorectal cancer screening in Canada have been published at the national level by four groups: the Canadian Cancer Society (CCS, 2006), Canadian Association of Gastroenterology/Canadian Digestive Health Foundation (CAG/CDHF, 2004), National Committee on Colorectal Screening (NCCS, 2002) and the Canadian Task Force on Preventive Health Care (CTFPHC, 2001). The NCCS initiative was established in 1998 by Health Canada and involved members from the provincial cancer agencies/foundations, the Canadian Cancer Society/ National Cancer Institute of Canada, professional and non-professional organizations, and Health Canada. Provicially, the Guidelines Advisory Committee of the Ontario Medical Association and Ministry of Health and Long-Term Care in Ontario (GAC, 2002) have also published recommendations for colorectal cancer screening; these recommendations are derived from the USPSTF (2002) guideline cited below. The screening recommendations from these groups is summarized below and in Appendix 1.

Five guidelines were identified from American agencies; the Institute for Clinical Systems Improvement (ICSI, 2006), American Cancer Society (ACS, 2004), University of Michigan Health System (UMHS, 2004), Multisociety Task Force on Colorectal Cancer (MTFCC, 2003), and the U.S. Preventive Services Task Force (USPSTF, 2002). Colorectal cancer is the third leading cause of death and the third most common cancer in both men and women, accounting for almost 10% of all cancer deaths and 11% of new cancer cases in the United States in 2007. The MFTCC guideline was a combined effort of the American College of Gastroenterology, the American Society of Gastrointestinal Endoscopy, the American Gastroenterological Association, and the American College of Physicians/Society of Internal Medicine.
Appendix I presents the screening recommendations by these groups for individuals who are at average risk (asymptomatic, no family history) for colorectal cancer. Various screening interventions are presented along with recommendations regarding frequency and administration of screening tests where applicable.

The method used to develop the recommendations by these groups was based on the best available data/literature in support of an intervention or test. This included evidence from controlled trials, observational studies and expert opinion where applicable. Appendix I provides a summary of the various evidence and recommendation rating schemes used by UMHS (2004), USPSTF (2002), and CTFPHC (2001). The NCCS (2002) also performed statistical modeling and reviewed recommendations/reports from other countries which had undertaken similar evaluations.

All groups represented in this synthesis recommend screening for colorectal cancer in average risk, asymptomatic adults. They all provided an age at which screening should begin (≥50 years). They also presented two or more acceptable screening options and do not explicitly recommend one screening test over another citing a lack of solid evidence to do so. These groups recognized fecal occult blood testing (FOBT), sigmoidoscopy, combination of FOBT and sigmoidoscopy, and optical colonoscopy as acceptable screening interventions for use in asymptomatic adults of average risk. The CTFPHC did not consider screening with barium enema because of the lack of direct evidence.

All groups recognized that a positive FOBT result requires diagnostic follow-up. Some agencies, including the CTFPHC and USPSTF, cite the lack of evidence to make a recommendation regarding screening intervals for the various interventions.

2. Do any current guidelines incorporate CT colonoscopy?

No Canadian guidelines published to date recommend CT colonoscopy for colorectal cancer screening in average risk, asymptomatic adults. The CAG/CDHF and the NCCS discuss CT colonoscopy within the context of an emerging screening test.

From all the American guidelines reviewed in this report, only the ICSI (2006) in the United States recommends CT colonoscopy as a reasonable colonic imaging examination in the specific clinical situations described in Appendix I. The ICSI acknowledges that only some of the listed indications are reimbursed by Medicare in the United States. Furthermore, in many locations, CT colonoscopy is not available and barium enema can be performed in the situations described.

The National Institute for Health and Clinical Excellence (NICE) in the United Kingdom published a guidance document on CT colonoscopy in June 2005. Colorectal cancer is the second most common cancer in women and the third most common cancer in men in the United Kingdom. In addition to its use as a diagnostic test in symptomatic patients, NICE recommends that CT colonoscopy may be used in asymptomatic patients with a high risk of developing colorectal cancer. Evidence reviewed by NICE on the safety and efficacy of CT colonoscopy was found to be adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.
3. Are any Canadian guidelines currently in development?

Alberta, British Columbia, Northwest Territories and Nova Scotia have guidelines currently in development for colorectal cancer screening (Huiming Yang, Alberta Cancer Board, Calgary, AB; Andrew Coldman, BC Cancer Agency, Vancouver, BC; Dr. Kami Kandola, Stanton Territorial Health Authority, Yellowknife, NT; Erika Nicholson, CancerCare Nova Scotia, Halifax, NS: personal communications, 2007 Sep). Cancer Care Ontario and the Ministry of Health and Long-Term Care in Ontario have launched Canada’s first population-based colorectal screening program in 2007.\(^{15}\)

Conclusions and implications for decision or policy making:

Recommendations for colorectal cancer screening have been published by both Canadian and American agencies. The agencies recognize FOBT, sigmoidoscopy, combination of FOBT and sigmoidoscopy, and optical colonoscopy as acceptable screening interventions for use in asymptomatic adults of average risk. In general, the timing/publication of the guideline with respect to available data (i.e., the best available literature in support of an intervention or test) is an important factor to consider when reviewing recommendations among the various groups.

No Canadian guidelines published to date recommend CT colonoscopy for colorectal cancer screening in average risk, asymptomatic adults. There is, at present, uncertainty regarding the clinical significance and impact of CT colonoscopy in comparison to currently available screening tests. As jurisdictions across Canada develop/revise guidelines for population-based screening, policy decisions facing jurisdictions will be to determine the appropriate role of CT colonoscopy within their respective programs. Discussions at the national level may consider the need/importance of harmonizing jurisdictional recommendations for colorectal cancer screening across Canada.

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Appendix 1: Screening recommendations for asymptomatic individuals who are at average risk for colorectal cancer.

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<th>Guidelines (Year of publication)</th>
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<td><strong>CANADA</strong></td>
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| Canadian Cancer Society (CCS, 2006)³ | - Recommendation that men and women age 50 and over have a FOBT at least every two years. The Society accepts convincing evidence that the death rate from colorectal cancer can be reduced significantly if this screening takes place widely among the Canadian population.  
- Follow-up for a positive test should include a colonoscopy or double contrast barium enema (DCBE) and flexible sigmoidoscopy. | Not stated |
| Canadian Association of Gastroenterology and the Canadian Digestive Health Foundation (CAG/CDHF, 2004)⁴ | Individuals over the age of 50 years with a negative family history should undergo screening with one of the following strategies. The strategies outlined below each have advantages and disadvantages. The CAG/CDHF do not contend that they are equally effective nor should this idea be suggested to patients.  
- FOBT every two years.  
- Flexible sigmoidoscopy every five years. The interval of five years between examinations is shorter than that recommended if colonoscopy is used, because flexible sigmoidoscopy may be less sensitive than colonoscopy even in the area examined, or;  
- Flexible sigmoidoscopy combined with FOBT every five years. The rationale for the interval is mentioned above, or;  
- DCBE every five years. The lesser sensitivity and specificity of this test compared with colonoscopy is the rationale for the shorter screening interval compared with colonoscopy, or;  
- Colonoscopy every 10 years. The high sensitivity and specificity of this test means that the interval between tests can be twice as long as that of the other tests mentioned above. | Not suitable for mass screening as of publication date. |
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| CANADA                          | • Screening be offered to a target population of adults aged 50 to 74 years of age, with FOBT using unrehydrated Hemoccult II or equivalent as the entry test.  
• Individuals be screened at least every two years, recognizing that annual screening would have slight improvement in mortality reduction over biennial, but require increased resources.  
• Positive tests be followed up by colonoscopy, with options of barium enema and flexible sigmoidoscopy where appropriate (e.g. patient preference/availability of services) | Future technology for screening |

**Canadian Task Force on Preventive Health Care (CTFPHC, 2001)**

- There is good evidence to include annual or biennial FOBT (grade A recommendation)* and fair evidence to include flexible sigmoidoscopy (grade B recommendation) in the periodic health examination of asymptomatic people over 50 years of age. There is insufficient evidence to make recommendations about whether only one or both tests should be performed (grade C recommendation).
- There is insufficient evidence to include or exclude colonoscopy as an initial screening test in the periodic health examination of people in this age group (grade C recommendation).

* Recommendation Grade: A- Good evidence to support the recommendation that the condition or maneuver be specifically considered in a periodic health examination (PHE); B- Fair evidence to support the recommendation that the condition or maneuver be specifically considered in a periodic health examination; C- Insufficient evidence regarding inclusion or exclusion of the condition or maneuver in a periodic health examination, but recommendations may be made on other grounds; D- Fair evidence to support the recommendation that the condition or maneuver be specifically excluded from consideration in a periodic health examination; E- Good evidence to support the recommendation that the condition or maneuver be specifically excluded from a periodic health examination.
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| Institute for Clinical Systems Improvement (ICSI, 2006) | Colorectal cancer screening is recommended for all patients 50 to 80 years of age, using one of the following methods based on joint decision making by patient and provider:  
• Flexible sigmoidoscopy every five years.  
• Annual FOBT.  
• Combination of flexible sigmoidoscopy every five years and annual FOBT.  
• Total colon evaluation as defined in the guideline (i.e., this can be accomplished by either optical colonoscopy, flexible sigmoidoscopy combined with fluoroscopic barium enema or DCBE, or CT colonoscopy. If the sigmoid is not well visualized on DCBE, a flexible sigmoidoscopy should be obtained). | See footnote† |
| American Cancer Society (2004) | The ACS recommends that adults at average risk should begin colorectal cancer screening at age 50, using one of the following five options for screening:  
• Annual FOBT.  
• Flexible sigmoidoscopy every five years.  
• Annual FOBT plus flexible sigmoidoscopy every five years. Flexible sigmoidoscopy together with FOBT is preferred compared with FOBT or flexible sigmoidoscopy alone.  
• DCBE every five years.  
• Colonoscopy every 10 years. | Not stated |

† Currently, CT colonoscopy seems to be a reasonable colonic imaging examination in the following clinical situations: 1) after incomplete screening or diagnostic colonoscopy; 2) in anticoagulated patients who cannot safely discontinue anticoagulation therapy; 3) patients who refuse optical colonoscopy and understand that their insurance may or may not cover the cost of the CT. If polyps or other pathology is seen on CT colonoscopy, this may require further evaluation with optical colonoscopy.
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| UNITED STATES                 | • Recommended methods include: FOBT, flexible sigmoidoscopy (FS), or optical colonoscopy. (Digital rectal exam is not effective in screening for colorectal cancer.)  
• Initiate. For average risk, asymptomatic patients, screening should begin at age 50.  
• Frequency: Average risk. FOBT: annually [A]. FS: every 5 years [A]. FOBT/FS: annually/every 5 years [B]. Optical Colonoscopy: every 10 years [B]. Air or double-contrast barium enema (acceptable modality, but not recommended): every 5 years [B]. The frequency of screening has not been adequately evaluated in clinical trials. | Not stated |

‡ Levels of evidence reflect the best available literature in support of an intervention or test: A- Randomized controlled trials; B- Controlled trials, no randomization; C- Observational trials; D- Opinion of expert panel
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| UNITED STATES                   | Men and women at average risk should be offered screening with one of the following options beginning at age 50 years. The rationale for presenting multiple options is that no single test is of unequivocal superiority and that giving patients a choice allows them to apply personal preferences and may increase the likelihood that screening will occur. The strategies are not equal with regard to evidence of effectiveness, magnitude of effectiveness, risk, or up-front costs. Reviewing the rationale section for each screening test (presented in the original guideline document) will provide clinicians with information that they can use in presenting the relative effectiveness of each test to patients.  
- Offer yearly screening with FOBT using a guaiac-based test with dietary restriction or an immunochemical test without dietary restriction. Two samples from each of 3 consecutive stools should be examined without rehydration. Patients with a positive test on any specimen should be followed up with colonoscopy.  
- Offer flexible sigmoidoscopy every 5 years.  
- Offer screening with FOBT every year combined with flexible sigmoidoscopy every 5 years. When both tests are performed, the FOBT should be done first.  
- Offer colonoscopy every 10 years.  
- Offer DCBE every 5 years. | Emerging screening test; Research setting |

Multisociety Task Force on Colorectal Cancer (MTFCC, 2003)\(^{11}\)
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| UNITED STATES                 | The USPSTF strongly recommends (Grade A recommendation)° that clinicians screen men and women 50 years of age or older for colorectal cancer.  
  - Good evidence that periodic FOBT reduces mortality from colorectal cancer and fair evidence that sigmoidoscopy alone [interval unspecified] or in combination with FOBT reduces mortality.  
  - The USPSTF did not find direct evidence that screening colonoscopy is effective in reducing colorectal cancer mortality; efficacy of colonoscopy is supported by its integral role in trials of FOBT, extrapolation from sigmoidoscopy studies, limited case-control evidence, and the ability of colonoscopy to inspect the proximal colon.  
  - Double-contrast barium enema offers an alternative means of whole-bowel examination, but it is less sensitive than colonoscopy, and there is no direct evidence that it is effective in reducing mortality rates.  
  - There are insufficient data to determine which strategy is best in terms of the balance of benefits and potential harms or cost-effectiveness. Studies reviewed by the USPSTF indicate that colorectal cancer screening is likely to be cost-effective (less than $30,000 per additional year of life gained) regardless of the strategy chosen.  
  - It is unclear whether the increased accuracy of colonoscopy compared with alternative screening methods (for example, the identification of lesions that FOBT and flexible sigmoidoscopy would not detect) offsets the procedure’s additional complications, inconvenience, and costs. | Insufficient evidence that technology is effective in improving health outcomes |

° The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.