Quality Determinants and Indicators for Measuring Colorectal Cancer Screening Program Performance in Canada

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Table of Contents

List of Abbreviations

Acronym	Definition
ADR	Adenoma detection rate
CAG	Canadian Association of Gastroenterology
CRC	Colorectal cancer
FOBT	Fecal occult blood test
FS	Flexible sigmoidoscopy
FT[i]	Fecal test
FTg	Guaiac fecal-occult blood test
FTi	Immunochemical fecal-occult blood test
PPV	Positive predictive value
RCT	Randomized controlled trial
UK	United Kingdom

[i]FT has been used in this document to refer to fecal test. Unless specified, FT is synonymous with FOBT and includes FTi and FTg.

Executive Summary

This document supports the implementation of population-based colorectal cancer (CRC) screening in Canada. There are many potential quality determinants and respective indicators, reflecting specific parts of the screening pathway. This document outlines specific quality determinants and indicators for CRC screening programs in Canada. Quality determinants are concepts, processes and activities that contribute to the quality of the program. Quality indicators are metrics that allow for practical, quantifiable and reliable comparison.

Quality determinants and indicators are listed below, by domain. The five domains of the colorectal cancer screening pathway are Participation, Entry-Level Screening Test, Follow-up Colonoscopy, Diagnosis and Initiation of Treatment, and Colorectal Cancer Screening Program Outcomes.

List of Quality Determinants by Domain

Participation

Invitation

Family physicians

Accommodation of special needs

Accessibility of information to support decision-making

Accounting for non-programmatic screening

Shared Quality Determinants for Entry-Level Screening Test, Follow-Up Colonoscopy and Diagnosis and Initiation of Treatment

Competence

Accreditation

Quality assurance

Safety, comfort and satisfaction

Accessibility and capacity

Entry-Level Screening Test

See Shared Quality Determinants

Follow-Up Colonoscopy

Implementation and uptake of other national guidelines

Diagnosis and Initiation of Treatment

Management

CRC Screening Program Outcomes

Access to record-level data

Monitoring and evaluation

List of Quality Indicators by Domain

Participation

Participation

Retention

Fecal test (FT) utilization

Entry-Level Screening Test

FT inadequacy rate

Positivity

Follow-Up Colonoscopy

Follow-up colonoscopy uptake

Wait time to follow-up colonoscopy

14-day unplanned hospitalization following colonoscopy

30-day mortality following colonoscopy

Diagnosis and Initiation of Treatment

PPV adenoma

PPV advanced adenoma

PPV CRC

PPV neoplasia

PPV advanced neoplasia

Wait time from follow-up colonoscopy to definitive pathological diagnosis

Wait time from screen-detected CRC to initiation of treatment

CRC Screening Program Outcomes

Invasive CRC stage distribution

CRC incidence

Adenoma detection rate

CRC detection rate

CRC mortality

Interval CRC

It is anticipated that the national and international comparison of these indicators and accompanying consultative processes will allow for continued progress and improvement in the delivery of colorectal cancer screening programs in Canada.

Background

In November 2008, the National Colorectal Cancer Screening Network (the Network) and the Canadian Partnership Against Cancer (the Partnership) mandated a group of experts to identify quality determinants and quality indicators for programmatic colorectal cancer (CRC) screening in Canada. This effort resulted in the publication of *Quality Determinants for Colorectal Cancer Screening in Canada*[1] in 2009. That report covers five key domains[ii] of the organizational structure, processes and outcomes of the CRC screening pathway. The publication was the first step of an iterative process and as such, the document will be updated regularly to reflect changing knowledge and practices related to CRC screening.

Network members identified a need to establish national targets for quality indicators. A Targets and Quality Indicators workshop was convened in St. John's, Newfoundland and Labrador, in October 2011 and consensus was obtained on six national targets.

This report updates the document published on September 30, 2009. Several additions to this report merit mention, as follows:

- Information is presented on the adopted national targets and the revised and new quality determinants and quality indicators.
- The domains and the distribution of the indicators within these domains have been slightly modified. A new section on processes for reporting quality indicators has been included.

[ii] These domains were participation, screening test, diagnostic follow-up, case management and program outcomes.

Introduction

This document supports the advancement of population-based CRC screening in Canada. It also supports the Network in its efforts to implement efficient, high-quality, organized monitoring of program performance. Network members will adopt and share this document with their jurisdictional stakeholders and partners to advance high-quality CRC screening, diagnosis and treatment initiation.

Quality determinants are concepts, processes and activities that contribute to the quality of the program. Quality indicators are metrics that allow for practical, quantifiable and reliable comparison.

There are many potential quality determinants and respective indicators, reflecting specific parts of the screening pathway (Figure 1). In developing quality determinants and indicators, it is assumed that some of the essential aspects of programmatic CRC screening will be addressed indirectly rather than directly. For example, the availability of resources, both human and financial, will be indirectly assessed by measuring wait times.

The definitions of quality in CRC screening vary among stakeholder groups. For example, for an endoscopist, quality means performing a complete procedure, visualizing everything there is to see and safely removing all polyps. In contrast, for a screening participant, overall comfort level is a key element of quality. It is noted that if participants have a bad experience, they will be less likely to return for follow-up or to recommend screening to family, friends and colleagues.[2]

For the purposes of this report, performance and quality indicators have been classified as either early or long term. Early indicators are those that can be "used early in the lifetime of a screening program to measure the quality of the screening process and to assess its potential longer-term impact."[3] Long-term indicators are those measuring the impact of CRC screening in the population (e.g., a reduction in CRC incidence or mortality).

The Network decided to include only those indicators providing large system measures that address core functions of the programs rather than those informing local processes.[4] The objective is to determine the success of programmatic CRC screening in reducing CRC incidence and mortality in the Canadian population.

Principles

Programmatic CRC screening consists of organized, population-based programs and involves multiple stakeholders, including a variety of health-care providers. A number of program features may differ, including type of fecal test (FT), the screening interval and the service delivery model. The overall success of programmatic CRC screening depends on ensuring that quality is maintained throughout all aspects of the program and service delivery. Such an approach will maximize the benefits of screening while minimizing the potential risks.

Quality is measured in the distinct domains of organizational and clinical structures, processes and outcomes. The success of high-quality, population-based programmatic CRC screening depends on these fundamental principles. The eight principles and the associated criteria are described below:[5, 6]

1) People Focused. Programmatic CRC screening involves two groups ofw people:

- Individuals who are eligible for or who have undergone screening, follow-up or diagnosis
- Health-care professionals who provide screening services

The goals of any program are to:

- Protect the safety of participants
- Ensure decisions made by health-care professionals respect individuals' needs and preferences
- Provide the highest-quality service as a means of optimizing the potential benefit to the target population

2) Partnership and a Multidisciplinary Approach. The approach for program planning, implementation and evaluation is based on collaboration and partnership among key stakeholders, including health-care professionals across all disciplines.

3) Evidence-Based Decision-Making. In theory, all health-care decisions should be based on the most current and highest-quality scientific evidence. Decisions should be available to the population and should specify who should be offered further diagnostic investigation, treatment or both. Where appropriate, the target population should be made aware of their choices.

4) Equity. The target population should have appropriate and timely access to CRC screening and follow-up services. Programmatic screening should ensure reasonable parity in the provision of benefits among geographic regions and different social, demographic and economic groups within the target population.

5) Ethical Responsibility. The goal is to establish programs that will reduce morbidity and mortality from CRC in the screened population while minimizing the harm and anxiety that can arise from screening. Programs are responsible for ensuring that positive screening effects are optimized and detrimental effects are minimized. Furthermore, all participants should receive sufficient information to make an informed decision, as some individuals may experience more harm than benefit.

It is also essential that screening does not limit access to health-care services for symptomatic patients who have diseases.

6) Phased-In Implementation. Programs should be launched using a phased approach to allow for ongoing evaluation, infrastructure enhancement and capacity building for service delivery over time.

7) **Integration.** The expectations of quality for program-related services should effectively integrate with the provision of health services and laboratory testing mechanisms currently in place. Furthermore, some quality determinants and quality indicators also apply to services provided for non-program-related clinical activities, such as therapeutic colonoscopy. Thus, it is expected that the implementation of programmatic screening will also have a positive impact on the quality of related clinical services offered through other programs.

8) **Sustainability.** Programs should be cost effective and sustainable. Adequate resources should be allocated to strengthen the infrastructure and capacity for programmatic CRC screening. These resources include well-trained health-care providers, functional program management, information systems and necessary supplies and facilities.

CHAPTER 1
Methodology

To identify quality determinants for programmatic CRC screening across Canada, it is essential to discuss, understand and gain consensus on a systematic process and to identify quality indicators and recommendations to evaluate program success over time. This process includes the following:

- Understanding quality determinants in the context of international, pan-Canadian, provincial and territorial, local and case-based settings and clearly differentiating among them
- Describing quality determinants and indicators in a structured format that then grounds quality determinants within the reality of programmatic CRC screening (a CRC screening pathway typically found in most organized programs is used for this purpose)
- Building consensus and providing clarity on quality indicators

Regardless of how programs differ, there are key quality determinants and measurable indicators that are common to all evidence-based programmatic screening. "Programmatic" is implied throughout the document when referring to screening unless otherwise specified.

Quality determinants and indicators have been grouped into five domains:

- Participation
- Entry-level screening test
- Follow-up colonoscopy
- Diagnosis and initiation of treatment
- Programmatic CRC screening outcomes

1.1
CRC Screening Pathway

Quality determinants are expected to cover all the processes included in the CRC screening pathway. Figure 1 presents the pathway typically adopted by evidence-based, programmatic CRC screening. Programmatic CRC screening in Canada primarily targets individuals between 50 and 74 years of age with average risk (i.e., those with no additional personal or family risk factors for colon cancer, other than being older than 50)[7] for CRC as described in the literature and as recommended by the Network. It is assumed that organized CRC screening programs use FT (either FTg or FTi) as the entry-level screening test.

CRC screening programs vary both within and among jurisdictions with respect to approaches and policies. The pathway captures these variations and includes additional screening scenarios that may not be implemented in every program. It also includes average- and high-risk screening by colonoscopy, average-risk screening using other primary screening modalities and/or diagnostic follow-up with modalities other than colonoscopy.

The pathway also identifies the quality determinants and indicators within the five key domains previously discussed.

1.2

Criteria for Selection of Quality Indicators

The identification and appropriateness of each of the proposed quality indicators was assessed using criteria developed by Bédard et al. (2006) (Table 1).[8] Only the quality indicators meeting all the criteria were selected.

TABLE 1
Criteria and Definitions for Selection of Quality Indicators

CRITERION	DEFINITION
Scientifically robust	An indicator is scientifically robust if it is valid (i.e., sensitive and specific) and reliable (i.e., reproducible across individuals and over time under the same conditions).
Measurable	The data required to assess the indicators must be available and easily accessible. If not, methods should exist to obtain the data in the near future.
Interpretable	An indicator has to be simple. Its interpretation should be easy and understandable by the majority of the population, not only by experts and stakeholders. The indicator should also have a desirable direction, either positive or negative.
Applicable	An indicator should be adequately estimated in several subgroups of the whole population. It should also be useable regionally, provincially, nationally and internationally.
Pertinent	An indicator represents an important aspect of cancer screening, gives useful information to different practice and policy stakeholders and stimulates efficient actions that may lead to quality improvement.
Ethical	Collection, treatment and analysis of indicator data respect individual rights of confidentiality, freedom of choice in providing data and informed consent about the nature and implications of data provided.
Relevant	An indicator is relevant to objectives, targets (or at least to a desirable direction) or norms. It will be possible to determine the level of achievement of objectives and targets, to verify whether norms have been respected and to evaluate services.

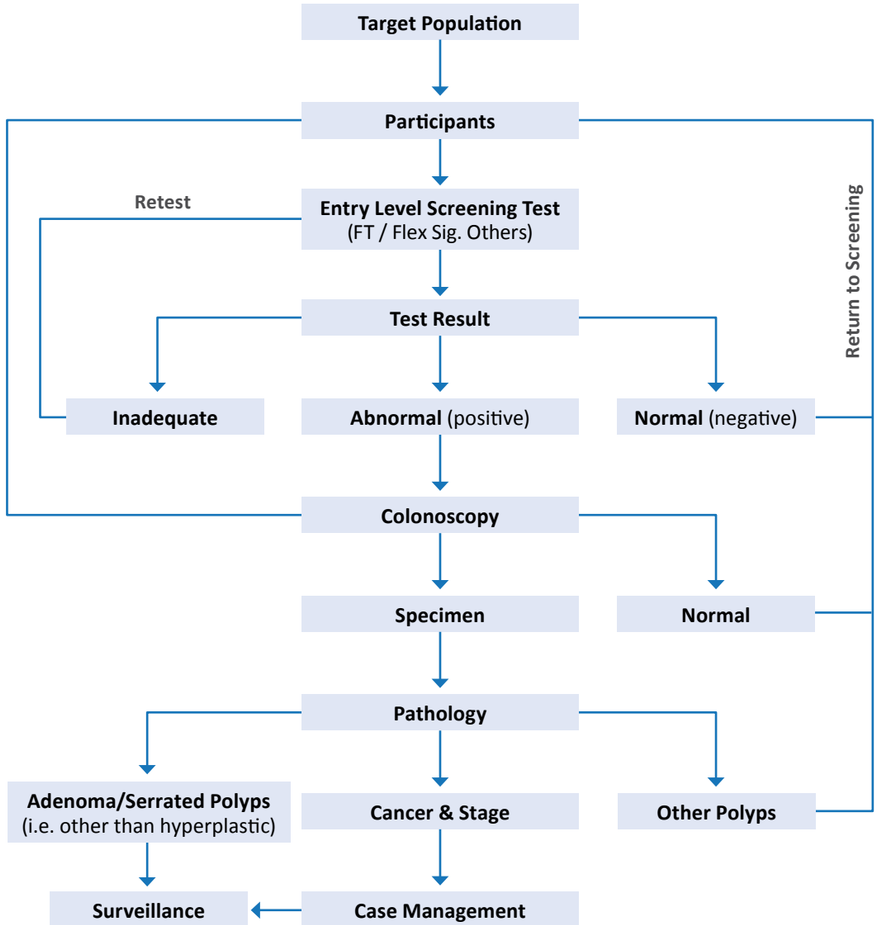
1.2.1 Targets for Quality Indicators

The process for establishing Canadian targets has begun. Where consensus has been achieved for a target it is noted in this report. Targets are points of reference against which screening programs can be compared. They also represent quality standards that programs should aim to achieve and exceed wherever possible.

FIGURE 1

Quality Determinants and Quality Indicators Based on Common Colorectal Cancer Screening Pathway (including possible variations)

CRC SCREENING PATHWAY



QUALITY DETERMINANTS BY DOMAIN

Participation

- Invitation
- Family physicians
- Accomodation of special needs
- Accessibility of information to support decision making
- Accounting for non-programmatic screening

Entry Level Screening Test

- See Shared Quality Determinants

Follow-Up Colonoscopy

- Implementation and uptake of other national guidelines

Diagnosis and Initiation of Treatment

- Management

Program Outcomes

- Access to record level data
- Monitoring and evaluation

Shared Quality Determinants

- Competence
- Accreditation
- Quality assurance
- Safety, comfort and satisfaction
- Accessibility and capacity

QUALITY INDICATORS BY DOMAIN

Participation

- Participtation
- Retention
- FT Utilization

Entry Level Screening Test

- FT inadequacy rate
- Positivity

Follow-Up Colonoscopy

- Follow-up colonscopy uptake
- Wait time to FU colonscopy
- 14-Day unplanned hospitalization following colonoscopy
- 30-Day mortality following colonoscopy

Diagnosis and Initiation of Treatment

- Wait time from follow-up colonoscopy procedure to definitive pathological diagnosis
- Positive Predictive Value:
  - adenoma
  - advanced adenoma
  - colorectal cancer
  - neoplasia
  - advanced neoplasia
- Wait time from screen-detected CRC and initiation of treatment

CHAPTER 2
Quality Determinants by Domain

Quality determinants are intended to guide the practice and advancement of CRC screening in Canada. They describe concepts, processes and activities that contribute to the quality of the program, which cannot be measured directly.

Quality indicators are metrics that allow for practical, quantifiable and reliable comparison all along the screening pathway. An example of a quality determinant for programmatic CRC screening is the use of personalized CRC screening invitations to increase the target population's participation. The participation rate is therefore a quality indicator that could be used to evaluate the impact of this specific quality determinant.

2.1
Participation Domain

Invitation. An informative and preferably personalized solicitation to participate in a screening program is an effective tool to motivate the target population to initiate screening and to adopt a regular screening practice.[9,10]

Family physicians. Family physicians have a strong influence on their patients' participation in programmatic CRC screening as well as on their health behaviours and practices. Family physicians benefit from reminders and encouragement to support CRC screening in the target population. Physicians who refer individuals for follow-up colonoscopy are provided with a comprehensive procedure report.[10–13]

Accommodation of special needs. Some participants may require special accommodations (e.g., because of disabilities or cultural differences) to ensure equitable access to screening services.

Accessibility of information to support decision-making. Screening participants require information related to screening to enable them to make informed decisions.

Accounting for non-programmatic screening. Use of non-programmatic CRC screening tests is taken into account.

2.2

Shared Quality Determinants for 2.3, Entry-Level Screening Test Domain; 2.4, Follow-up Colonoscopy Domain; and 2.5, Diagnosis and Initiation of Treatment Domain

Competence. Health-care professionals and laboratory specialists involved in programmatic CRC screening are trained and keep abreast of technological advances and guideline revisions through various means. Their performance is evaluated regularly and results are provided regularly for comparison.

Accreditation. Formal accreditation will be obtained when available.

Quality assurance. Quality assurance protocols are in place to guide procedure evaluation. The evaluation is facilitated by thorough documentation of the necessary data quality elements.

Safety, comfort and satisfaction. Participant safety, comfort and satisfaction throughout the screening pathway are paramount. Thorough and continuous monitoring is required to ensure that:

- Participants are informed of the limitations of the screening and diagnostic tests and of the risks associated with the tests
- The instructions for performing the test are clear
- Participants are navigated through the health-care system
- Participants provide consent before the follow-up colonoscopy is performed
- Complications from follow-up colonoscopy are integrated into the screening program evaluation
- Wait times between procedures are minimized and test results and diagnoses are provided quickly

Accessibility and capacity. Initiating programmatic screening secures the availability and accessibility of the appropriate screening and diagnostic tools and treatments. Resources required to allow participants to complete the entire screening journey should be available. Programmatic CRC screening services are available to the target population, including individuals with special needs and those living in remote areas. Higher-risk individuals are expected to have different needs for screening and may therefore be excluded from some population-based programs; these individuals have to be managed appropriately, with programmatic or non-programmatic CRC screening.

2.3

Entry-Level Screening Test Domain

See Section 2.2, Shared Quality Determinants

2.4

Follow-Up Colonoscopy Domain

See Section 2.2, Shared Quality Determinants

Implementation and uptake of other national guidelines. Colonoscopy quality and safety are based on Canadian Association of Gastroenterology (CAG) guidelines and are regularly evaluated at the local level and by screening programs.

2.5

Diagnosis and Initiation of Treatment Domain

See Section 2.2, Shared Quality Determinants

Management. Individuals diagnosed with polyps undergo proper follow-up, including short- and long-term surveillance. Information regarding diagnostic outcomes is transferred in a timely and efficient manner to providers responsible for the care and surveillance of the individuals, as well as to the referring physicians. Consensus on recommendations and guidelines for surveillance based on individual risk should be obtained in the near future.

2.6

CRC Screening Program Outcome Domain

Access to record-level data. Infrastructure and personnel involved in gathering and storing personal information on CRC screening participants are in place.

Monitoring and evaluation. Programs have access to data and resources, allowing for both qualitative and quantitative assessment of their outcomes and targets.

CHAPTER 3
Quality Indicators by Domain

Quality indicators within the five domains provide meaningful information, especially when stratified by characteristics such as age group, sex, screening round (first and subsequent), socioeconomic status and ethnicity; however, data are not routinely available on all these variables. The Network recognizes the importance of these factors and will address this issue when reporting systems are further developed.

3.1
Participation Domain

3.1.1. Background

Reduction in CRC mortality is attained only if there is sufficient uptake of the screening test in the target population. Participants must go through several rounds of screening before the impact of programmatic screening on CRC mortality can be observed. An important objective of programmatic screening is to optimize uptake by making the screening test widely available and promoting it. Participation of the target population is considered an important measure of the program's success and ultimately determines the outcomes and cost effectiveness of population-based programmatic CRC screening.[14–18]

3.1.2. Recommendations

In an attempt to maximize uptake, programs should send personal invitations and reminders to individuals in the target population. Other approaches include working with primary and other health-care providers to promote participation in screening, as well as a process for self-referral for those who wish to be screened after learning about it through promotional events or the media.

Programmatic screening should address access for individuals with special needs (e.g., disabilities). To increase reach and uptake, identification and monitoring of under-participation in screening by target-population subgroups should be ongoing. Special efforts should be made where non-programmatic screening is high to try to identify why this is happening, along with ways to bring those individuals into programs when appropriate.

3.1.3. Indicators

The indicators within the participation domain are classified as early performance indicators. Participation, retention of individuals with normal FTs and utilization are currently the three indicators defined for this domain (Table 2). They provide information on the exposure of the population to screening and are a measure of the program's potential effectiveness.

- The term "participation" is restricted to participation in programmatic screening.
- The term "utilization" describes those who participated either in programmatic or non-programmatic screening.

TABLE 2
Quality Indicators for the Participation Domain

INDICATOR	TARGET	DEFINITION
Participation	≥ 60%	Percentage of the target population who successfully complete an FTg or FTi within a respective date frame
Availability (temporary indicator)	N/D	Percentage of target population to whom the program is available within a respective date frame
Retention	N/D	Percentage of individuals who had a normal screening test or a follow-up colonoscopy with a normal outcome who were rescreened within a respective date frame
FT utilization	N/D	Percentage of individuals with at least one FT (programmatic or non-programmatic) within a respective date frame

N/D = not yet determined

Participation

The percentage of people in the target population participating in programmatic CRC screening can be calculated many ways. The following two methods for calculating participation were adopted:

1) The numerator is the number of participants with successful initial or subsequent FTs in the program in a specified period.
2) Participation includes individuals with successful FTs; those with equivocal laboratory results are excluded because an equivocal result will not affect CRC incidence/mortality.

Special efforts should be made to identify the true average-risk population.[7]

Availability

The availability of a program is measured by the percentage of the target population to whom programmatic screening is available. In Canada, depending on the jurisdiction, programmatic screening may be initially implemented as a pilot project or phased in and therefore only offered to the target population in limited numbers or in specific geographic areas. To measure programmatic participation at the early stages, it is necessary to include only the population to whom the program was available at that time. This indicator will cease to be reported when all intended CRC screening programs are available to the entire target population.

The first programmatic CRC screening in Canada was launched in 2007. By 2012, availability of programmatic CRC screening in the provinces varied from 0% to 100%.

Retention

Retention is the percentage of individuals who had a screening test or follow-up colonoscopy with normal results who were rescreened within a defined period. In Canada, decisional algorithms and strategies for individuals with abnormal FT results followed by a normal colonoscopy vary by jurisdiction. For now, it might be more feasible to include only normal FT results in retention rates.

As Canadian CRC screening programs are implemented and go through successive rounds of invitations and screening, it will be important to measure the retention rate, especially among individuals with normal FT results. This is because FTs have a low sensitivity[19,20] and repeating the tests at regular intervals increases the probability of finding a lesion.[21] Individuals with an abnormal FT result

and normal follow-up colonoscopy should be monitored according to the program's policies, guidelines or recommendations (see Other Considerations).

FT Utilization

Utilization is the percentage of the target population who had at least one successful FT (either programmatic or non-programmatic). When fecal testing is available through non-programmatic screening it is important to have an indicator to reflect screening as a whole because this can provide a more accurate reflection of the portion of the target population that is up to date on screening using FT. Moreover, this indicator has to be taken into consideration when interpreting the participation in programmatic CRC screening; there is a need to capture those individuals and an opportunity to engage them to increase program participation.

3.1.4. Other Considerations

It is desirable to identify high-risk individuals[22,23] within the target population and to track this information in a program registry. High-risk individuals are expected to have different needs for screening-related services. For example, they may require initiation of screening at an earlier age, different screening intervals, the use of different screening modalities or a combination of these adjustments.[22] Therefore, some programs may choose to exclude high-risk individuals.

Ongoing follow-up of high-risk individuals will almost certainly occur outside the program. Since approximately 15% to 20% of all CRC occurs in high-risk individuals, it is important to appropriately manage these patients.[23] If possible, their participation rate should be documented separately from that of the average-risk population. Ways to identify and track elevated risk need to be developed. Individual self-identification, health-care providers charting risk status and information provided to specialists involved in care are fragmented at this time. Tailored approaches are also required to identify and improve participation of under-screened populations.

Consideration should also be given to the proportion of the target population who have undergone any colorectal test that would deem them up to date for CRC screening. The target population must also be informed about the benefits and harms of screening.

Retention in programmatic screening should be reported for each screening round. This is because participation is likely to decrease following each screening cycle and after individuals undergo colonoscopy. Programs need to establish policies or guidelines for ongoing surveillance of participants with abnormal FT followed by colonoscopy.

Where screening-related data are not readily available, surveys have proven useful.[24]

Several strategies can be used to engage populations in programmatic CRC screening and many can be used at the same time.[25,26] Strategies for improving uptake can be directed toward the target population, health professionals or both. Multiple evidence-based promotion and recruitment strategies are necessary to address factors that affect participation.[10,27,28] Specific strategies commonly used, with varying degrees of success, suggested in the Guide to Community Preventive Services,[29] include the following:

- Providing screening test kits directly to the target population (e.g., by mail)
- Personalizing invitations, reminder letters or postcards to alert individuals to the importance of screening
- Using general media messaging and printed materials to inform and motivate the broad target population, or tailoring these materials to the needs of specific, hard-to-reach populations
- Using family physician notification strategies
- Using tools to support physicians and other health-care professionals for programmatic CRC screening—for example, providing programmatic CRC screening guidelines and fact sheets
- Targeting social marketing campaigns to the public and to health-care providers
- Using age-dependent self-referral or family physician referral

The fact that in Canada some individuals have no family physician, and the impact on the program of some provincial privacy and information-sharing legislation (e.g., on invitations, data collection and reporting), should also be addressed.

3.2

Entry-Level Screening Test Domain

3.2.1. Background

Currently all CRC screening programs follow the national guidelines, based on randomized controlled trials, recommending FT as the entry-level test.[7,30]

In Canada in 2012, both FTg and FTi were used; FTi could be quantitative or qualitative. In addition, provinces employ different procedures for sample collection and analysis. In some instances analyses are centralized in one laboratory and in other instances, processed by multiple laboratories.

3.2.2. Recommendations

Participants should be provided with clear, simple instructions in order to minimize inadequate samples and maintain adherence to screening program standards. Programs should provide participants with program contact information to ensure access to clarify any concerns or problems with the screening test. Programs should be attentive to manufacturer specifications, especially regarding the transportation conditions and storage period standards for samples. If many laboratories are analyzing tests, common analytical platforms and quality standards are preferred to minimize inter-laboratory variability; laboratories providing FT analysis for screening should be accredited.

3.2.3. Indicators

The indicators in the entry-level screening test domain are early performance indicators. Inadequacy rate and positivity are currently the two indicators for this domain (Table 3). While the FT inadequacy and positivity rates can be affected by the type of test used and by the number of samples collected, they also provide information on how well the target population understands how to complete the entry-level test and consequently, about the quality of the information communicated.

TABLE 3
Quality Indicators for Entry-Level Screening Test Domain

INDICATOR*	TARGET	DEFINITION
FT inadequacy rate	≤ 5%	Percentage of individuals whose FT was inadequate and who have not repeated the test to get a successful FT result within a respective date frame
Positivity rate	N/D	Percentage of individuals with an abnormal FT result within a respective date frame

*Indicators should be reported by age group, sex, type of test and first and subsequent screen. N/D = not yet determined

FT Inadequacy Rate

The FT inadequacy rate is the percentage of individuals whose FT sample was inadequate and have not repeated the test to get a successful FT result. Inadequate FTs reflect the capacity of the participant to understand the instructions and to perform the entire procedure correctly; it may also reflect system issues such as delays in processing. The general recommendation in Canada, and elsewhere, is to keep the rate of inadequate FTs as low as possible. The current Canadian target is to have fewer than 5% of samples deemed inadequate.

Positivity

Positivity is the percentage of individuals with an abnormal FT result within a specific period. Positivity depends on many factors, such as the type of test, the manufacturer, the number of samples per test and the number of collection days. For FTg specifically, whether or not the sample is rehydrated influences positivity. Similarly, for FTi the cut-off threshold influences positivity, if using automated testing and sampling reproducibility. It is essential to document the decisions relating to these factors. The two common FTs (FTg and FTi) also differ in sensitivity and specificity.[31,32]

The 2010 European Guidelines on CRC screening provide additional information.[3] The authors of these guidelines recommend that the "[a]doption of a test device and the selection of a cut-off concentration should follow a local pilot study to ensure that the chosen test, test algorithm and transport arrangements work together to provide a positivity rate that is clinically, logistically and financially acceptable." Positivity is also expected to be higher in men than in women and to increase with age in both sexes.[33] Being male has been suggested as a risk factor for CRC[34] and the rates of CRC increase with age for both sexes.[35]

Considerations should be given to the amount of time between submission of the FT and notifying the individual of the results, especially if results are positive. The target for this indicator, as published in the European Guidelines, is 15 days.[3] This type of indicator should be considered in Canada. It is important to remember that "[w]hile small delays and clumsy processes may not impact on cancer outcomes, they can have a huge negative effect on patient experience."[36]

3.2.4. Other Considerations

Technologies other than fecal testing exist for CRC screening, but outside the context of organized screening programs, which means that individuals lose all the benefits of the program. The following is a quick overview of some of these technologies:

- Recent trials suggest that **flexible sigmoidoscopy** is an effective screening modality. The UK flexible sigmoidoscopy trial provides the strongest evidence to date that screening with a single examination can result in a significant 31% reduction in CRC mortality and a 23% reduction in CRC incidence.[37] Both FT and flexible sigmoidoscopy screening are now considered to have the strongest level of evidence as entry-level tests for CRC screening. With these new findings, the role of flexible sigmoidoscopy within programmatic CRC screening should be monitored and considered.[38]
- **Colonoscopy** enables the examination of the entire colon and is considered the most sensitive test for detecting advanced neoplasia. Its capacity for reducing CRC incidence and mortality has not been demonstrated in randomized controlled trials (RCT),[39] but case–control[40–46] – and cohort[47,48] studies support it. In a recent RCT, colonoscopy was compared with colonography and proved to be better at identifying advanced neoplasia, although participation was better with colonography.[49,50] When used as a population-based screening test on average-risk individuals, the discomfort involved and the risk of complications are substantial compared with other tests. A colonoscopy also requires more resources than an FT or flexible sigmoidoscopy. Canadian guidelines do not recommend colonoscopy as an entry-level test for CRC screening.[7]
- **Colonography** (virtual colonoscopy) is quickly gaining popularity given that it is a minimally invasive imaging technique that is more comfortable than colonoscopy and enables visualization of the entire colon. Colonography is almost as sensitive as colonoscopy for detecting cancers and large adenomas (10 mm or larger).[49–51] At this time, there are no RCTs to support colonography as an entry-level screening modality. However, emerging evidence suggests colonography may have benefits as a surveillance tool.[51]
- **Capsule endoscopy** has also been considered for screening, primarily as an alternative to colonoscopy because it examines the entire colon without the major risks associated with colonoscopy. Although no serious adverse effects have been reported using the capsule, accuracy data suggest that it is inferior to colonoscopy. In addition, more extensive bowel cleansing is needed than for colonoscopy.[52] A meta-analysis of seven studies reported a sensitivity of 69% and a specificity of 86% for significant polyps (> 6 mm).[53] A recent study using the second-generation capsule showed a sensitivity of 85%.[54,55] Further diagnostic performance results from large multicentre trials in the average-risk population are necessary before recommending this technology as a screening modality.[2]
- Progress on early **molecular biomarker** research is encouraging. A variety of DNA mutations and proteins have been identified in stool and serum that could be used as pre-clinical indicators.[56–59] These technologies have a high potential because the colonic epithelium is renewed every three to four days and cells are shed in the stool; thus turnover for tumours is even greater.[60] However, the evidence is not yet strong enough to consider the biomarkers as an alternative to fecal testing, particularly FTi.
- It has been suggested that offering individuals attending CRC screening a choice of different screening tests would improve screening rates.[27,61–63] Others argue that doing so would lessen enthusiasm about screening.[64,65] In their review, Partin et al. (2011) concluded that the evidence does not support either assumption and that decisions on which test to offer to the target population should be based on the physical and economic environment of the program.[66] The authors also noted that a "[s]creening program limited to FT and colonoscopy is likely to be ideal in most settings." Keeping screening modalities cost effective, timely and effective across the whole continuum are key priorities.[2,52,67]

3.3

Follow-Up Colonoscopy Domain

3.3.1. Background

Colonoscopy is currently the gold standard for follow-up of an abnormal FT. The two key components to colonoscopy are (1) safely, comfortably and completely examining the colon to the cecum within a reasonable time, and (2) successfully detecting and removing CRC and adenomas.[3,68]

This complex, invasive diagnostic procedure requires skill, experience and knowledge to be performed efficiently and safely. Timely follow-up after an abnormal FT is important and may be optimized by an efficient referral process, which may be facilitated by a navigation system. Colonoscopy quality can be monitored using a variety of indicators, many of which are relevant at the provider and health unit level rather than the national level.

3.3.2. Recommendations

A large body of literature exists on quality determinants and indicators for colonoscopy. Armstrong et al. (for the Canadian Association of Gastroenterology, 2012) identified processes and indicators of quality and safety relevant to endoscopy service delivery in the Canadian context.[69] The CAG working group identified 23 recommendations on ethics, facility standards and policies, quality assurance, training, education, competence and privileges, endoscopy reporting and standards, and individuals' perceptions. The group also identified 18 quality indicators, 20 safety indicators and 23 endoscopy reporting elements. Canadian CRC screening programs and endoscopy practitioners are encouraged to consult the CAG document and to adopt the recommendations wherever possible.

3.3.3. Indicators

At the national level, the indicators retained within the follow-up colonoscopy domain are early performance indicators. There are currently four indicators that have been identified for this domain:

- Uptake of colonoscopy following an abnormal FT
- Wait time between an abnormal FT and the follow-up colonoscopy
- Unplanned hospitalizations following the procedure
- Deaths following the procedure (Table 4)

These indicators reflect the referral system as well as the safety of the procedure itself.

Follow-Up Colonoscopy Uptake within 180 Days

The uptake of colonoscopy within 180 days of an abnormal FT result is an indicator of the capacity of the program to connect with the individual and facilitate the referral process so that the individual promptly attends a diagnostic procedure. The measure is the percentage of participants with an abnormal FT result who go on to a follow-up colonoscopy within 180 days of the date of the FT result.

The current target is uptake of 85% within 180 days, with point measurements at 60 and 180 days.

The Network has agreed that follow-up colonoscopies performed within 180 days of the abnormal FT result are most likely triggered by the abnormal result. There are many reasons (personal and organizational) that an individual may not have a follow-up colonoscopy after an abnormal FT. Nevertheless, effort should be made to keep the number of people with no follow-up as low as possible.

TABLE 4
Quality Indicators for the Follow-up Colonoscopy Domain*

INDICATOR	TARGET	DEFINITION
Follow-up colonoscopy uptake	≥ 85% within 180 days	Percentage of individuals with an abnormal FT result who go on to a follow-up colonoscopy within 180 days
Wait time to follow-up colonoscopy	≤ 60 days from abnormal FT for ≥ 90% of people	Time from an abnormal FT result to follow-up colonoscopy among those who had a colonoscopy within 180 days
14-day unplanned hospitalization following colonoscopy	N/D	Percent of individuals who have unplanned hospitalizations within 14 days of follow-up colonoscopy
30-day mortality following colonoscopy	N/D	Percent of individuals who die within 30 days of follow-up colonoscopy

*Indicators should be reported by age group, sex, type of test and first and subsequent screen. N/D = not yet determined

Wait Time to Follow-Up Colonoscopy

The wait time to follow-up colonoscopy is an indicator of the effectiveness of the referral system and the availability of the diagnostic procedure. It is calculated for participants who are followed up within 180 days based on the time between the first abnormal FT laboratory result and the follow-up colonoscopy. It is the percentage of individuals with an abnormal FT having a follow-up colonoscopy within a delineated time; the median and the 90th percentile are reported.

The current target is for at least 90% of individuals who do receive follow-up within 180 days to have a follow-up colonoscopy within 60 days.

14-Day Unplanned Hospitalization after Follow-Up Colonoscopy

The rate of unplanned hospitalizations in the 14 days after a follow-up colonoscopy captures some of the risk of the procedure; it includes only individuals for whom the hospitalization is not attributable to surgical or other curative interventions initiated because of a colorectal cancer diagnosis. Harm is represented by the percentage of individuals who had unplanned hospitalization within 14 days of a follow-up colonoscopy. The individuals included are those who had a follow-up colonoscopy within 180 days of an abnormal FT result. There is currently no Canadian target for this indicator.

This indicator is not restricted to hospitalizations for complications of colonoscopy; it remains a reliable indicator for which specificity can be improved by comparing to a control group or the baseline rate in the age-specific population. This indicator will have to be estimated using provincial and territorial administrative databases or by locally following up with those who have had a colonoscopy (e.g., retrospective chart review).

30-Day Mortality after a Follow-up Colonoscopy

The 30-day mortality rate after a follow-up colonoscopy is another indicator of the harm that could result from the procedure. For now, the rate is defined as the percentage of individuals deceased from any cause within 30 days of the follow-up colonoscopy. All causes of death are included in the calculation of this indicator, which makes it less specific for colonoscopy. However, its specificity may be improved by comparison with a control group or a baseline rate in the age-specific population. Further discussions or investigations, on a case-by-case basis, could be initiated to determine the deaths directly related to the colonoscopy.

3.3.4. Other Considerations

As discussed below, other indicators of colonoscopy quality have been recognized as important in monitoring CRC screening. These indicators may be measured by provincial and territorial screening programs, but are not currently reportable nationally.

In 2011, at the Targets and Quality Workshop held in St. John's, Newfoundland and Labrador, the importance of measuring and reporting on colonoscopy quality was stressed; it was suggested that standardizing colonoscopy training and credentialing be considered. Some participants suggested adding training as an additional quality indicator. Two recent studies also present some interesting observations:

- The observed disparity in endoscopic performance between surgical and gastroenterology trainees suggests the need for common training standards.[70]
- A withdrawal time of 10 minutes or more could be a good indicator for trainees, especially when a female is examined.[71] Colonoscopies are often classified as more difficult in females than in males because women have a

transverse colon that is significantly longer, and so have a greater total colonic length, than men despite women's smaller stature.

When evaluating colonoscopy, there are two important criteria to consider: the technical aspects of the procedure and the quality of the procedure.[3] A good technical indicator is the cecal intubation rate. A good indicator for the quality of execution of this procedure is the rate of adenoma detection.[36]

Other important quality determinants for colonoscopy are the annual volume performed by each endoscopist involved in the CRC screening program, their rates of polyp recovery and the quality of the bowel preparation of their patients. Participants in the 2011 St. John's workshop emphasized the importance of collecting data on these quality indicators. However, they did not think these indicators needed to be reported nationally because this information is more relevant at the program or provider level. Some workshop participants suggested adding training to the present list of quality indicators.

The most frequent complications related to colonoscopy are perforation and bleeding. However, cardiopulmonary complications and infectious complications can also occur. Programs should institute a quality assurance program that would allow them to track complications arising from colonoscopies. Acquiring an accurate estimate of colonoscopy harm requires a rigorous approach to capture complications after the patient has left the endoscopy department; otherwise, harm will always be underestimated.[36]

The variation in complication rates between the studies is due partly to differences in methodologies and to underreporting.

3.4

Diagnosis and Initiation of Treatment Domain

3.4.1. Background

Colorectal cancer control stakeholders have focused on accurate diagnosis and timely treatment for many years.[71–73] A powerful performance indicator for any screening test is the positive predictive value (PPV); that is, the proportion of individuals with a positive FT result that have the condition, divided by the number of individuals that had a positive FT result. This indicator reflects the probability that a positive test result indicates the underlying condition being tested for.

3.4.2. Recommendations

Individuals diagnosed with polyps should undergo proper follow-up, including short- and long-term surveillance. Timely and accurate information on diagnostic outcomes should be transferred to health-care providers and individuals.

3.4.3. Indicators

An important performance indicator for any screening test is the proportion of positive entry-level tests that are true positives (correct diagnosis), namely the PPV.

The indicators retained within the diagnosis and initiation of treatment domain are early performance indicators. Currently, six indicators have been identified for this domain. They are PPV for adenoma, advanced adenoma, neoplasia, CRC and advanced neoplasia, as well as the wait time from the colonoscopy to the definitive pathological diagnosis and to the initiation of treatment (Table 5). These indicators reflect the accuracy of the diagnostic procedure and case management.

For adenomas, all diagnoses are considered and each individual is counted once, based on the most advanced lesion.

Positive Predictive Value

The PPV is the proportion of individuals with one or more of the diagnoses of interest (adenoma, advanced adenoma, CRC, neoplasia or advanced neoplasia) among those with a positive FT result confirmed by pathology from a follow-up colonoscopy within 180 days of the abnormal FT result.

Adenoma detection rate (ADR), expressed as PPV, is a widely used indicator of colonoscopy quality. It can be a marker of both the technical quality of the procedure and

the efficacy of the screening strategy.[74] The Canadian target is a PPV ≥ 35% for adenomas identified with FTg and a PPV ≥ 50% for adenomas identified using FTi.

An advanced adenoma is an adenoma that is either 1 cm or more in size, has a villous or tubulovillous component or high-grade dysplasia.

TABLE 5
Quality Indicators for the Diagnosis and Initiation of Treatment Domain*

INDICATOR	TARGET	DEFINITION
PPV adenoma	≥ 35% for FTg; ≥ 50% for FTi	Percentage of individuals with an abnormal FT result diagnosed with adenoma(s)
PPV advanced adenoma	N/D	Percentage of individuals with an abnormal FT result diagnosed with advanced adenoma(s)
PPV invasive CRC	N/D	Percentage of individuals with an abnormal FT result diagnosed with invasive CRC
PPV neoplasia	N/D	Percentage of individuals with an abnormal FT result diagnosed with adenoma or CRC
PPV advanced neoplasia	N/D	Percentage of individuals with an abnormal FT result diagnosed with advanced adenoma or CRC
Wait time from follow-up colonoscopy procedure to definitive pathological diagnosis	N/D	Time from follow-up colonoscopy to definitive pathological diagnosis
Wait time from screen-detected CRC to initiation of treatment	N/D	Time from CRC diagnosis (date of pathology report) to initiation of first treatment (surgery, radiotherapy, chemotherapy)

*Indicators on PPV should be reported by age group, sex, type of test and first and subsequent screen. N/D = not yet determined

While cancer detection rate is important, it is not a sensitive measure of colonoscopy quality and depends more on the underlying prevalence of CRC in the population than on the technical skills of the colonoscopist.

As in many other countries, in Canada *in situ* CRCs are reported with advanced adenomas. The proportion of individuals with any adenoma or CRC confirmed by pathology and detected from programmatic screening is often reported internationally to evaluate and compare the impact of screening. "Rates of adenoma and cancer per 100 colonoscopies are designed to maintain a high quality of screening by minimizing the number of false-positive referrals."[75]

Wait Time to Pathological Diagnosis

The wait time to pathological diagnosis can be calculated using the median and 90th percentile between the follow-up colonoscopy procedure and the definitive pathological diagnosis. If specimens have been collected by polypectomy during the follow-up colonoscopy, diagnosis will be confirmed by pathology. The *European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis* (2010) suggest that the diagnosis should be available to individuals within 15 days of the colonoscopy. There is very little information on this measure, but in their article on the uptake and early outcomes of the first million people screened in England, Logan et al. (2012) stated, "Where one or more polyps have been removed, the patient is offered an appointment at a follow-up clinic in the next week."[76]

The date of definitive pathological diagnosis refers to the date of the initial pathological report after a complete colonoscopy that confirms the presence (or absence) of CRC or adenoma. It does not refer to any additional colonoscopies or pathological reports required for the characterization of CRC.

Wait Time from Screen-Detected CRC to Initiation of Treatment

When CRC cases are identified through programmatic CRC screening, access to the cancer care system can largely determine whether a CRC program is successful or not,

including early screening for psychological distress and initiation of psychosocial support.

No target has been proposed for now, but mortality reduction through CRC screening and early detection can be achieved only when patients receive timely, adequate treatment.

3.4.4. Other Considerations

With the implementation of programmatic CRC screening, increased numbers of individuals will not only require diagnostic follow-up colonoscopy as a result of abnormal entry-level test results, but will also require ongoing surveillance colonoscopy if adenomatous polyps are found. This follow-up will further increase pressure on colonoscopy services. An organized and measured approach is required to address capacity issues and appropriate use of limited endoscopic resources. This includes surveillance intervals for those with a history of adenomatous polyps. Individual programs should adopt protocols according to evidence-based clinical practice guidelines and recommendations regarding surveillance intervals.[77]

Individuals diagnosed with, and treated for, adenomatous polyps require adequate ongoing surveillance. Cases with other incidental clinical findings should also be managed appropriately based on program parameters. A well-designed patient navigation system, with adequate staffing, should be in place to facilitate timely movement of individuals through the health-care continuum.

Since calculation of PPV is not uniform among countries offering programmatic CRC screening, calculating PPV for cancer for all patients with abnormal FT results, with or without follow-up colonoscopy, must be considered. If the follow-up colonoscopy uptake is very high, the two ways of calculating PPV will be very similar. For now, in Canada, the Network has agreed to calculate PPV for participants who undergo follow-up colonoscopy after an abnormal screening FT.

The term “advanced adenoma” describes a range of lesions that vary widely in terms of cancer progression risk. It was originally created because researchers required a surrogate outcome more common than CRC.[78]

Advanced adenoma may be considered a convenient proxy for CRC, but its use as an outcome measure may be misleading in screening studies since the natural history of this lesion is unknown.[78]

Case management includes strategies such as patient navigation that are effective in programs within and across the continuum of care, primarily when patients have a diagnosis of cancer and are chronically ill. Where necessary, these strategies must also address ethno-cultural and socio-economic barriers.[79] Measuring the effectiveness of case management strategies and determining the quality of case management approaches will require different evaluation metrics and techniques; this is best accomplished locally.

3.5

CRC Screening Program Outcomes Domain

3.5.1. Background

The primary goal of programmatic CRC screening is to reduce CRC mortality through early detection and effective follow-up and treatment. Program outcomes depend on many factors, including effective program planning, co-ordination and management, adequate resources, capacity, high participation, quality service provision along the screening pathway and integrated patient care. Therefore, program outcomes reflect the collective efforts of all stakeholders and ultimately allow program performance evaluation at all steps along the screening pathway.

3.5.2. Recommendation

Programmatic CRC screening should establish and maintain a system that collects information about incidence, mortality and staging of CRC for the screened population and the general population.

3.5.3. Indicators

It may take years to see the impact of programmatic CRC screening on mortality. In the meantime, surrogate outcomes such as the adenoma detection rate can be monitored and can assist in evaluating the long-term outcomes of programmatic screening. Six indicators have been identified for the programmatic CRC screening outcomes domain (Table 6):

- Stage distribution of invasive CRC
- CRC incidence
- Adenoma detection rate
- CRC detection rate
- CRC mortality rate
- Interval CRC rate

Stage Distribution of Invasive CRC

Screening aims to reduce the incidence of cancer, especially the incidence of late-stage CRC. A shift toward detection of cancer at earlier stages and overall improvements in survival rates are anticipated as participation in programmatic CRC screening increases. However, "It is too soon to see a measurable impact of CRC screening on stage at diagnosis in Canada. As CRC screening programs achieve higher uptake, we anticipate a reduction in the incidence of CRCs diagnosed in late stage, as seen in the US."[80]

TABLE 6
Quality Indicators for the CRC Screening Program Outcomes Domain*

INDICATOR	TARGET	DEFINITION
Invasive CRC stage distribution	N/D	Distribution of screen-detected invasive CRC by stage within a respective date frame
CRC incidence	N/D	Age-adjusted CRC incidence in target population and by exposure to CRC screening within a respective date frame
Adenoma detection rate	N/D	Number of individuals with one or more adenoma(s) confirmed by pathology from a follow-up colonoscopy performed within 180 days of an abnormal screening FT per 1,000 screened within a respective date frame
CRC detection rate	≥ 2 per 1,000 screened	Number of individuals with CRC confirmed by pathology from a follow-up colonoscopy performed within 180 days of an abnormal screening FT per 1,000 screened within a respective date frame
CRC mortality rate	N/D	Age-adjusted CRC and non-CRC mortality rates in target population exposed to CRC screening within a respective date frame
Interval CRC rate	N/D	Percentage of individuals with normal screening results (i.e., normal FT, or abnormal FT followed by normal colonoscopy) subsequently diagnosed with CRC before next scheduled screening test
Wait time from screen-detected CRC to initiation of treatment	N/D	Time from CRC diagnosis (date of pathology report) to initiation of first treatment (surgery, radiotherapy, chemotherapy)

*Indicators of invasive CRC stage distribution, adenoma detection rate and cancer detection rate should be reported by sex and first and subsequent screen.
N/D = not yet determined

Incidence of CRC

Strong evidence indicates that CRC screening reduces the incidence of CRC through removal of premalignant polyps. A United States study on CRC incidence and mortality among individuals aged 50–75 years concluded that CRC incidence decreased 3.4% per year from 2003 to 2007;[81] the authors attributed 50% of the decrease in incidence to higher uptake of screening and 50% to reductions in risk factors such as smoking and obesity, but it must be noted that conclusions from this study were based mainly on screening with flexible sigmoidoscopy or colonoscopy. In another study, Mandel et al., evaluating the effect of fecal occult blood screening on the incidence of colorectal cancer, concluded that "The use of either annual or biennial fecal occult-blood testing significantly reduces the incidence of colorectal cancer."[82]

Adenoma Detection Rate (per 1,000 Screened)

Participants at the Target and Quality Indicators Workshop suggested that the ADR should be reported per 1,000

screened in addition to reporting the PPV for adenoma (see 3.4.3). This indicator is a marker of both the technical quality of the colonoscopy procedure and the efficacy of the whole screening program strategy.[74] Adenoma detection rate could be an independent predictor of the risk of interval CRC.[83]

Cancer Detection Rate (per 1,000 Screened)

While cancer detection rate is crucially important, it is not a sensitive measure of colonoscopy quality and tends to depend more on the underlying prevalence of CRC than on the technical skills of the colonoscopist.[74] However, it is important to measure the cancer detection rate at the program level to evaluate the effectiveness of a screening program.

The 2011 workshop participants suggested that the target for programmatic CRC detection rate in Canada be set at ≥ two per 1,000 screened.

CRC Mortality

Mortality from CRC is an important link in the chain of indicators that assess performance of programmatic CRC screening. Randomized controlled trials have demonstrated that CRC screening using an FT can reduce mortality from the disease.[84]

Population-level data are also emerging. In a recent publication, the United States Centers for Disease Control reported a decrease in CRC incidence of 3.4% per year and a decrease of 3.0% per year in the CRC death rate from 2003 to 2007.[81] The largest declines were observed in states with the highest screening prevalence. The authors concluded that approximately 50% of the mortality reduction could be attributed to increased screening, with 35% attributed to reductions in risk factors and 12% to improved CRC treatment.

Interval Cancers

Interval cancers are defined as cancers that occur after a normal FT or after an abnormal test result followed by a negative assessment (usually a colonoscopy) and before the next FT is due. Endoscopist factors and tumour etiology are the two main factors that contribute to the occurrence of interval CRCs. The precise contribution of each of these factors can be difficult to determine.[85]

Steele et al. (2011) compared the stage and outcome of interval cancers with cancers arising in populations not screened through programs. They concluded that although FTg is associated with substantial interval cancer rates that increase with each screening round, the absolute numbers do not increase, and these interval cancers had a better prognosis than those diagnosed in the non-screened population.[86]

Zappa et al. (2010) reported that the risk of developing an interval cancer was almost three times higher when FTg is used as a screening test rather than FTi.[87]

3.5.4. Other Considerations

- The targets for ADR and cancer detection rate should be met to achieve the reduction in CRC mortality estimated in clinical trials.[75]
- Population screening is performed to prevent morbidity and mortality in asymptomatic individuals. Although complications are rare, every effort should be made to minimize morbidity and mortality related to screening.
- The capacity of, and access to, the cancer care system when CRC cases are identified through programmatic screening are significant factors in determining whether programmatic CRC screening is successful or not. Early identification of psychological distress and initiation of psychosocial support should not be overlooked by the clinical treatment team.
- The adenoma detection rate is an important marker of programmatic screening effectiveness. The mean number of adenomas per procedure and mean number of adenomas per positive procedure provide additional useful information for this indicator[74] and should be considered as a future indicator.
- When comparing interval cancer rates, it is important to take into account the type of screening FT used, as well as the adenoma detection rate in the context of colonoscopy performed after an abnormal FT result.
- A shift in overall invasive CRC stage distribution in the general population could take many years. However, comparison of stage distribution between screened and unscreened individuals should show disease detection at an earlier stage in the screened population.[88]

3.6

Program Performance Reporting

3.6.1. Background

"Quality improvement is underpinned by robust and reliable methods of data collection and reporting that are not burdensome."[36]

To measure screening performance it is necessary to develop a systematic and efficient reporting process using a set of high-level, agreed-upon indicators. These will provide policy-makers and health-care providers with the knowledge necessary to assess and improve the delivery of CRC screening.

Collection of indicator information has the potential to highlight data quality issues and gaps and any caveats that exist. It can also guide others in collecting data and producing similar types of reports. Previous results reports have proven useful for participating CRC screening programs because they were able to identify gaps in their data accessibility and improve consensus on definitions. Overall, at the end of the process, both local and pan-Canadian reporting was improved.

In the investigation of the programmatic CRC screening performance reporting process, several tools have been developed and are continuously adapted to the specific round of data collection. These tools include the following:

- A survey of the availability of data for each indicator
- A summary of the program's characteristics
- Instructions on data definitions and calculations
- A template for data collection related to quality indicators (including logical checks and warnings)

3.6.2. Considerations Regarding the Reporting Process

- The feasibility of providing data on quality indicators, and the availability of these data locally, will be evaluated for each round of data collection until the collection process is sufficiently mature.
- Only aggregated data are currently collected at the national level.
- An indicator should not be reported if fewer than three provinces or territories can provide data on it. Nevertheless, the information on these indicators can be gathered locally and shared among other CRC screening programs.
- Reports on quality indicators will be produced regularly, initially every year (until all programs are reporting) and ultimately every two years.

3.6.3. Next Steps for Development of Quality Determinants and Quality Indicators

- Continued work to reach consensus on national quality indicator targets is necessary, including indicators that have already been defined and new indicators that provide a complete understanding of performance along the CRC screening pathway.
- New quality determinants, quality indicators and targets will continue to be developed and included in the document, wherever appropriate.
- Refinement of data definitions for indicators will be ongoing in order to adhere to international definitions and calculations (e.g., advanced adenoma) and to address provincial and territorial requests for improved clarity.
- Provincial and territorial data experts will continue to be regularly invited to participate in an exchange of experience and knowledge through face-to-face meetings and webinars. These interactions will help to address the challenges related to quality determinants and quality indicators and to support local standardization and improvement of processes and data collection.

CHAPTER 4
Conclusion

This document provides an updated compilation of quality determinants and quality indicators for colorectal cancer screening programs in Canada. Ongoing review of the emerging evidence and timely updating of the quality determinants and indicators is important for measuring the success of CRC screening in Canada. Review also fosters a national forum where knowledge, ideas, innovations and experiences are shared and discussed between stakeholders; this forum is an important part of the iterative process.

Although the indicators are tailored to the Canadian context, reporting will depend on each program's stage of development and interests. Over time, it is anticipated that all provinces and territories will be able to participate fully.

The indicators have been selected and developed with the additional objective of including Canada in the international community of CRC screening programs. It is anticipated that the national and international comparison of these indicators and the consultative process surrounding this comparison will allow lessons to be learned, better ways of providing services to be revealed and evidence to become available for supporting program development. Clinical services provided to symptomatic patients or patients with cancer could also benefit from the adoption of some of the determinants and indicators for CRC screening programs.

While it is widely recognized from the evidence that the reported benefits of CRC screening outweigh the potential harms and the costs to the health-care system, continuous improvement of the quality of organized programs will ensure that harms associated with CRC screening will be minimized and benefits maximized.

4.1

Future Directions

Organized CRC screening programs in Canada are in various stages of planning and implementation. As more programs become operational and available across the provinces and territories, there will be an ongoing need to explore the more complex aspects of quality, additional quality determinants and new targets.

As other entry-level screening test technologies, such as flexible sigmoidoscopy, demonstrate effectiveness, it will be necessary to consider their use as a standard of care for Canadians. It will be important to evaluate these tests for acceptability, efficiency, effectiveness and cost effectiveness when used for population screening.

In the longer term, as screening uptake increases, some inequities may become apparent; some populations may be under-screened or there may be over-diagnosis or over-treatment. It will be important to address these

possibilities as they come to the attention of the Network and its partners.

The management of average-risk individuals with abnormal fecal test results and normal colonoscopies at follow-up should be addressed. There is a paucity of evidence, and substantial variation in opinion and practice, with respect to ongoing clinical management of these individuals. The objective is to limit the strain on program resources—many clinicians choose further investigation in the absence of evidence-based guidelines. In addition, the greater number of polyps requiring surveillance will increase demand on the health-care system. It will be important for the Network to provide feedback to help programs to stay up to date with these trends.

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Definitions and Useful Terminology

Variables related to FT screening

The following process variables are described in the context of CRC screening in which FT is used as the primary screening test.

Screened/tested
(screened or tested participants)

People who have used and returned an FT, irrespective of the test result, including people with inadequate or incomplete results. Each person is counted once, regardless of the number of tests performed.

Inadequate test

An FT returned by a participant in which the results cannot be reliably determined (see Section 1). The quality is insufficient for processing and the test cannot be used for recording a result according to the program policy.

Abnormal test
(also referred to as a positive test)

An abnormal FT result based on the last adequate test that, according to the program policy, leads directly to a follow-up colonoscopy referral.

Normal test
(also referred to as a negative test)

A normal FT result based on the last adequate test according to the program policy.

Follow-up colonoscopy

Participants with an abnormal FT require a follow-up colonoscopy. Ideally all participants with abnormal FTs are referred for follow-up colonoscopy.

Variables related to endoscopic screening

The following process variables are described in the context of CRC screening in which either flexible sigmoidoscopy (FS) or colonoscopy is used as the primary screening test.

Screened

Screened participants who have attended the FS or colonoscopy screening examination, irrespective of the result, including people with inadequate or incomplete results. Each person is counted once regardless of the number of exams performed.

Inadequate test

Participants who attended FS or colonoscopy screening for whom the test results could not be interpreted within the reporting period. A new screening examination should be performed.

Abnormal test
(also referred to as a positive test)

An abnormal screening FS or colonoscopy resulting either in diagnosis of cancer, removal of an adenoma or other lesion or referral for further investigation, according to the program policy.

Normal test
(also referred to as a negative test)

An FS or colonoscopy screening test that reports no abnormalities based on the last adequate test according to the program policy.

Follow-up colonoscopy

Participants with an abnormal screening FS or colonoscopy require a follow-up colonoscopy.

Referral to surgery or tertiary endoscopy

Participants who require surgery or tertiary endoscopy for removal of challenging lesions following a positive FS or colonoscopy.

Severe complications requiring hospitalization

Severe complications requiring hospitalization within 14 days of FS or colonoscopy due to serious hemorrhaging involving transfusion, or due to perforation, vagal syndrome or peritonitis-like syndrome.

30-day mortality

Deaths that may occur within 30 days after an FS or colonoscopy, whether diagnostic or therapeutic. If the death is attributed to complications caused by the endoscopy, the participant should be counted in this group.

Lesion

Any lesion removed or biopsied at endoscopy or surgery (whether or not it is diagnosed as adenoma).

Adenomas

Pathological specimens removed at endoscopy or surgery that have been reported by a pathologist to be adenomatous.

Cancers

Colorectal cancer diagnosed by the screening program, or diagnosed as a direct result of participating in the screening program.

Appendix

CRC Screening Monitoring Program Performance Working Group Membership

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