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Quality Determinants for Colorectal Cancer Screening in Canada

Published September 30, 2009

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List of Abbreviations

CRC	Colorectal cancer
FIT	Fecal immunochemical test
gFOBT	Guaiac fecal-occult blood test
GRS	Global Rating Scale
NCCSN	National Colorectal Cancer Screening Network
PPV	Positive predictive value
QD	Quality determinant
QI	Quality indicator
SPMG	Screening Action Performance Measurement Group

Note: The term “positive” may be used interchangeably with “abnormal” when referring to fecal test result.

Executive Summary

In November 2008, the Canadian Partnership Against Cancer (the Partnership) and the National Colorectal Cancer Screening Network (NCCSN) mandated a Working Group to identify quality determinants (including quality indicators) to be delivered in a formal report for use by organized colorectal cancer screening programs in Canada.

The Working Group engaged stakeholders from across Canada to participate in the process and gathered input from participants attending the NCCSN-sponsored Quality Determinants Workshop in May 2008 and a forum in April 2009; the *Quality Determinants for CRC Screening Programs in Canada* report was developed and then reviewed by independent nationally and internationally acknowledged CRC screening experts.

The quality determinants (QD) identified in this report are based on a conceptual colorectal cancer (CRC) screening pathway and are comprised of five key domains within the screening pathway: participation, screening, diagnostic follow-up, case management and program outcomes. This report also focuses on average risk, using entry-level fecal tests with colonoscopic diagnostic follow-up for those with abnormal fecal test results.

QDs are considered conceptual. They describe processes and activities that are related to quality but they cannot be measured directly. Quality indicators (QI) are metrics that allow for practical, quantifiable and reliable comparison

The QDs and QIs presented here will not only allow programs to evaluate internal processes, but—importantly—will also facilitate comparison of results, both in Canada and internationally. It is through measurement and comparison that lessons can be learned, better ways of providing services revealed and evidence made available to support program development and change.

Quality determinants have been proposed within each of the five domains; a total of 20 indicators have been identified and defined to date, as listed below.

- Participation
  - Participation
  - Screening retention
  - Utilization
- Screening Test
  - Positivity
  - Positive predictive value for CRC
  - Positive predictive value for adenoma
- Diagnostic Follow-Up
  - Colonoscopy completion
  - Wait time to colonoscopy

  - Wait time to pathological diagnosis
  - Colonoscopy CRC detection
  - Colonoscopy adenoma detection
  - 30-day non-CRC-related hospitalization after follow-up colonoscopy
  - 30-day non-CRC mortality after follow-up colonoscopy
- Case Management
  - Wait time from screen-detected CRC diagnosis to initiation of treatment program
- Outcomes
  - Program CRC detection rate
  - Interval CRC incidence
  - CRC stage distribution
  - CRC incidence
  - CRC mortality
  - Non-CRC mortality

Introduction

Context (Preamble)

In 2002, the Canadian National Committee on Colorectal Cancer Screening (National Committee) published a report with key recommendations for colorectal cancer screening in Canada. Following an extensive review of the literature, the National Committee recommended that:

- CRC screening be available to Canadians via organized, high-quality, safe, effective and efficient programs
- A screening pathway be developed, including a fecal test as an entry-level test
- A defined interval for screening be specified
- Abnormal results on the entry-level test be followed up with a more definitive test.

Since 2007, several provinces have committed to and/or are implementing organized CRC screening programs. Most are generally in agreement with the recommendations of the National Committee and have primarily adopted an average-risk approach using entry-level fecal tests with colonoscopic diagnostic follow-up as the basic pathway for population-based organized CRC screening. However, there are and will continue to be multiple program approaches in Canada to accommodate regional or local needs. These programs may use a variety of entry-level or diagnostic follow-up tests and may or may not include varying levels of risk for CRC.

In 2007, the Canadian Partnership Against Cancer launched the National Colorectal Cancer Screening Network. The NCCSN is a group of provincial/territorial CRC screening program representatives and key stakeholders that engage in collaborative discussions, projects and information-sharing. The NCCSN capitalizes on shared expertise and identifies collaborative opportunities for efficiencies in the planning, implementation and evaluation of CRC screening programs. A key priority identified by the NCCSN is to identify pan-Canadian quality determinants to support organized CRC screening programs.

The NCCSN also recognized that all jurisdictions plan to monitor the quality and effectiveness of their programs and since variation among programs exists, there is an opportunity to conduct a natural study comparing approaches, which further supports the adoption of a common set of QDs and QIs.

Concurrent with and in addition to the work of the NCCSN, the Partnership had also established a Screening Action Performance Measurement Group (SPMG). In 2008, the SPMG delivered a list of generic performance measures and definitions that could be adapted for use in any organized cancer screening program in Canada; these measures and definitions would serve as a guide to promote consistent reporting, calculation and interpretation of key performance measures for cancer screening and would support efforts for optimal program performance (SPMG 2008).

In May 2008, under the leadership of Dr. Heather Bryant, Vice-President of Cancer Control for the Partnership and Chair of the NCCSN, a pan-Canadian Colorectal Cancer Screening Quality Determinants Workshop was convened. The purpose of this workshop was to discuss issues pertaining to, and build a culture of quality into, organized CRC screening programs in Canada.

In November 2008, the Partnership and the NCCSN mandated a group of experts to build on the workshop's conclusions and related projects, such as the SPMG guidelines, and to propose quality determinants for organized CRC screening in Canada.

This historical background is provided to set the context for this report and to provide the rationale for focusing on average risk, using entry-level fecal tests with colonoscopic diagnostic follow-up for those with abnormal fecal test results. The report does, however, address program variation where applicable and appropriate.

Goal and Objectives

The purpose of the *Quality Determinants for Colorectal Cancer Screening in Canada* report is to provide pan-Canadian quality determinants to support organized CRC screening programs.

This goal was accomplished by:

- Identifying and selecting characteristics of quality (referred to as quality determinants and consisting of principles, processes and activities) essential for maximizing the benefits of organized CRC screening in Canada while minimizing the potential risks
- Ensuring that quality determinants are relevant and evidence-based
- Defining measurable quality indicators that objectively assess the level of conformity of the determinants and allow for meaningful interpretation and pan-Canadian comparison of program components over time and among programs
- Prioritizing quality indicators to support phased implementation of data collection and reporting
- Fostering a pan-Canadian collective understanding, agreement and commitment to an initial set of essential quality determinants and related quality indicators.

Adoption of a common set of quality determinants has the potential to benefit each CRC screening program through provision of local, pan-Canadian and international evidence to inform program status and improvement through the ability to meaningfully compare performance across jurisdictions.

Quality Determinants for Colorectal Cancer Screening in Canada is a preliminary step in an iterative process. Quality-related initiatives such as setting targets,

standardizing processes and research, however, are beyond the scope of this first report.

This report supports the NCCSN in its efforts to implement efficient, high-quality, organized, population-based CRC screening in Canada. The NCCSN's members should in turn adopt and share this report with the stakeholders in their jurisdictions and with partners to advance high-quality colorectal cancer screening, diagnosis and case management.

Principles

Provincial/territorial CRC screening programs are organized, population-based programs involving multiple stakeholders and a variety of health services and providers. Programs may differ, however, with respect to the target population, primary entry-level screening test, screening interval, service delivery model and other parameters. The overall success of these programs depends on ensuring that quality is maintained in all program components and services to maximize the benefits of screening while minimizing the potential risks.

Quality will be measured in the distinct domains of organizational and clinical structures, processes and outcomes. This report describes the essential quality determinants and indicators for organized CRC screening programs in Canada.

The pan-Canadian Working Group on Quality Determinants in Colorectal Cancer Screening in Canada acknowledges that quality has multiple facets. The success of a high-quality, organized, population-based CRC screening program depends on fundamental principles, including the criteria described below.

People Focused

All programs involve individuals who receive services (that is, individuals who undergo screening, follow-up or diagnosis) and health-care professionals who provide those services. The goals of any program are to provide the highest-quality service to optimize the benefit to the population, to protect the safety of recipients and to ensure that decisions by health-care professionals respect individuals' needs and preferences.

Partnership and a Multidisciplinary Approach

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

Evidence-Based Decision-Making

All 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—and the available choices.

Equity

The population should have appropriate and timely access to CRC screening and follow-up services. Organized programs should ensure reasonable parity in the

provision of benefits among geographic regions and among different social, demographic and economic groups within the target population.

Ethical Responsibility

The goal is to conduct programs that will reduce morbidity and mortality from colorectal cancer in the screened population while minimizing the harm and anxiety that can arise from screening. Programs have the responsibility to ensure that the balance between positive and detrimental effects of screening is optimized to the benefit of the population. However, some individuals will experience more harm than benefit and all participants should have enough information to make an informed decision.

It is also essential to ensure that screening does not limit access to health-care services for patients who are suffering from diseases (Strong et al. 2005).

Stepwise Implementation

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

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 in the health system. Furthermore, some quality determinants and quality indicators also apply to services provided for non-screening-related clinical activities—therapeutic colonoscopy, for example. Thus, it is expected that the implementation of screening programs will also have a positive impact on the quality of related clinical services offered beyond screening programs.

Sustainability

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

Methodology

For the purposes of this report, quality determinants are considered conceptual. They describe principles, processes and activities that contribute to the quality of the program but they cannot be measured directly. Quality indicators are metrics that allow for practical, quantifiable and reliable comparison. An example of a quality determinant for a CRC screening program might be use of personalized CRC screening invitations to increase the participation of the targeted population. The participation rate would be a quality indicator that could be used to evaluate the impact of this specific quality determinant.

To identify quality determinants for CRC screening programs across Canada, it is essential to discuss, understand and gain consensus on a systematic process and the required tools. This process includes:

- Understanding QDs in the context of international, pan-Canadian, provincial/territorial, local and case-based settings and clearly differentiating between them
- Describing QDs and their respective indicators in a structured format that grounds quality determinants to the reality of CRC screening programs (a CRC screening pathway typically found in most organized programs is used for this purpose)
- Building consensus and providing clarity on the QD deliverable.

Regardless of how programs differ, there are key QDs and measurable indicators that are common to all organized evidence-based programs; these indicators may be used for pan-Canadian reporting purposes. Further definition, subdividing or detailing of quality indicators will depend on the needs and reporting priorities of the provincial and local programs and on the availability of relevant data.

CRC Screening Pathway

Quality determinants are expected to cover all the processes included in the CRC screening pathway. The Working Group adopted a pathway for this report (Figure) typical of an evidence-based CRC screening program that primarily targets 50- to 74-year-old people with average risk as described in the literature and recommended by the National Committee and commonly used in Canada. It is assumed that organized CRC screening programs use fecal tests as the primary screening tests for individuals aged 50 to 74 with average risk. Fecal tests can be guaiac fecal-occult blood tests (gFOBTs) or fecal immunochemical tests (FITs).

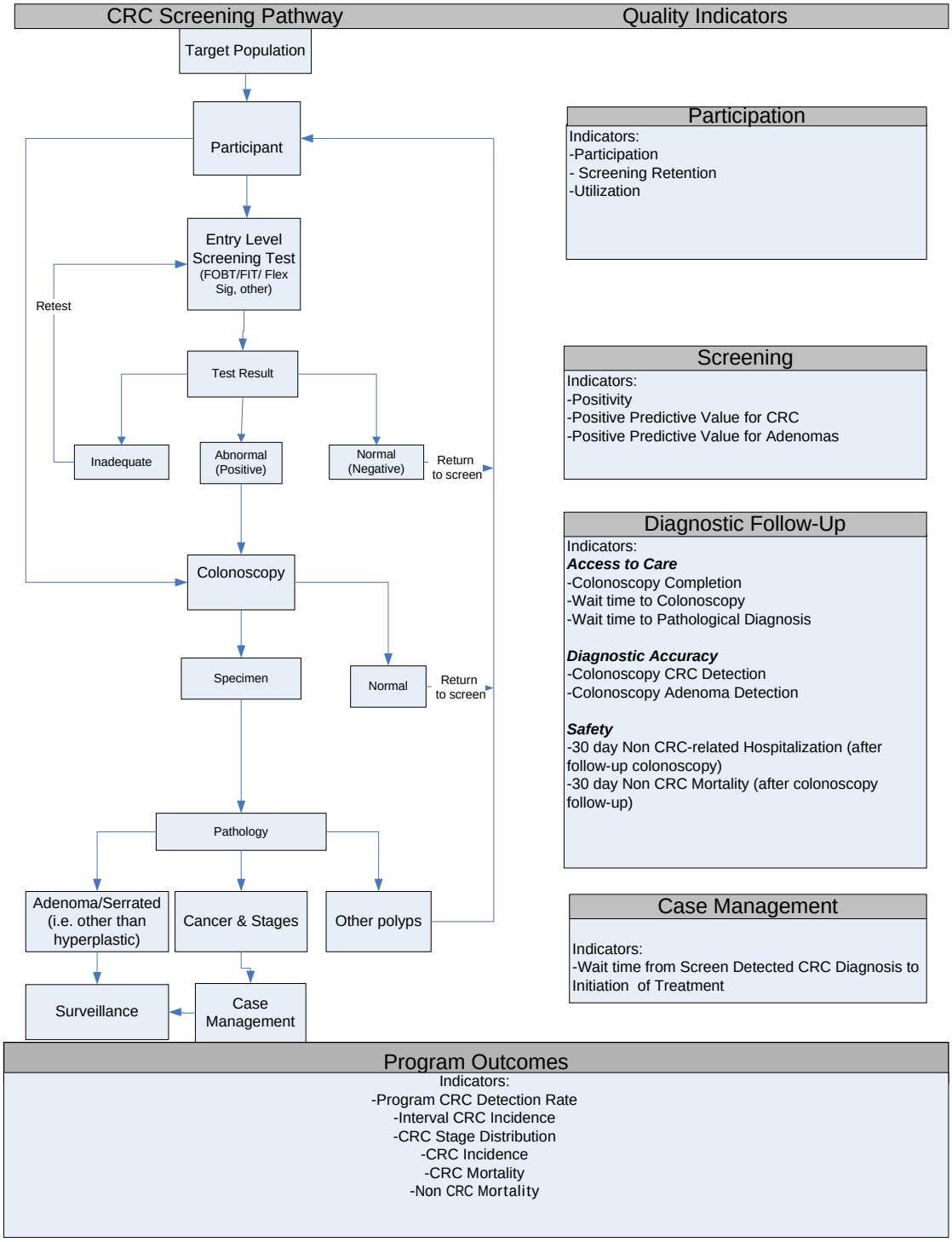
However, to reflect the diversity in CRC screening programs, approaches and policies within and across jurisdictions in Canada, this pathway includes additional screening scenarios (depicted by arrows, boxes or both) that will not be implemented everywhere and include higher risk levels screened by colonoscopy, and average-risk screening using other primary screening modalities and/or diagnostic follow-up with modalities other than colonoscopy.

The pathway also serves to identify the five key domains of any organized CRC screening program, namely:

- Participation
- Screening Test
- Diagnostic Follow-Up
- Case Management
- Program Outcomes

It should be noted that the "program outcomes" domain cuts across all four of the "activity" domains of the CRC screening pathway. Treatment and palliative care are recognized as critical factors contributing to the condition of participants; however, it is also recognized that treatment of CRC is highly specialized and also involves patients whose cancers were not detected by screening. Recommendations for QDs in these areas are therefore beyond the scope of this report.

Figure. Common Colorectal Cancer Screening Pathway (including possible variations) and Quality Indicators in Each Pathway Domain



Quality Determinants and Indicators

As discussed, QDs are conceptual and QIs are the metrics by which QDs are quantified. The identification of key QDs and the adoption of a common set of QIs across jurisdictions and over time will allow for meaningful and reliable comparisons of screening programs.

The appropriateness of each proposed QI was assessed using criteria developed by Bédard et al. (2006) (Table 1). Only the QIs 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	Data needed to assess the indicators need to be available or 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 a large majority of the population, not only by experts or 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 at regional, provincial, national and international levels.
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.

Indicators can provide meaningful interpretation and information only when calculated according to specific characteristics (e.g., demographic, social and clinical). Age group and gender are most commonly used for this purpose. Other QIs need to differentiate socioeconomic status or cancer stage at diagnosis. These characteristics are valuable and should be used for further investigation and research. Indicators in this report will include these characteristics where appropriate (referred

to as cross-tab variables in the Appendices). They are essential for interpretation and meaningful comparisons.

In the development of a first set of quality determinants and indicators, it is assumed that some essential aspects of the quality of a CRC screening program will be addressed indirectly rather than directly. For example, the availability of resources (human and financial) will be indirectly assessed by measuring wait times.

Since this report constitutes the first of its kind for CRC screening in Canada, some of its limitations are acknowledged. For example, addressing costs directly would require different concepts, methods and data (Levin et al. 2008). Socioeconomic status and ethnicity are important determinants of participation in screening and could be partially assessed using different methodologies. In addition, the impact of opportunistic screening occurring outside organized CRC screening programs will need to be reconciled so that the overall outcomes of CRC screening can be better assessed. Those issues, as well as other important aspects that could not be fully addressed in this report, are briefly discussed in the Future Directions section.

Consensus Building

The success of the CRC screening program is a responsibility shared by many care and service providers along the screening pathway. These individuals contribute to the delivery of high-quality programs and include communicators, program managers, primary care providers, laboratory technologists, endoscopists (gastroenterologists and others), surgeons, pathologists, nurses, support staff and other health-care professionals. The QD Working Group ensured that representatives from all stakeholders across Canada had an opportunity to participate in the identification and development of the QDs for CRC screening. This participation occurred through the members of the Working Group, external reviewers and participants in the NCCSN-sponsored QD Workshops (May 2008 and April 2009).

Quality Determinants and Indicators for Organized CRC Screening Programs in Canada

The QDs and respective QIs detailed in this section are the results of the interactive process between experts, stakeholders and the Working Group described in the Introduction.

Each of the five QD domains (Figure) is addressed in a separate section below that includes objectives, background, quality determinants, quality indicators (with definitions) and other considerations (such as limitations) when relevant.

Participation

Objectives

The objective is to optimize uptake of the target population in CRC screening.

Background

A CRC screening program is not effective if the target population does not participate in the initial round of screening, undergo screening at program-specific intervals or follow up with a colonoscopy when results of entry-level tests (i.e., fecal tests) are abnormal. Many factors influence an individual's decision to participate in CRC screening or in a specific CRC screening program. Successful population-wide participation requires multi-modal efforts to address these differences in motivation of the individual (Sewitch et al. 2008).

Participation of the target population is one of the most critical immediate measures of success for the program and ultimately determines the outcomes of a population-based CRC screening program (Frazier et al. 2000).

Programs should also consider conducting surveys as another means of measurement for participation and retention. Surveys can also provide valuable insight into the perceptions and satisfaction of the eligible population and therefore willingness to participate in ongoing screening (UK Colorectal Cancer Screening Pilot Group 2004).

Quality Determinants for Participation

Participation in screening is relatively easy to measure, though it is affected by many external factors. From a QD perspective, many variables influence individual participation in initial and ongoing screening, including the social and environmental context where the target population exists. For example, gender, education level and the sociocultural and economic status of individuals in the target population will determine who may be more or less likely to participate (Marchant and Sutton 1990).

Personal fears and health beliefs associated with screening tests and results, and health promotional activities focusing on a continuum of health behaviours or stages

of change, influence individual participation. Individuals who choose not to participate may change their behaviour over time (Rogers 2003; Farmer et al. 2008). Those who choose to have an initial fecal test may not necessarily choose to adhere to repeat screenings or to continue to participate as recommended throughout the diagnostic pathway (refer to Diagnostic Follow-Up—Colonoscopy section).

The influence of family physicians' beliefs about CRC screening and whether they recommend it is a strong predictor of participation by their patients (Fox, Murata and Stein 1991; Farmer et al. 2008; Drolet, Dion and Candas 2008).

There is also a fine balance between recruiting the target population to participate in CRC screening and ensuring that they are well informed of the risks as well as the benefits of all aspects of CRC screening.

Strategies for improving uptake of population-based CRC screening programs using fecal tests 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. Specific strategies commonly used, with varying degrees of success, suggested in the Guide to Community Preventive Services (US CDC 2005), include the following:

- Providing screening test kits directly to the target population—for example, by mail
- Personalizing invitations, reminder letters or postcards to alert individuals to the need for 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 populations, such as hard-to-reach populations
- Providing reminders to health-care professionals to alert them that their patients require or are overdue for screening
- Using tools to support physicians and other health-care professionals for CRC screening—for example, providing CRC screening guidelines and fact sheets
- Targeting social marketing campaigns to the public and to health-care providers.

Other Considerations

Careful consideration is required when defining participation indicators. Identifying individuals at higher risk within the recruitment plan and tracking this information in a program registry is desirable. Higher-risk individuals are expected to have different needs for screening-related services—for example, initiation of screening at an earlier age, different screening intervals or use of different screening modalities (Winawer et al. 2003). Therefore some population-based programs may therefore choose to exclude higher-risk individuals; ongoing follow-up of very-high-risk individuals will almost certainly occur outside the program. Approximately 15 to 20% of all CRC occurs in individuals at higher risk so it is important that these individuals be managed

appropriately (UICC 2007). If possible, their participation rates should be documented separately from those of the average-risk population.

Retention in the screening program needs to be captured individually for each screening round as it is likely to decrease with each screening cycle (Kronborg et al. 2004; Jorgensen, Kronborg and Fenger 2002) and after patients undergo colonoscopy.

Consideration should be given to changing the retention metric for easier and more meaningful interpretation—for example, "percentage of people who have been screened at least once within a designated number of years after the initial screening." Furthermore, it is expected that age, gender and other factors, such as the experience of the previous screening round and program reminders, may influence retention as well.

While there may be varying opinions about the appropriateness of selecting these indicators for the participation domain, in some jurisdictions in Canada, opportunistic CRC screening using other screening modalities for average-risk people occurs outside organized screening programs. Capturing this information is important to ensure that individuals who are up to date on screening are not over-screened if and when they are recruited into the organized CRC screening program.

Table 2. Quality Indicators for Participation

Indicator	Definition	Cross-Tab Variables (subgroups)
Participation	Percentage of target population that engages in entry-level screening test in an organized screening program	– Age group – Gender – Calendar year(s)
Screening retention	Percentage of individuals with a negative entry-level screening test or with a negative follow-up colonoscopy who participate in subsequent entry-level screening tests according to the program parameters	– Age group – Gender – Calendar year(s) – Screening cycle (within last one, two, three, etc., rounds)
Utilization	Percentage of target population considered up to date for CRC screening, including those who do not participate in an organized program and who have been screened using other acceptable screening modalities	– Age group – Gender – Calendar year(s)

Screening (Entry-Level Fecal Test)

Objectives

The objective of screening is to ensure that acceptable, appropriate, effective and safe screening modalities are available and accessible to program participants in a timely manner.

Background

Several tests are available for opportunistic CRC screening, including:

- Fecal tests
- Flexible sigmoidoscopy alone or in combination with fecal tests
- Colonoscopy
- Double-contrast barium enema
- CT colonography

A fecal test is the most common entry-level test used by organized CRC screening programs to screen individuals at average risk. The fecal test may be guaiac-based or immunochemical.

Quality Determinants for Screening

There are multiple QDs for entry-level screening using fecal tests. Key considerations for laboratories providing fecal test–related services to, and working with, CRC screening programs include:

- Accreditation of laboratory facilities
- Organized laboratory quality assurance and quality-control programs in place
- Adequate staffing and training
- Adequate methods for kit distribution, collection of returned kits, specimen processing and interpretation and reporting of test results
- Provision of effective and appropriate stool collection instructions, which increase compliance and ensure adequate stool sampling
- Timely communication of test results to care providers and screening programs.

A list of quality data elements for fecal tests is presented in Appendix 1.

Other Considerations

Many programs in Canada use guaiac fecal occult blood tests (gFOBTs) as the primary screening test. An abnormal result is defined as one or more positive windows on a gFOBT card. The association between the number of positive windows and positive predictive value (PPV) for colorectal cancer can be estimated if relevant data elements are collected by the screening program.

If a quantitative fecal immunochemical test (FIT) is used, positive is defined as a result above a predetermined threshold/cutoff level.

It is important to differentiate between the sensitivity for CRC of a screening test (e.g., six windows for gFOBT) and a CRC screening program (e.g., a series of such a test at program-defined intervals). While the sensitivity of a fecal test for CRC may be relatively low, program sensitivity can be high when individuals are screened at regular intervals using the test.

Adequate samples will be available only if participants understand and follow clear instructions. While no QI is proposed in this document to assess this determinant, some programs may decide to document the percentage of inadequate samples received at the laboratory. Numerous factors throughout the fecal test collection and processing stages can influence this factor, however. A single in-office gFOBT in combination with a digital rectal examination is not an adequate screening test and this practice should be proscribed (Finnish Cancer Organisations 2007; Levin et al. 2008; UK NHS Department of Health 2006).

It is recognized that cancers and adenomas may bleed intermittently and therefore all abnormal fecal test results should be referred for diagnostic follow-up. Repeating the test in an attempt to confirm an abnormal fecal test result will reduce the sensitivity of the screening procedure.

Because screening is a process that involves all services along the screening pathway, it is important to ensure that the fecal test is seamlessly connected to all other program components. Factors such as cost, access to test kits and ease of use, including consistent and clear patient instructions, are important QDs but should be considered in the context of the program as a whole.

Table 3. Quality Indicators for Fecal Screening Tests

Indicator	Definition	Cross-Tab Variables (subgroups)
Positivity	Number of individuals with abnormal fecal test results divided by number of individuals with an adequate kit returned and processed (%)	– Age group – Gender – Screening tests (gFOBT, FIT) – Calendar year(s)
PPV	Proportion of people with abnormal fecal test results who are diagnosed with cancer or adenoma For cancer: number of individuals with abnormal fecal test results who are subsequently confirmed cancer cases at diagnostic follow-up, divided by total number of individuals with abnormal fecal tests who undergo diagnostic follow-up (%) For adenoma: number of individuals with abnormal fecal test results who are subsequently confirmed as having one or more adenomas at diagnostic follow-up, divided by total number of individuals with abnormal fecal tests who undergo diagnostic follow-up(%)	– Age group – Gender – Screening tests (gFOBT, FIT) – Follow-up test type – Calendar year(s)

Diagnostic Follow-Up (Colonoscopy)

Objectives

The objectives of colonoscopy follow-up are to ensure that colonoscopy and pathology services are available and are performed in a timely, accurate and safe manner, and to ensure that patients are well informed and have a positive experience while undergoing these procedures.

Background

Although the diagnostic follow-up of an abnormal entry-level screening test is typically colonoscopy—it is used by most organized CRC screening programs in Canada and elsewhere and is the focus of this report—it is important to note that other modalities may be used for this purpose. Modalities that may be used for diagnostic follow-up include CT colonography, air-contrast barium enema and flexible sigmoidoscopy. Typically these modalities are used when there is limited or delayed access to colonoscopy services, a contraindication for colonoscopy or individual patient or provider preferences.

All screening programs must have processes in place to regularly evaluate and audit all aspects related to performance of colonoscopies and reporting. Ideally, this process is facilitated by the establishment of a computerized information system.

Apart from the tracking of quality data elements, there should be a general commitment and policies in place to ensure competency in all aspects of the system providing colonoscopy services, with attention to all details concerning patient safety and comfort, test accuracy, credentialing and reporting.

QDs and QIs for colonoscopy are best categorized according to:

- Access to care
- Diagnostic accuracy
- Safety
- Client satisfaction.

It should be noted that some of the QDs described are not unique to one category and therefore will be repeated as appropriate.

Access to Care

Background

Colonoscopy is currently considered the best-practice diagnostic test for disorders of the colon; it represents a pivotal aspect of the screening pathway. Full optimization of the benefits of the screening program cannot materialize unless the impact of colonoscopy is carefully and critically evaluated. Colonoscopy services and providers do not exist in isolation. Instead they are placed along the screening pathway and, most importantly, are integrated within the highly complex health-care system.

Factors affecting the quality of colonoscopy for CRC screening programs are therefore numerous and the true measure of quality is more difficult to obtain.

Quality Determinants for Access to Care

Access to colonoscopy as the diagnostic follow-up test can be a rate-limiting factor of the CRC screening program, one that could counteract the benefits of increased screening awareness and screening practices. Comprehensive knowledge of baseline colonoscopy resources, complemented by a detailed projection of future screening-related colonoscopy resource use, is critical to achieving a high-quality CRC screening program. Assessments to gather this information should account for the following:

- Baseline assessment of colonoscopy resources should measure physical capacity, human resources, the nature of services provided and the demand for services.
- To make projections regarding future screening-related demands, including capacity for building and enhancing infrastructure, determination of the proportion of colonoscopies performed for each of the following reasons is required:
  - Evaluation of symptomatic patients
  - Follow-up of abnormal fecal tests
  - Screening (opportunistic)
  - Screening (family history CRC, polyposis syndromes, predisposing conditions)
  - Surveillance (personal history of CRC or polyps).
- Wait times for colonoscopy at baseline for the indications above should be measured and followed as the program evolves to ensure that screening does not usurp colonoscopic resources required for symptomatic patients, and that diagnostic follow-up colonoscopy can be delivered in a timely manner. Wait times for colonoscopy may also reflect patients' booking preferences. Patients may deliberately defer the procedure for personal reasons or fear of the test.
- Enforcement of screening guidelines and surveillance intervals may yield additional capacity. Appropriate use of colonoscopy resources can also be facilitated by guideline-based, standardized triage processes.
- Planning future screening-related colonoscopy resources should take into account local demographics, including age of the population and baseline CRC incidence.
- Projecting and planning for adequate capacity requires an understanding that prevalent screening rounds will yield higher positivity rates and over time, a proportion of these individuals with polyps will require surveillance colonoscopies, which typically occur at three- to five-year intervals.

Other Considerations for Access to Care

Facilities that perform a high proportion of primary screening colonoscopies for average-risk individuals may experience an increase in complexity and duration of the

procedure with a shift in indication from primary screening of average-risk individuals to following up abnormal fecal test results, as the prevalence of polyps will be greater in the latter scenario.

Colonoscopy screening for moderate- and high-risk individuals may or may not be monitored by the screening program, but could be expected to increase as awareness of CRC screening increases in the population.

Patients requiring follow-up with colonoscopy may be noncompliant or may never undergo the procedure for a number of reasons:

- Fear of the procedure or results
- Choosing an alternative diagnostic follow-up modality
- Lack of timely physician follow-up of an abnormal entry-level test
- An entry-level test performed for inappropriate reasons
- Screening not being indicated
- Screening being previously performed
- The patient not being screen eligible
- Patients being lost to follow-up.

Table 4. Diagnostic Follow-Up: Quality Indicators for Access to Services

Indicator	Definition	Cross-Tab Variables (subgroups)
Follow-up completion	Percentage of participants with abnormal screen test result undergoing recommended diagnostic follow-up within program-defined interval	– Age group – Gender – Calendar year(s) – Follow-up test type
Wait time to colonoscopy	Time from abnormal screening test result (date of lab result) to colonoscopy (date of procedure)	– Age group – Gender – Calendar year(s)
Wait time to pathological diagnosis	Time from colonoscopy (date of procedure) to definitive (pathological) diagnosis (date of pathology report)	– Age group – Gender – Calendar year(s)

Diagnostic Accuracy

Background

The degree of sensitivity of colonoscopy for the target lesions depends on bowel cleanliness, the completeness of the exam, withdrawal time and the expertise of the operator (Rex et al. 2002). Although these indicators are integral to the quality of colonoscopy, collecting data on such discrete elements at the program level is challenging and at least initially, resource intensive. Programs may be better served by relying on surrogate markers of quality. A Canadian Consensus on Quality and Safety Indicators and Reporting for Colonoscopy steered by the Canadian Association of Gastroenterologists is underway and will address this particular issue.

Quality Determinants for Diagnostic Accuracy

There should be measures in place to ensure that all colonoscopies are performed according to standard clinical guidelines and by professionals with proper credentials and skills. This duty is particularly important in persons undergoing screening-related procedures, where the balance between harm and benefit is more difficult to maintain.

Synoptic colonoscopy reporting with inclusion of all necessary quality data elements is an important tool to inform patients, referring physicians and the screening program of the quality of the colonoscopic examination. Ideally, reporting should be linked to a regional information system to permit tracking of patients and of essential data elements related to quality.

To assist in pathology reporting, the complete patient colonoscopy record should be forwarded along with specimens.

Other Considerations for Diagnostic Accuracy

Although some other QIs may be significant and relevant for diagnostic accuracy, discussion is required at the national level to determine the possibility and feasibility of standardizing definitions and capturing data elements to support these indicators across all jurisdictions. These other indicators may not correlate with CRC mortality as well as the ones proposed here and may be more susceptible to change with advances in technology. Therefore, these other indicators may be best addressed locally or in a research setting given the complexity and challenges associated with their data collection, and will be considered as a future indicator for pan-Canadian reporting.

Table 5. Diagnostic Follow-Up: Quality Indicators for Diagnostic Accuracy

Indicator	Definition	Cross-Tab Variables (subgroups)
Colonoscopy cancer detection	Number of individuals with abnormal fecal test results with subsequently confirmed cancer cases at follow-up colonoscopy, divided by total number of individuals with abnormal fecal tests who undergo colonoscopic follow-up (%)	– Age group – Gender – Site (proximal to splenic flexure vs. distal) – Calendar year(s)
Colonoscopy adenoma detection	Number of individuals with abnormal fecal test results, subsequently confirmed as having one or more adenomas at follow-up colonoscopy, divided by total number of individuals with abnormal fecal tests who undergo colonoscopic follow-up (%)	– Age group – Gender – Calendar year(s) – Clinically significant adenomas (advanced; SSA)

Safety

Background

Population screening is performed to prevent morbidity and mortality in a small proportion of participants who are not aware of or identified as having a disease. Although complications are rare, all efforts should be made to minimize morbidity and mortality related to screening.

Thorough and continuous monitoring of complications should be an integral part of any screening program and must be conducted both during and after procedures.

Complications from colonoscopy may arise from several factors, including (but not limited to):

- Colonic perforation
- Bleeding from the colonic wall
- Respiratory failure and risk of delayed effects due to sedation
- Electrolytic imbalances, fluid overload, renal failure or dehydration from bowel preparation
- Underlying co-morbidities predisposing to cardiac or respiratory events
- Medication complications from altered intake or discontinued use during the procedure

- Infection due to either contamination (lack of proper reprocessing) of the instruments or intravascular bacterial seeding induced by the procedure
- Mechanical trauma to adjacent organs.

Quality Determinants for Safety

Risk minimization for colonoscopy takes place at several levels. Key considerations include (but are not limited to):

- Infrastructure, including well-functioning equipment for the procedure and patient monitoring during and after the procedure
- Decontamination
- Staffing levels, ensuring an adequate number of appropriately trained nurses and other support staff
- Patient care processes and policies(e.g., anticoagulation policy, diabetic policy, sedation and monitoring), quality assurance (e.g., reporting adverse events and review policy)
- Case selection
- Competence of the colonoscopist.

Table 6. Quality Indicators for Safety

Indicator	Definition	Cross-Tab Variables (subgroups)
30-day non-CRC-related hospitalization after follow-up colonoscopy	Percentage of non-CRC-related hospitalizations (not attributed to surgical or other interventions initiated because of CRC diagnosis) within 30 days of follow-up colonoscopy	– Age group – Gender – Calendar year(s) – With or without polypectomy
30-day non-CRC mortality after follow-up colonoscopy	Percentage of non-CRC-related deaths (not attributed to surgical or other interventions initiated because of CRC diagnosis) within 30 days of follow-up colonoscopy	– Age group – Gender – Calendar year(s) – With or without polypectomy

Client Satisfaction

Background

A high-quality patient experience can be determined with the following measures:

- **Equity:** Every individual with an abnormal screening test result has equal opportunity to access timely colonoscopic services and to be adequately

informed prior to the procedure about appropriate wait time for colonoscopy, to avoid unnecessary anxiety. Needs assessment surveys should be performed to identify prevalent languages in the population so that information is available in those languages. Translation services should be made available to those who cannot communicate with the staff, as should assistance for those with special needs such as wheelchair access or sign language.

- **Scheduling flexibility:** Aim to provide all individuals with timely and convenient scheduling of tests.
- **Informed consent:** There is an obligation to provide accurate verbal and written information about the benefits and risks of colonoscopy both at the time of invitation to screen and when colonoscopy is recommended following an abnormal screening result. Patients should communicate that they understand and are confident that they will receive a safe and accurate procedure.
- **Comfort:** All individuals should be given realistic expectations of possible pain or discomfort during the test. Patient comfort should be monitored during and after the procedure.
- **Privacy and dignity before, during and after the procedure**: Individuals' sense of dignity and their right to privacy must be respected throughout their time in the endoscopy unit.
- **Timely and effective communication of results to referring physicians and patients**: Referring physicians should receive a comprehensive procedure report, including indicators of appropriateness, quality and safety, as well as instructions for follow-up, within one week of the procedure. Patients should be made aware of the results of their colonoscopy and given information about follow-up as indicated. Follow-up information should be communicated verbally and in a written report. If pathology results are required to establish recommendations, indications of how, by whom and when the results will be communicated should be provided.
- **Aftercare:** Individuals must receive verbal and written aftercare instructions. Individuals should be given a contact name and phone number and be encouraged to contact the facility if they have any questions, concerns or comments immediately following their procedure. They must not be left unattended for an extended period of time following the procedure or leave the facility without a responsible adult.
- **Ability to provide feedback:** Endoscopy services must obtain patient feedback about the quality of their experience via various modalities, such as post-discharge surveys, focus groups or invited comments. The screening program should make an effort to conduct longer-term follow-up surveys of a representative sample of individuals to ascertain their experience and attitudes toward the colonoscopy procedure.

Quality Indicators of Client Satisfaction

At this stage of QD and QI development, indicators have not been recommended for client satisfaction. However, the Endoscopy Global Rating Scale (GRS) (Valori et al. 2004) includes comprehensive suggestions of relevant indicators and should serve as a

template for implementation of quality assurance and quality improvement of endoscopy services. These suggestions are listed in Appendix 2.

Diagnostic Follow-Up (Pathology)

Objectives

The objectives of diagnostic follow-up in pathology are to ensure that pathology services are available to deliver timely, accurate, complete and interpretable diagnostic results to practitioners providing CRC screening–related care.

Background

Pathology quality cannot be isolated and is directly and indirectly affected by many of the QDs described in the Diagnostic Follow-Up (Colonoscopy) section. Specifically, those quality features that reflect colonoscopists' practice in the collection and reporting of polyp findings, and the quality of pathologists' practice, will affect the appropriate care and ongoing management of the patient. Colonoscopists and pathologists are equally affected by the overall state and quality of the health-care system (e.g., capacity will ultimately affect the quality of the CRC screening program).

Quality Determinants for Diagnostic Follow-Up (Pathology)

At the May 2008 Quality Determinants Workshop, a number of highly specific quality-related concepts and processes were identified as valuable and necessary to adopt or implement. The following components should be considered by all organized CRC screening programs in Canada:

- **Collection of polyps:** Each individual polyp should be received in a separate container. Multiple polyps should not be aggregated in a single container.
- **Reporting:** Systematized pathology reporting using uniform terminology and criteria is a necessary adjunct to ensure consistency in pathology reporting, follow-up, management and further surveillance of the patient. Reports should include the following:
  - **Location** of the lesion (polyp) should be specified with an anatomical identifier. Preferable terminology may be cecum, ascending, transverse, descending, sigmoid, rectum or anus. Suspected malignant sites should be tattooed.
  - **Size and morphology** of the polyp should be provided:
    - Clinician's evaluation of the size of the polyp in millimetres or centimetres and description of shape (sessile vs. pedunculated)
    - Pathologist's measurement of the completely removed polyp
  - **Number** of polyps should be specified.
  - **Completeness of removal** should be described:
    - Clinician's assessment
    - Pathologist's evaluation where the stalk is identified
    - How polyp was removed (e.g., complete or piecemeal)

Standardized Nomenclature and Definitions

- **Diagnosis:** The diagnosis provided must use standard diagnostic terms**.**
- **Grade of dysplasia:** For all adenomas, the grade of dysplasia should be provided using a binary grading system. The preferred terms are "with" or "without" high-grade dysplasia.
- **Presence of a villous component:** This information can be abstracted from the diagnostic term (both tubulovillous and "pure" villous adenomas have a villous component).

Classification

- **Adenoma:** A benign intra-epithelial neoplasm composed of dysplastic cells
- **Advanced adenoma:** An adenoma that is either 1 cm or more in size, has a villous component (villous or tubulovillous) or has high-grade dysplasia (characterized by architectural distortion—cribriform or back-to-back crypts)
- **Sessile serrated adenoma** (also referred to as a sessile serrated polyp): A benign polyp characterized by non-dysplastic crypts that are dilated and serrated (saw-toothed) and have architectural distortion and an increased proliferative zone
- **Malignant polyp:** If there is invasion beyond the muscularis mucosae, the polyp is classified as malignant and various additional data elements become essential, as recommended by groups such as the College of American Pathologists (CAP):
  - Grade of the malignant element
  - Presence or absence of lymphovascular invasion
  - Proximity of invasive focus to the cauterized margin.

Table 7. Quality Indicators for Diagnostic Follow-Up (Pathology)

Indicator	Definition	Cross-Tab Variables (subgroups)
Wait time from colonoscopy to definitive pathological diagnosis	Wait time from date of colonoscopy to date of pathology report	– Age group – Gender – Calendar year(s) – CRC risk level of individual

A list of suggested synoptic reporting elements for CRC screening–related pathology is presented in Appendix 3 and synoptic reporting elements for CRC screening–related polyps appear in Appendix 4.

Other Considerations

Although other indicators, such as completeness of procedure, are significant and relevant indicators of diagnostic accuracy, the data elements to support these indicators will require significant effort and resources to capture and this may not be feasible in some jurisdictions at the early stages of program implementation. However, these indicators and related data elements may be captured and reported locally or studied in a research setting to better understand the impact on quality of the pathologist and pathology services.

Case Management

Objectives

The goal of good case management is to ensure that cases identified throughout the CRC screening pathway requiring further assessment and treatment move seamlessly within and across health-care services through improved planning, coordination and provision of care.

Background

As a screened individual moves further along the CRC screening pathway, it is critical that services are integrated and that appropriate support mechanisms are in place so these individuals can navigate the system and receive the care they need.

Mortality reduction through CRC screening and early detection can be realized only when patients receive timely and adequate treatment.

Quality Determinants for Case Management

Patients who are diagnosed with and treated for adenomatous polyps require adequate ongoing surveillance. Cases with other incidental clinical findings identified in the screening process should be managed appropriately based on program parameters. A well-designed patient navigation system with adequate staffing should be put in place to facilitate timely movement of patients through the health-care continuum.

While cancer case management is not considered to be under the auspices of a population-based CRC screening program, it is desirable to engage service providers "downstream" in the screening pathway during program planning and implementation.

The capacity of, and access to, the cancer-care system, when CRC cases are identified through CRC screening, can largely determine whether a CRC screening program is successful or not. Organized breast cancer screening programs that are well coordinated and aligned with comprehensive breast cancer treatment programs help decrease patient fear and anxiety and improve quality and outcomes of care (Bickell and Young 2001). It is expected that CRC cases identified through screening programs will benefit from similar health service configurations. Early screening for psychological distress and initiation of psychosocial support should not be overlooked by the clinical management team.

With the implementation of an organized CRC screening program, 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 there are adenomatous polyp findings. This follow-up will further increase pressures on colonoscopy services. An organized and measured approach is required to address capacity issues and appropriate use of limited endoscopic

resources, including 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 (Winawer et al. 2006).

A comprehensive program information system that can support health-care practitioners in timely care provision and service delivery, as well as robust reporting, is needed.

Evidence-based CRC screening and surveillance guidelines, and where evidence is weak or limited a regularly scheduled review process (including the tracking of yields), have to be used to ensure that colonoscopic resources are maximized and harms minimized.

Other Considerations

Case management includes strategies, such as patient navigation, that are effective for use in programs that require complex navigation 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 or socioeconomic barriers (Freeman 2006).

Measuring the effectiveness of case management strategies and determining the quality of case management approaches will require different evaluation metrics and techniques, as well as measurement at the local level.

Table 8. Quality Indicator for Case Management

Indicator	Definition	Cross-Tab Variables (subgroups)
Wait time from screen-detected CRC diagnosis to initiation of treatment	Wait time from date of CRC diagnosis (date of pathology report) to date of initiation of first treatment (surgery, radiotherapy, chemotherapy)	– Age group – Gender – Calendar year(s) – CRC risk level of individual – Cancer stage

Program Outcomes

Objectives

The objectives of the program outcome domain are to assess the impact of organized CRC screening programs and to provide the necessary information for programs to allow for an iterative quality improvement process.

Background

The primary goal of an organized CRC screening program is to reduce CRC mortality. The program may also reduce CRC incidence and morbidity. Program outcomes depend on many factors, including effective program planning, coordination and management; adequate resources and capacity; high participation; quality service provision along the screening pathway; and integrated patient care. The program outcomes therefore reflect the collective efforts of all stakeholders and ultimately allow evaluation of program performance at all steps along the client pathway.

Quality Determinants for Outcomes

A quality CRC screening program requires ongoing monitoring and evaluation that assesses the activities, processes and functions of the program and measures program outcomes and health-system impact. This information can be used to address program implementation issues and improve program effectiveness, safety, efficiency and accessibility.

CRC screening programs should establish and maintain a system that collects information about the program that is necessary for systematic tracking and evaluation of screening recruitment, screening and follow-up services, outcomes, program operations and quality assurance.

Program evaluation at the local level can use multiple quantitative and qualitative methods and measures to assess the quality of an organized screening program. Program evaluation at the local level is also necessary for ongoing quality assurance and improvement. The results of these types of evaluations are more difficult to compare on a pan-Canadian level but nonetheless are important to capture.

Other Considerations

Interval cancer incidence—that is, colorectal cancer diagnosed between screening cycles—is difficult to capture before a CRC screening program is well established or a robust database exists. That said, interval cancer is best defined as cancer that is diagnosed between a negative FOBT, or cancer-negative colonoscopy, and when the subsequent screening cycle would fall due. Interval cancer incidence measures the quality of the screening pathway by indirectly reflecting the number of false negatives. Interval cancer incidence may reflect the quality of care some years before, not necessarily the service as it is currently being provided.

Reduction in CRC mortality is a key program outcome measure. However, because organized CRC screening is in the early stages of implementation in Canada, this indicator may not be useful in the short term. Successful implementation of CRC screening programs will result in more prevalent CRC cases being identified and will lead to an increase in CRC incidence in the early years of programs. The next evidence that a successful screening program will provide is a shift of the diagnosed cases toward the lower stages, thus reducing the incidence of higher-stage cancer in the population generally.

Table 9. Quality Indicators for Program Outcomes

Indicator	Definition	Cross-Tab Variables (subgroups)
Program CRC detection rate	Proportion of participants diagnosed with cancer by screening process	– Age group – Gender – Calendar year(s) – Cycle
Interval CRC incidence	Percentage of participants with normal screening results (i.e., normal fecal test, or abnormal fecal test followed by normal colonoscopy) subsequently diagnosed with CRC before next scheduled screening test	– Age group – Gender – Time interval (one year, two years, etc. post screening test)
CRC stage distribution	Incidence of CRC by stage in target population	– Age group – Gender – Calendar year(s) – Screened population
CRC incidence	Age-adjusted CRC incidence in target population and by exposure to CRC screening	– Age group – Gender – Calendar year(s) – Stage – Screened population – Cycle
CRC mortality	Age-adjusted CRC mortality in target population and by exposure to CRC screening	– Age group – Gender – Screened population – Cycle
Non-CRC mortality	Age-adjusted non-CRC mortality in target population exposed to CRC screening	– Age group – Gender – Cycle – Screened population

Conclusions

Through substantial consultation with stakeholders across Canada, this report provides an initial compilation of quality determinants and respective quality indicators for colorectal cancer screening programs for comparing and contrasting both the quality and performance of CRC screening. The selected QIs were tailored to the Canadian context, where CRC screening is largely at the initiation stage.

Adoption of the quality determinants and indicators described in this report is essential for the ongoing success of collective CRC screening across Canada, and will have tremendous benefits for all participating screening programs. The QDs and QIs identified in this report will not only provide every program with opportunities for internal evaluation, but will also allow for comparison of results across programs, both within Canada and internationally. Comparison will allow lessons to be learned, better ways of providing services to be revealed and evidence to be available for supporting program development and change. Furthermore, clinical services provided to symptomatic patients or patients with cancer could also benefit from the adoption of QDs and QIs for services associated with CRC screening programs.

This report is a first step and is expected to be further refined through an iterative process that will eventually allow different jurisdictions to demonstrate their contribution to CRC screening in Canada and allow Canada to participate as a partner in the fight against CRC internationally.

Although it is anticipated that these QD and QIs will be adopted on a pan-Canadian basis through the NCCSN, it is the responsibility of each jurisdiction to commit to using this tool and to embed it in operational resource requirements for local CRC screening programs.

Next Steps

Operationalization of the QIs provided is an important next step and will require the involvement of appropriate experts to ensure that data collection and reporting are robust.

Some specific next steps for programs to consider immediately and in the longer term are the following:

- At the program level, the next step is to adopt the pan-Canadian QD framework indicators. Doing so will include
  - Creating a detailed plan, including assessing the feasibility of collecting and reporting data for specific indicators and/or the timelines for phased collection of data (if required)
  - Securing resources to ensure that a data collection and reporting infrastructure is in place for ongoing reporting of indicators
  - Selecting standardized data elements, developing a data dictionary (locally and nationally) and ensuring that the selected data elements can be collected from local databases
  - Involving local experts in each step of the process to ensure that indicators are measured accurately and consistently.
- As programs mature and indicator data are progressively collected and reported, development of targets, including input from professional groups, and national database planning are to be considered.
- Comparing and contrasting different program operational elements, approaches and models over time, both nationally and internationally, will benefit all jurisdictions because there will be greater opportunities to optimize programs.

Future Directions

Organized colorectal cancer screening programs in Canada are in various stages of planning and implementation and screening rates remain relatively low. As plans are implemented and programs become fully operational, however, there will be an ongoing need to explore the more complex aspects of quality and possibly identify additional or revised quality determinants over time.

Population-based CRC screening programs have limitations and are not failsafe systems. While it is widely recognized from the evidence that the reported benefits of CRC screening far outweigh the potential harms and the costs to the health-care system and society, continuous quality improvement of organized programs will ensure that harms associated with CRC screening will be minimized and benefits maximized.

As increasing numbers of CRC screening programs are implemented in Canada, some important quality issues related to fecal tests may be addressed. Furthermore, additional research can further delineate acceptability and feasibility of new fecal tests. Similarly, as new CRC screening technologies emerge and become available to Canadians, it is imperative that population screening programs remain vigilant about these newer methods and technologies; examples might include capsule colonoscopy and fecal DNA testing. It will be important for CRC screening programs to evaluate these tests in terms of acceptability, efficacy, efficiency and cost effectiveness so that the target population always has access to the best screening tests available. It is beyond the scope of this brief to explore these areas further.

In the longer term, as screening uptake increases and more people in the target populations are screened, some disadvantages and complications of screening will become more apparent. There may be over-diagnosis and over-treatment in patients with non-serious conditions or abnormalities, leading to increased anxiety for these individuals and additional costs to the health-care system (Holland and Stewart 2005).

For CRC screening specifically, as uptake increases, so too will colonoscopy-related morbidity; in addition, the greater numbers of polyps requiring surveillance will increase demand on the health-care system. Also needing to be addressed will be unidentified/interval cancers, false negative and false positive test results, and delays in accessing appropriate and timely follow-up services and treatment. These realities are counterbalanced, however, by the many more lives being saved and the reduced burden on other resource-intensive treatment areas of the health-care system as a result of earlier detection.

It will also be important and somewhat challenging to extract complication data pertaining to asymptomatic CRC screening–related colonoscopy from complication data pertaining to symptomatic or therapeutic colonoscopy. Without this data extraction, a major confounding factor exists. In the spirit of, and commitment to, quality, there is a long-term need to focus efforts on addressing these more complex and less desirable aspects of population-based CRC screening.

Endoscopy resources, including the appropriate use of surveillance colonoscopy, will require ongoing review. Also, the appropriate management of average-risk individuals with abnormal (positive) fecal test results and negative colonoscopies at follow-up should be addressed. There is a paucity of evidence, and substantial variation in opinion and practices, with respect to ongoing clinical management of these individuals. This scenario will increasingly affect population-based CRC screening programs in terms of increased risks to patients and providers and strain on resources of the program as many clinicians choose to do further investigations in the absence of evidence-based formal guidelines.

It is unlikely to be feasible or cost-effective to perform these investigations (e.g., esophagogastroduodenoscopy) in all fecal-test-positive, colonoscopy-negative patients, particularly in those asymptomatic CRC-screened patients participating in population-based programs. However, the decision to conduct further investigations in the presence of symptoms, anemia or other gastric cancer risk factors needs to be made individually (McLoughlin and Telford 2007).

The questions and further research needed to address this scenario could include the following:

- Is there a greater risk of pathology if the fecal test is positive but the colonoscopy negative, versus a negative primary screening colonoscopy?
- What would be the positivity rate and PPV for repeat fecal tests at, for example, five-, six- and seven-year intervals following an initial positive fecal test with negative colonoscopy?
- What would be the most appropriate pathway for CRC screening programs to best mitigate clinical risks and harms to patients, and medico-legal risks for clinicians, while maximizing use of limited endoscopic and other health-care resources?

Longer-term considerations should also include exploring methods of assessing pathologist reporting for evaluating quality of pathology.

Another area of importance—beyond the scope of this QD framework but nonetheless important to consider as a future direction—is the identification of quality determinants and quality indicators for treatment in those individuals diagnosed with colorectal cancer. One area of particular concern is access to surgical resection of rectal carcinomas, including total mesorectal excision performed by surgeons adequately trained and experienced in this procedure. It has been demonstrated that survival is markedly increased with this procedure over other methods because of the reduced local recurrence associated with it (Wibe et al. 2002). Other countries have adopted this procedure as the standard of care but restrict its execution to surgeons specifically trained in the technique. Therefore, a future direction may include exploring a similar approach in Canada in the pursuit of high-quality treatment and/or targets for surgical care. This work is best conducted and championed by those surgeons providing such care.

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Appendices

Appendix 1: Suggested Data Elements for Fecal Tests

The following quality data elements are suggested for each program database to enable capture of quality indicators for fecal occult blood tests:

- Demographic information (address, postal code)
- Geographic boundary of the service
- Site of test
- Ordering physician (or other care provider)
- Type of FOBT
- Batch number of kit
- Lab case number/report accession number
- Date of specimen collection (recorded on test kit by participant)
- Date FOBT specimen received
- Adequacy of returned kits
- Number of test cards (windows) completed
- Date of FOBT results
- FOBT results (positive should be defined as any positive window) and total number of positive windows
- Hemoglobin concentration (if quantitative FIT is used)
- Threshold/cutoff value (if quantitative FIT is used)

Appendix 2: Global Rating Scale for Canada

Clinical Quality

1	Consent Process, Including Patient Information	Level
1.1	There is a published patient information sheet for all diagnostic procedures performed in the unit.	D
1.2	The policy for consent is available in the unit in written and electronic form.	D
1.3	There is a published patient information sheet for all endoscopy procedures performed in the unit.	C
1.4	All patients are given an opportunity by a professional trained in the consent process to ask questions about the procedure prior to the endoscopy.	C
1.5	Signatures are obtained on a consent form for all patients who can sign the form and procedures are in place for patients who require assistance with the process (e.g., because of disability, language, activity).	C
1.6	All patients are given sufficient time to ask questions before entering the procedure room.	B
1.7	All consent signatures are obtained outside the procedure room.	B
1.8	There is written guidance within the unit for withdrawal of consent during an endoscopic procedure.	B
1.9	All published patient information sheets are reviewed annually and changed as necessary.	A
1.10	Patients' frequently asked questions are incorporated into the patient information sheets.	A
1.11	There is at least one annual survey of patients' experience of consent for endoscopic procedures.	A
1.12	Findings of the patient survey are reviewed and acted upon within three months of survey completion.	A
1.13	Failure to comply with withdrawal of consent guidelines established by the unit is registered as an adverse clinical incident.	A

2	Safety	Level
2.1	There is a system for recording adverse events in the endoscopy unit.	D
2.2	The endoscopy unit adheres to the appropriate regional and/or provincial guidelines for acting on adverse events.	C
2.3	Adverse events are reviewed by the unit management team regularly (at least three times per year).	C
2.4	Key safety indicators and auditable outcomes for safety are available in the unit in written and electronic form.	C
2.5	Guidelines for endoscope reprocessing are available in the unit in written and electronic form.	C
2.6	A system is in place for monitoring safety outcomes and key indicators.	B
2.7	A system is in place for identifying and reviewing all unit deaths within 30 days of an elective endoscopic procedure and within eight days of a non-elective procedure.	B
2.8	Actions on adverse events (expected and unexpected) are implemented within three months of review.	B
2.9	Auditable outcomes for reprocessing are agreed on and monitored.	B
2.10	Auditable outcomes for actions on adverse events are identified and monitored.	A
2.11	Action is taken within three months if auditable outcomes for actions on adverse events are not achieved.	A
2.12	Action is taken within three months if auditable outcomes for reprocessing are not achieved.	A
2.13	If there are resource constraints for responding to adverse events (e.g., having 24/7 on-call bleed rotas), these are identified and the adverse event is placed on the unit “risk register.”	A

3	Comfort	Level
3.1	There is basic monitoring of patient comfort.	D
3.2	Patients are given a realistic expectation of discomfort and pain prior to the procedure.	C
3.3	All endoscopy personnel have been taught to recognize and help to comfort patient anxiety during endoscopic procedures.	C
3.4	Personnel monitor and record patient pain and discomfort during and after the procedure.	C
3.5	Patient surveys of patient comfort are undertaken at least once a year.	C
3.6	Monitoring of patient comfort (surveys and care records) is reviewed at least twice per year.	B
3.7	Anonymous data on patient comfort levels is provided to individual endoscopists and to the treatment team at least twice per year.	B
3.8	Patient expectations, patient preparation, endoscopic technique and sedation levels are reviewed if there are concerns about comfort level.	B
3.9	Action is taken if patient comfort falls below agreed levels.	B
3.10	Action on patient comfort is reviewed within six months to ensure it has dealt with the issues.	A
3.11	If patient comfort does not reach acceptable levels within three months of review of an endoscopist's safe sedation practice and technique, that endoscopist's practice is reviewed by the unit's medical director.	A

4	Quality of the Procedure	Level
4.1	Key quality indicators and auditable outcomes defined by the unit for the procedures performed in the unit are available in the unit in written and electronic form.	D
4.2	Systems are in place for monitoring Level C BSG* auditable outcomes and quality standards.	C
4.3	The outcomes and standards are reviewed regularly (at least twice per year).	C
4.4	Individual endoscopists are given feedback on their outcomes and standards.	C
4.5	Action is agreed to with an individual if performance falls below acceptable levels.	B
4.6	Auditable goals and timescales for the above action are agreed on and monitored.	B
4.7	There is an information technology system in place to capture auditable outcomes and quality standards.	B
4.8	Systems are in place for monitoring Level B BSG* auditable outcomes and quality standards.	B
4.9	Systems are in place for monitoring Level A BSG* auditable outcomes and quality standards.	A
4.10	Actions taken in response to poor performance are reviewed within an agreed time.	A
4.11	Endoscopists who fail to achieve agreed standards after an agreed implementation plan have their practice reviewed by the medical director.	A

*BSG: British Society of Gastroenterology

5	Appropriateness	Level
5.1	There are some guidelines for all diagnostic procedures.	D
5.2	All guidelines are available in the department in written and electronic form.	D
5.3	There is a local policy for vetting referrals that includes auditable outcomes for timeliness and completeness of the vetting.	D
5.4	Guidelines for open-access procedures have been agreed on with representatives from primary care.	C
5.5	Guidelines for other procedures have been agreed on by all who perform those procedures.	C
5.6	All referrals from non-endoscopists within primary and secondary care are vetted by an endoscopist who performs that procedure, unless agreed straight-to-test protocols exist.	C
5.7	All referrals for endoscopy are vetted according to local policy.	C
5.8	Patients referred for a surveillance procedure are informed that their case will be reviewed according to the latest guidance at least two months before their procedure is due.	B
5.9	All surveillance procedures are validated clerically and clinically according to the latest guidance at least two months prior to the due date.	B
5.10	There is annual review of all guidelines and of the policy for vetting referrals.	B
5.11	An audit of the vetting process (see 5.6) is undertaken once a year and action plans created if problems are identified.	B
5.12	There is evidence that action plans for the vetting audit are successfully acted upon.	A
5.13	The vetting policy and the results of annual audits of vetting are presented to local directors each year.	A
5.14	Clinical pathways for at least three common gastrointestinal symptoms, and processes to monitor them, are agreed on with local directors.	A
5.15	Reviews of 30-day mortality include an assessment of the appropriateness of the procedure.	A

6	Communicating Results to Referrer	Level
6.1	All endoscopy reports are completed on the day of the procedure.	D
6.2	Results for all inpatients are placed in the hospital file before the patient leaves the unit.	D
6.3	All endoscopy reports are dispatched to the referrer within five working days of the procedure.	C
6.4	All endoscopy reports include follow-up details.	C
6.5	All endoscopy reports are dispatched within two working days of the procedure.	B
6.6	There are processes in place for ensuring that pathology reports are reviewed by the nurse/endoscopist responsible for acting upon them within five working days of receipt of the report.	B
6.7	If it is necessary for the referrer to receive additional information (usually in the form of pathology reports) this information is dispatched to the referrer within five working days of receipt of the report.	B
6.8	All endoscopy reports are dispatched within 72 hours of the procedure.	A
6.9	If the endoscopist has responsibility for taking action or making recommendations based on pathology reports, that action is taken, or recommendations are dispatched, within five days of receipt of the report.	A

Quality of Patient Experience

7	Equality of Access and Equity of Provision	Level
7.1	The equality/diversity policy is available in the unit.	D
7.2	All endoscopy unit staff have had orientation on the equality/diversity policy.	D
7.3	A demographic/language profile of the local population (needs assessment) is available.	D
7.4	Communication needs are recorded as part of the nursing assessment.	C
7.5	Resources exist for medical interpreting for the majority of community languages and sign language, appropriate to the needs assessment.	C
7.6	Written information is available in the unit for some community languages identified by the needs assessment.	C
7.7	The use of family and friends as interpreters is discouraged unless it is the patient's choice to use them as interpreters. If patients exercise this choice it is documented in the patient's file.	C
7.8	All patients with special communication needs are offered a medical interpreter, trained bilingual staff member, telephone interpreting service or signing interpreter.	B
7.9	Written information is available in the unit for most prevalent community languages.	B
7.10	Information is provided via different methods as appropriate to the needs assessment. The unit has a policy that clearly states how this is delivered to meet the needs of diverse groups.	B
7.11	All booking procedures are assessed for equality of access.	A
7.12	Feedback is actively sought from minority groups on the services provided by the unit, using questionnaires, telephone interviews or focus groups.	A
7.13	User participation in planning and evaluation services is representative of the local population in terms of gender, ethnicity and disability.	A

8	Timeliness	Level
8.1	The endoscopy unit has a waiting-list management system that records new and recall (planned/surveillance) patients.	D
8.2	There is a named person responsible for the waiting list.	D
8.3	Waits are less than eight weeks for urgent procedures and/or less than 52 weeks for routine procedures.	D
8.4	Waits for recall (surveillance) procedures are less than 52 weeks beyond the planned date.	D
8.5	Waits are less than four weeks for urgent procedures and less than 26 weeks for routine procedures.	C
8.6	Waits for recall (surveillance) procedures are less than 26 weeks beyond the planned date.	C
8.7	Endoscopy waiting-list information is communicated to the endoscopy team at least monthly.	C
8.8	There is some pooling of endoscopy lists.	C
8.9	Waits are less than two weeks for urgent procedures and less than 13 weeks for routine screening colonoscopy.	B
8.10	Waits for recall (surveillance) procedures are less than 13 weeks beyond the planned date.	B
8.11	There is regular administrative validation of waiting lists.	B
8.12	Waits are less than two weeks for urgent procedures and less than six weeks for routine procedures.	A
8.13	Waits for recall (surveillance) procedures are less than six weeks beyond the planned date.	A
8.14	Capacity can be flexed according to demand to ensure waits are within the above limits.	A

9	Booking Responsiveness and Flexibility	Level
9.1	Patients are informed by letter, phone or email of their appointment.	D
9.2	Patients are informed that there is a booking system in operation.	C
9.3	More than 25% of new referrals are directly booked.	C
9.4	No-show and cancellation data are monitored.	C
9.5	Patients are informed that there is both a direct and recall/future booking system in operation.	B
9.6	More than 50% of new referrals are directly booked.	B
9.7	Action is taken in response to high (greater than 1%) no-show and cancellation rates.	B
9.8	Patients are informed of appointment choices available and processes are in place by which patients are told how appointments will happen.	A
9.9	There is a reminder booking system in place for recall (surveillance) appointments.	A
9.10	More than 67% of new referrals are directly booked.	A

10	Privacy and Dignity	Level
10.1	There is a facility for conversation before and after the procedure.	D
10.2	There is a safe area in which patients are cared for.	D
10.3	The unit has screens/curtains to provide limited privacy pre- and post procedure.	C
10.4	There are patient toilet and washing facilities.	C
10.5	The unit has access to a quiet room that provides sufficient privacy to allow for a conversation beyond the hearing of other patients.	B
10.6	Standards of care are in place and understood by all staff.	B
10.7	Patient feedback on privacy and dignity is sought by at least two methods each year.	B
10.8	The unit has access to a separate room that provides complete privacy for discussions with patients.	A
10.9	All patients are asked whether they wish to have their clinical care discussed in private.	A
10.10	Privacy standards are reviewed (in response to patient feedback) at least annually.	A
10.11	Users participate in the reviews of privacy standards.	A
10.12	Changes suggested by the privacy review are implemented within three months.	A

11	Aftercare	Level
11.1	There is a general aftercare patient information sheet.	D
11.2	There is a contact number for patients who have questions or experience problems.	D
11.3	There are procedure-specific aftercare patient information sheets for all procedures performed in the unit.	C
11.4	There is a 24-hour contact number for patients who have questions or experience problems.	C
11.5	All patients are told whether they are suspected of having a malignancy on the day of the procedure unless it is considered inappropriate to do so.	C
11.6	If it is considered inappropriate to tell the patient whether malignancy is suspected, a note is made in the file of the reason.	C
11.7	All patients are discharged with verbal and written information about next steps appropriate for their care.	B
11.8	All patients are told the outcome of the endoscopic procedure prior to discharge.	B
11.9	All patients are told whether further information about pathological specimens will be available, from whom and when.	B
11.10	Patients' views on aftercare are sought at least once a year.	B
11.11	All patients are offered a copy of the endoscopy report or a patient-centred version of it. If this is deemed inappropriate the reason is recorded in the file.	A
11.12	All patients that require a follow-up appointment agree on one prior to discharge.	A
11.13	All patients are notified of pathology within seven working days of the procedure if they have been told further information will be available and do not have an outpatient appointment.	A
11.14	Users participate in review of aftercare processes.	A
11.15	Changes suggested by the aftercare process review are implemented within three months.	A
11.16	If a patient experiences problems and needs further advice they are able to discuss these problems with an adequately trained health professional via a 24-hour contact number.	A

12	Ability to Provide Feedback to the Service	Level
12.1	The unit policy for patient complaints is available in the unit in written and electronic form.	D
12.2	Action is planned (with auditable outcomes) in response to patient complaints.	C
12.3	Patient satisfaction is measured on an ad hoc basis.	C
12.4	Action for patient complaints is reviewed within three months to ensure it has dealt with the issues.	B
12.5	Patient feedback is sought via at least one method annually—for example, discovery interviews, focus groups, PPI forums, questionnaires or invited comments.	B
12.6	Action is planned (with auditable outcomes) in response to patient feedback by at least two methods annually.	B
12.7	Annual user feedback on services is sought via at least two methods.	A
12.8	Action for patient feedback is reviewed within six months to ensure it has dealt with the issues.	A
12.9	Users participate in planning and evaluating services.	A
12.10	Details of changes made in response to patient feedback are offered to patients who have participated in feedback surveys.	A

Appendix 3: Draft Synoptic Reporting for Colorectal Carcinoma Resection

Check one response unless otherwise indicated.

Procedure

___ Total proctocolectomy ___ Total abdominal colectomy
___ Right hemicolectomy ___ Transverse colectomy
___ Left hemicolectomy ___ Sigmoidectomy
___ Rectosigmoid colon (low anterior resection)
___ Abdominoperineal resection ___ Transanal disk excision (local excision)
___ Total mesorectal excision ___ TME and anus
___ Proctectomy + anus
___ Other (specify): _____
___ Not specified

Specimen Length (if applicable)

Specify: ___ cm

Tumour Site (check all that apply)

___ Cecum ___ Right (ascending) colon
___ Hepatic flexure ___ Transverse colon
___ Splenic flexure ___ Left (descending) colon
___ Sigmoid colon ___ Rectosigmoid
___ Rectum
___ Colon, not otherwise specified
___ Cannot be determined
___ Other (specify): _____

Tumour Size

Length: ___ cm × ___ cm (transverse) unless circumferential ___

Macroscopic Tumour Perforation

___ Present ___ Absent ___ Cannot be determined

Macroscopic Intactness of Mesorectum

___ Not applicable ___ Complete ___ Near complete (defects < 5 mm)

___ Incomplete (reaches muscularis propria) ___ Cannot be determined

Histologic Type

___ Adenocarcinoma NOS ___ Mucinous adenocarcinoma

___ Signet-ring cell carcinoma ___ Small-cell carcinoma

___ Squamous cell carcinoma ___ Adenosquamous carcinoma

___ Medullary carcinoma ___ Undifferentiated carcinoma

___ Other (specify): _____

___ Carcinoma, type cannot be determine

Histologic Grade

___ Not applicable ___ Cannot be assessed

___ Low-grade (well differentiated to moderately differentiated)

___ High-grade (poorly differentiated to undifferentiated)

___ Other (specify): _____

Histologic Features Suggestive of Microsatellite Instability

Intratumoral Lymphocytic Response (tumour-infiltrating lymphocytes)

___ None ___ Mild to moderate (0 to 2 per high-power [×400] field)

___ Marked (3 or more per high-power field)

Peritumoral Lymphocytic Response (Crohn-like response)

___ None ___ Mild to moderate ___ Marked

Tumour Subtype and Differentiation (check all that apply)

___ Mucinous tumour component (specify percentage: ____%)

___ Medullary tumour component

___ High histologic grade (poorly differentiated)

Tumour border

___ Pushing ___ Infiltrating

Microscopic Tumour Extension (pT staging)

pT1 Tumour invades submucosa but not muscularis propria

pT2 Tumour invades into but not through muscularis propria

pT3a/b Invasion through muscularis propria, 5 mm or less beyond muscularis propria

pT3c/d Invasion through muscularis propria, > 5 mm beyond muscularis propria

pT4a Tumour penetrates visceral peritoneum

pT4b Tumour directly invades other organs or structures

Margins of Resection

R0 No tumour identified at margins

R1 Tumour present at proximal/distal/radial margin (state which) microscopically

R2 Tumour present at proximal/distal/radial margin (state which) grossly

State clearance at deep or radial margin: ___ mm (note: involved if < 1 mm)

State site of the margin if possible (o'clock): _____

Regional Lymph Nodes (pN)

___ pNX: Cannot be assessed

___ pN0: No regional lymph node metastasis

___ pN1: Metastasis in 1 to 3 regional lymph nodes

___ pN2: Metastasis in 4 or more regional lymph nodes

Specify number examined: ___

Number involved: ___

Distant Metastasis (pM)

___ Cannot be assessed (pMX) ___ pM1: Distant metastasis

Specify site(s): _____

Perineural Invasion

___ Present ___ Not identified

Vascular (Large Vessel) Invasion (V)

___ Not identified

___ Present

___ Indeterminate

___ Extramural (beyond muscularis propria)

___ Intramural

Lymphatic (Small Vessel) Invasion (L)

___ Not identified

___ Present

___ Indeterminate

Discontinuous Extramural Extension (irregular tumour nodules in pericolorectal adipose tissue without histologic evidence of residual lymph node; smooth contoured nodules are counted as lymph nodes)

___ Not identified

___ Present

___ Cannot be determined

Treatment Effect (applicable to carcinomas treated with neoadjuvant therapy)

___ No prior treatment ___ Present

___ No residual tumour (complete response, grade 0) ___ Acellular mucin pools

___ Marked response (grade 1, minimal residual cancer)

___ Moderate response (grade 2)

___ No definite response identified (grade 3, poor or no response)

___ Not known

Type of Pre-existing Polyp in Which Invasive Carcinoma Arose

___ None identified Specify type: _____

Polyps Present Elsewhere in Specimen

Specify number ___ and type _____

Additional Findings

___ Ulcerative colitis ___ Crohn's disease ___ Diverticular disease

___ Immunohistochemistry (e.g., MMR genes, E-cadherin): _____

___ Other (specify): _____

Tumour/Node/Metastases Descriptors

___ None

___ m (multiple primary tumours)

___ r (recurrent)

___ y (post-treatment)

Final TNM Stage _____

Note: As new TNM/AJCC publications become available, revisions to this list of data elements may be required.

Appendix 4: Draft Synoptic Reporting for Polyps

(Source(s): CancerCare Manitoba and CancerCare Ontario)

Complete one form for each polyp found.

Specimen number ___

Size on endoscopy ___ cm

Location: ___ cm on withdrawal ___ not stated

Colon Segment

___ Terminal ileum

___ Cecum

___ Ascending

___ Hepatic flexure

___ Transverse

___ Splenic flexure

___ Descending

___ Sigmoid

___ Rectum

___ Not stated

Pathology

___ Yes ___ No

If yes:

1. Size of polyp from pathology report:
   ___ cm

   ___ Indeterminate (if more than 1 polyp per container, removed piecemeal or biopsied only)

   ___ Not stated

Diagnostic code ___

Current Classifications

(Snover et al. 2005; Odze and Goldblum 2009)

Code	Term
	A. Neoplastic polyps (must be dysplastic by definition)
A1	Tubular adenomas
A2	Tubulovillous adenoma
A3	Villous adenoma
A4	Sessile serrated adenomas / sessile serrated polyps
A5	Combined serrated polyps
A6	Mixed polyps
A7	Malignant polyps
A8	Adenomas with misplaced submucosal glands (“pseudoinvasion”)
A9	Carcinoids
A10	Other polyps with dysplasia (state type)
	Grading dysplasia in neoplastic polyps (score the highest grade)
L	Low-grade dysplasia
H	High-grade dysplasia
	(the suffix L or H is added to any of the above, e.g., A1L)
	B. Non-neoplastic mucosal polyps (must be non-dysplastic at time of diagnosis)
B1	Hyperplastic polyps
B2	Inflammatory polyp
B3	Peutz-Jegher polyp
B4	Juvenile polyp
B5	Prolapsed polyps (state variant if known)
	C. Other polyps
C1	Mesenchymal (state type)

C2 Lymphoid (state type)

C3 Other (state type; include unremarkable mucosa)

Additional classification

(add grade of dysplasia [L or H] when using these classifications)

A4a Dysplasia in sessile serrated polyp/sessile serrated adenoma with dysplasia (synonymous)

A4b Traditional serrated adenoma

A4c Filiform serrated adenoma

A4d Tubular adenomas with overt serrated features

A4e Dysplastic serrated polyps in inflammatory bowel disease

2. Grade of dysplasia for neoplastic polyps

___ High

___ Low

___ Not stated

3. If A10 (other), state type: _____

4. If C1, C2 or C3, state type: _____

5. If A7 (malignant):

5.1 Histological type

___ Adenocarcinoma

___ Mucinous adenocarcinoma (> 50% mucinous)

___ Medullary carcinoma

___ Signet-ring cell carcinoma (> 50% signet-ring cells)

___ Small-cell carcinoma

___ Undifferentiated carcinoma

___ Other (specify): _____

___ Carcinoma, type cannot be determined

5.2 Histological grade of cancer

___ High-grade (poorly differentiated; < 50% glands)

___ Low-grade (well differentiated; > 50% glands)

___ Indeterminate

___ Not stated

Notes:_____

_____

_____

CANCER REPORT (to be completed for every cancer)

Specimen number ___

Size on endoscopy ___ cm

Location: ___ cm on withdrawal ___ not stated

Colon Segment

___ Terminal ileum
___ Cecum
___ Ascending
___ Hepatic flexure
___ Transverse
___ Splenic flexure
___ Descending
___ Sigmoid
___ Rectum
___ Not stated

Pathology

___ Yes ___ No

If yes:

6. Malignant Tumour

6.1 Histological type

___ Adenocarcinoma

___ Mucinous adenocarcinoma (> 50% mucinous)

___ Medullary carcinoma

___ Signet-ring cell carcinoma (> 50% signet-ring cells)

___ Small-cell carcinoma

___ Undifferentiated carcinoma

___ Other (specify): _____

___ Carcinoma, type cannot be determined

6.2 Evidence of invasion beyond muscularis mucosa

___ Present

___ Absent

___ Indeterminate

___ Not stated

6.3 Histological grade of cancer

___ High-grade (poorly differentiated; < 50% glands)

___ Low-grade (well differentiated; > 50% glands)

___ Indeterminate

___ Not stated

6.4 Presence of desmoplasia

___ Present

___ Absent

___ Indeterminate

___ Not stated

6.5 Evidence of lymphovascular invasion

___ Present

___ Absent

___ Indeterminate

___ Not stated

Notes:_____

_____

_____

Production of this report has been made possible through a financial contribution from Health Canada, through the Canadian Partnership Against Cancer.

The views expressed herein represent the views of the Quality Determinants in Colorectal Cancer Screening Working Group Members.