



Alberta Colorectal Cancer Screening Program

Standards and Guidelines

Version 4.0 of 4.0

Part 1

Standards and Guidelines Draft Document Leaders

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Note: The Standards and Guidelines Part 1 and Part 2 documents are considered a work in progress and living documents. They will be reviewed annually for changes to practice and/or updates.

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Abbreviations

AHS – Alberta Health Services
ACRCSP – Alberta Colorectal Cancer Screening Program
AHCIP – Alberta Health Care Insurance Plan
AMA – Alberta Medical Association
ASGE – American Society of Gastrointestinal Endoscopy
CAG - Canadian Association of Gastroenterology
CLS- Calgary Lab Services
CPG – Clinical Practice Guideline
CPSA College of Physicians and Surgeons of Alberta
CRC – Colorectal Cancer
FIT – Fecal Immunochemical Test
gFOBT or FOBT – Fecal Occult Blood Test (guaiac)
GRS – Global Ratings Scale
PCP- Primary Care Provider
PHN – Personal Health Number
RCT - Randomized Controlled Trial
SOP – Standard Operating Procedures
TOP – Toward Optimized Practice
ULI – Unique Lifetime Identifier

Introduction

Colorectal cancer (CRC) is a serious threat to the health of Albertans. It is the second leading cause of cancer deaths and the third most commonly diagnosed cancer in Alberta. In 2013, the most recent data shows that there was about 1900 new cases of CRC diagnosed in Alberta and 650 deaths that occurred from the disease in 2011 (*Alberta Cancer Registry Statistics, 2011*). Despite the fact that there has been consistent evidence that colorectal cancer screening can significantly reduce mortality, and screening rates are improving, only about 50% of average risk Albertans aged 50-74 self-reported having participated in colorectal cancer screening (CPAC survey, 2012)

The Alberta Colorectal Cancer Screening Program (ACRCSP) is an evidence-driven population-based cancer screening program within Population, Public and Aboriginal Health, Alberta Health Services.

The ACRCSP goals are:

- **Short-term** – Develop access, infrastructure and capacity for a provincial population-based CRC screening program
- **Medium-term (within 5 years)** – 70% of the target population in Alberta will participate in CRC screening (defined as being up-to-date with CRC screening)
- **Long-term (within 10 years)** – Reduce CRC incidence by 20% and CRC mortality by 30% through enhanced prevention and screening

When fully implemented, the ACRCSP will include all components of an organized population-based screening program, namely:

- Key policy parameters including target population age range, screening interval, primary screening test and diagnostic follow-up test
- An evidence-based screening pathway
- Multi-pronged approach to recruitment and recall of the target population for screening and monitoring/follow-up on screening activities
- Coordination of education and health promotion efforts for the target population and health professionals and partnership with Toward Optimized Practice (TOP) Clinical Practice Guideline (CPG) for CRC screening. See Appendix 2 for link to revised TOP CPG published November 2013
- Quality assurance/improvement initiatives that operate across all stages of the screening pathway and process at each stage of the pathway
- Evaluation of all program components and overall program effectiveness

This document (Part 1) describes the standards, guidelines, recommendations and/or expert consensus that will serve to ensure that the ACRCSP program and respective CRC screening-related services (Part 2) within the province can provide high quality, safe, efficient and effective screening to the target population as they move through the CRC screening pathway. ***The Standards and Guidelines Part 1 and Part 2 documents are considered a work in progress and living documents. They will be reviewed annually for changes to practice and/or updates.***

Purpose

The purpose of creating Standards and Guidelines is to provide all stakeholders involved with CRC screening and related services, the evidence and/or consensus-based quality and safety “points of reference” so they can provide the highest level of quality and safe care and services to all individuals.

In addition, the Standards and Guidelines will, in the long term, serve as a benchmarking tool for the ACRCSP Quality Assurance/Quality Improvement Program. These benchmarks will be the impetus for a continual cycle of quality and safety assurance through regular monitoring of specific indicators and follow up action to resolve situations where standards and guidelines are not met.

A CRC screening program that is committed to adopting Standards and Guidelines, and ensures quality assurance and improvement processes are in place, will foster:

- Acceptance and use of the screening program by the target population
- Testing of sufficient sensitivity to detect colorectal cancer at an early stage
- People-centered approach and prompt, sensitive means of communicating with people and practitioners
- Highly qualified practitioners using an interdisciplinary team delivery approach
- Investment of resources for on-going education of practitioners and staff involved in the program
- Cost efficiency

A high-quality, safe and effective CRC screening program:

- Maximizes participation of the target population
- Ensures patients fully understand the risks and benefits associated with CRC screening
- Prevents unnecessary anxiety and suffering for patients with positive results
- Prevents unnecessary or inappropriate interval repeat fecal tests and/or colonoscopies
- Minimizes missed colorectal cancers
- Minimizes complications associated with diagnostic follow up procedures
- Ensures timely access to any/all services associated with the CRC screening path of care

Program and Practice Standards and Guidelines

Program and practice Standards and Guidelines ensure high quality program and services are delivered; suggest requirements and methodologies for implementing program policy and delivering service; and facilitate:

- Achievement of the program goals and outcomes to ultimately reduce mortality from CRC
- Assessment of CRC screening services to determine that acceptable levels of performance are being achieved or to identify specific needs for strengthening the program
- Development of baseline information on the ACRCSP from which to plan future program needs and directions, including monitoring and surveillance as well as the funding/resources needed to sustain the program
- Collaboration and coordination among all stakeholders involved in CRC screening by having commonly understood expectations regarding their respective roles, responsibilities and accountabilities
- Integration of flexibility within professional practices while ensuring that the practices remain client and outcome-focused

For the purposes of this document, the terms “standard” and “guideline” may be used interchangeably particularly in situations where formal standards do not exist i.e. legislated standards.

The following definitions apply:

- **Program standard:** the acceptable requirements for conducting a program, integrating resources, activities and services directed at a specific target population and focused on achieving specific outcomes;
- **Practice standard:** the acceptable requirements for the provision of professional care and services to an individual/group, integrating relevant knowledge, attitudes, skills and judgments. Professional activities are performed in a systematic manner in order to achieve program outcomes. Professionals are expected to be accountable and responsible for their practice to assure safe, competent and ethical care.

Principles Underlying Standards Development

The program standards describe the essential services for, and approaches to, the target population. The following principles will guide standards development:

1. Population and People Focused
All standards and guidelines will serve to provide the highest quality service and protect the safety of the population accessing screening and related diagnostic services.
2. Partnership Focused
Developing and implementing the CRC screening Standards and Guidelines is a collaborative effort including but not limited to cancer services, health care facilities/services/operations, specialists, primary care providers and users (target population) of the services.
3. Open and Transparent
This document will explain what will be done, why and how it will be done and will be written in simple clear language and in a format that is easily understood and accessed for use by relevant stakeholders.
4. Evidence Based and/or General Consensus
All decisions will be based on best evidence available at the time and/or where evidence is inconclusive, based on general consensus.
5. Sensitive and Professional
Recognizing needs, beliefs and opinions may differ and therefore respect and encourage diversity.

Accountability

The Minister of Health has final responsibility and authority for the overall quality of the health system in the province, for maintaining the health system, and for ensuring that the health needs of Albertans are met.

Alberta Health Services (AHS) has responsibility for the provincial coordination and operations and/or facilitation of the ACRCSP in partnership with health care facilities/services/operations across the province.

The health care facilities/services/operations are responsible for overall operations of the screening pathway processes and respective service delivery of the ACRCSP and/or their own specific CRC screening programs.

All health service providers are expected to possess and practice the required competencies in carrying out their designated roles and responsibilities in the CRC screening process. Each stakeholder is ultimately accountable for the quality and outcomes of CRC screening services for which they are responsible.

ACRCSP Standards

The ACRCSP standards (also referred to as the “provincial program” in this document) address the requirements for conducting a program, integrating resources, activities and services directed at a specific target population and focused on achieving specific outcomes. Standards will correspond with and exist for each step in the CRC screening pathway and include those processes that support each step. This will ensure quality is addressed throughout the entire program.

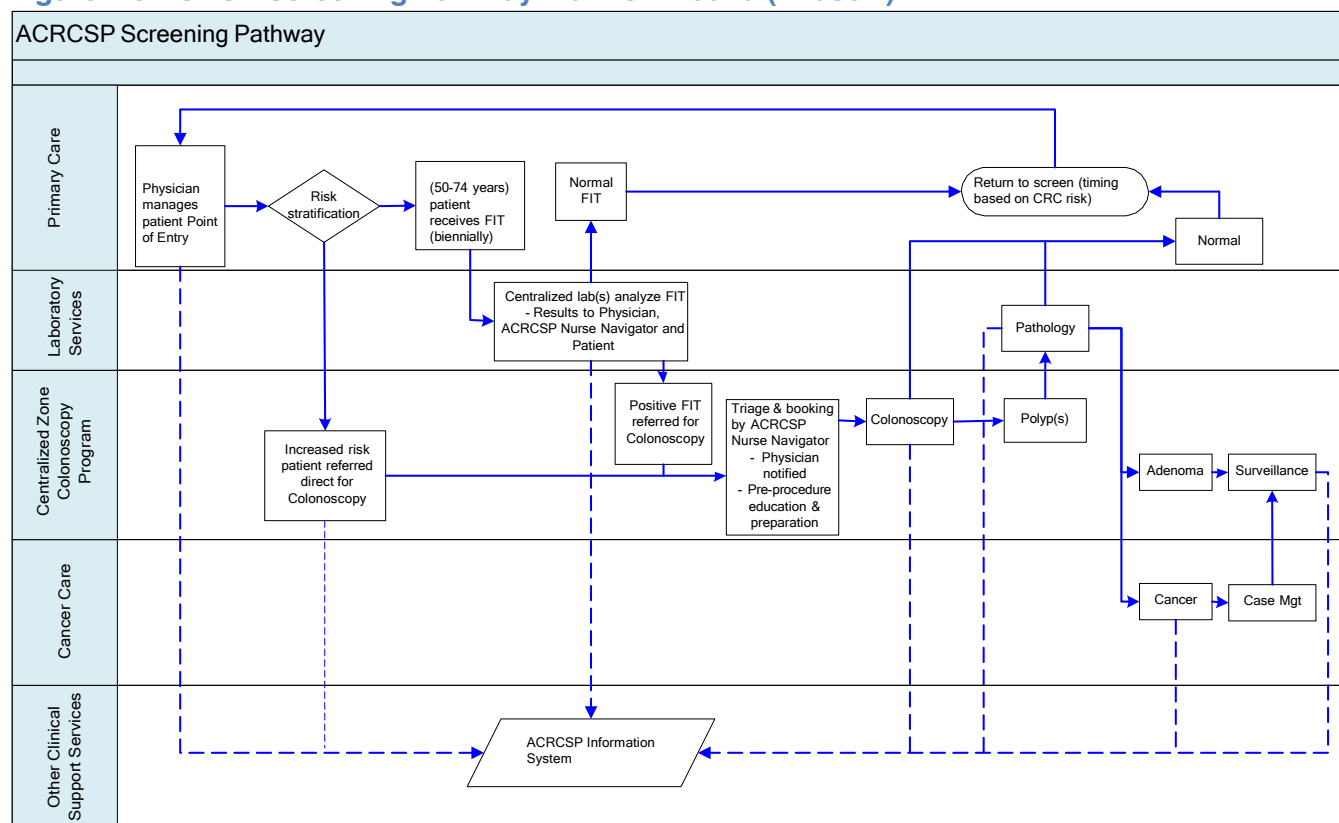
Note: The Standards and Guidelines will be a living document and require ongoing updates as emerging evidence and developments in CRC screening-related technologies, program, clinical service and practice change over time.

Each of the program standards contains the following:

1. Standard
Includes a brief description of the standard where necessary
2. Rationale
Includes a description of the evidence and/or consensus supporting the standard
3. Implementation Guidelines
Describes how the standard is expected to be implemented by the ACRCSP

Future versions of this document may include additional standards, additional detail including timelines for implementation, accountability for implementation, indicators for monitoring standards and sustaining/changing standards over time.

Figure 1.0 ACRCSP Screening Pathway Plan for Alberta (Phase 1)



Key decision points in the pathway for Phase 1 are:

1) Point of Entry – Primary Care/Family Physicians

Rationale:

- Consistent with the AHS Strategic Direction of access, quality and sustainability for all health services in Alberta.
- Allows for immediate integration with family physicians and leverages the Primary Care Network (PCN) model as well as other primary health care providers in Alberta
- Extension of current practice and existing organized local screening activities (e.g. Edmonton, Calgary and Lethbridge)
- Family physician entry into screening program adopted in other jurisdictions (e.g. Ontario)
- Allows for identification and management of those at increased risk for CRC
- Recommendation by family doctor is strongest predictor of completing CRC screening (McGregor, 2010)

2) Primary Entry Level Test – Fecal Immunochemical Test (FIT) for Average Risk Screening

Rationale:

- Higher sensitivity for CRC and advanced adenomas, and comparable specificity to guaiac-FOBT previously used
- Increased compliance compared with guaiac-FOBT
- Supports access, quality and sustainability for an entry level CRC screening test (when compared with primary screening of average risk by colonoscopy)
- Automated processing supports centralized analysis at designated labs and reduced labour costs
- Found to be more cost-effective than guaiac-FOBT by the Canadian Agency for Health and Drugs in Health Technology Assessment
- Adopted by four other provincial CRC screening programs

3) Diagnostic Test – Colonoscopy

Rationale:

- Current standard of care and consistent with the CPG
- Allows the entire colon to be visualized
- Allows pre-cancerous polyps to be removed, thereby reducing the incidence of CRC

In the case of a failed colonoscopy, the preferred strategy is repeat colonoscopy by a designated expert endoscopist. Other options, listed in order of preference are balloon endoscopy (if available), CT colonography and air-contrast barium enema.

Future pathway development will include:

- Expanded patient identification and recruitment including direct mailed invitations
- Direct uptake and colonoscopy booking of screen positive patients; prospective identification and recall of high risk patients requiring surveillance
- Complex management of some screened/surveillance patients, geographically isolated and other hard to reach populations (e.g. those without a family doctor, ethnic minorities), others under/over-screened
- Inclusion of other screening and/or diagnostic modalities into pathway
- Further strengthening the Quality Assurance (QA) program
- Other expansions supporting program operations over the longer term

ACRCSP Governance Structure

Standard

As of 2013, the ACRCSP operates as a provincial population-based cancer screening program. The “provincial” section of ACRCSP functionally reports within the Cancer Screening Programs Department in the Division of Healthy Living, Population, Public and Aboriginal Health (PPAH), within AHS. Clinical and lab services support the program but functionally report and operate within their respective Health Zones. There is a collaborative partnership between the provincial ACRCSP and the related services in the Zones but no formal reporting structure is in place. The provincial program sets policy direction and the Zones provide the service infrastructure to comply with program policy taking into consideration local needs and context.

Roles and Responsibilities are as follows:

Alberta Health/Alberta Health Services (AHS)

- Support for the ACRCSP population-based cancer screening program-related components and clinical services coordination functions.
- Funding mechanisms for the program’s facilities providing CRC screening-related clinical services must be obtained as a collaborative request or provided through additional or annualized resource allocation, and for practitioners, fee for service mechanisms.

AHS Population, Public and Aboriginal Health: Healthy Living, Cancer Screening Programs

- AHS is ultimately responsible for the central program elements of all coordinated cancer screening programs including: engagement including awareness, information and education; correspondence functions; systematic measurement of quality indicators to support a systematic approach to performance and quality assurance/improvement; information system development and maintenance for program performance and quality indicator reporting of program outcomes and process evaluation.
- The ACRCSP is integrated with the Breast and Cervical Cancer Screening Programs and works collaboratively with health facilities/services/operations throughout the province of Alberta, whether facilities are establishing a local approach to CRC screening or providing the operations required to support the ACRCSP. In both situations, the relationship will ensure integration, no duplication of services and consistent messaging to Albertans.

CRC screening related service provision across the province

- All CRC screening related clinical services are funded by the Zones’ global funding routes, including laboratory services for fecal tests, histopathology and operational costs related to primary screening and follow-up colonoscopies.
- Local management of the ACRCSP includes clinical and health services including colonoscopy suites, central intake, laboratory processing, FIT physician engagement and awareness of the CRC screening pathway, patient education and follow up.

Health Care Providers

- Health Care Providers include but are not limited to laboratory personnel, endoscopists, general practitioners, pathologists, nurses and other non-physician providers.
- They provide the operations and services for the ACRCSP, adhere to quality assurance and improvement standards and where appropriate/required, provide performance and quality indicator data to the ACRCSP.
- Health Care Providers provide input to the ACRCSP through direct participation in committees and working groups, as well as professional organization representation.

Stakeholder Collaboration

- Different groups of stakeholder representatives convene for a variety of ACRCSP implementation activities. These will be formed and change over time based on needs of the ACRCSP.

Rationale

The ACRCSP follows the World Health Organization (WHO) principles of population-based organized cancer screening programs while adhering to the mission and vision of AHS. Program policies are evidence-based and implementation priorities are guided by needs of the target population. Decision-making occurs using a collaborative process of key stakeholder groups that provide invaluable insight, guidance and advice to the provincial CRC screening program leadership team as the implementation process proceeds.

Implementation Guidelines

A number of steering committees and working groups have been established and have evolved over time to meet the needs of specific program implementation activities.

General

Identification of Target Population

Standard

- i. All residents of Alberta, as defined in the Alberta Health Care Insurance Act, aged 50-74, are potential participants for the ACRCSP.
- ii. Participants that are asymptomatic, without personal or family history of CRC or adenomas, without inflammatory bowel disease, without known genetic syndromes or predisposing medical conditions or other individual risk factors, and have not been identified as positive on any previous CRC screening test will be defined as „average risk“.
- iii. Alberta residents defined as „higher risk,“ or any criteria outside of the criteria described above for average risk, shall be identified by their primary care practitioner in the current phase of the ACRCSP. Future phases may include identification of average and higher risk using other approaches such as invitation or self-referral. Individuals at higher risk, in particular those with known colonic adenomas or those with a documented family history who have already been in contact with the screening centers/programs in the Zones, will be identified and recalled at appropriate intervals. This will be performed within the Zones in concert with primary care. Otherwise, they will be advised to contact or continue to be managed by their family physician.
- iv. Residents outside the target population age range i.e. those younger than 50, are encouraged to discuss screening if at higher risk for CRC or prevention of CRC, and for those older than 74, discuss the benefits and risks of screening with their family physician.

Rationale

- Multiple RCTs conducted in UK, Denmark, USA and Sweden support an average risk population-based program approach to CRC screening. The identification of the target population and associated exclusion criteria is generally consistent with most existing Clinical Practice Guidelines and/or recommendations.
- A resident of Alberta is defined as “a person lawfully entitled to be or to remain in Canada, who makes his home and is ordinarily present in Alberta and any other person deemed by the regulations to be a resident, but does not include a tourist, transient or visitor to Alberta.”

Implementation Guidelines

- Individuals who fall within the target age range and are not residents of Alberta can access CRC screening services but will not be actively recruited to participate in the organized CRC screening program as they cannot be followed over time. They may have obtained a ULI (unique lifetime identifier) or have a health care number from another province.
- Other individuals, without ULIs (i.e. students who have partial residence in Alberta, federally insured persons such as those in the Canadian Forces, RCMP or First Nations) may be included in the ACRCSP invitation, recall, or follow-up reminder processes provided their health information can be obtained and tracked over time. However, if this is not possible, these residents have access to CRC screening and follow-up tests and treatment but their primary care physicians will be responsible.

Engagement of the Target Population

Standard

- i. An organized CRC screening program is intended to identify all people who meet the age and risk criteria for population-based fecal test screening.
- ii. General recruitment of the target population will be the responsibility of the provincial program using a variety of recruitment and health promotion strategies implemented in a stepwise approach.
- iii. AHCIP (or a new source) will be used as the information source to recruit eligible Alberta residents.
- iv. Strategies to recruit “harder to reach” but eligible populations will include education and information materials available in multiple languages, targeted information sessions through media and community venues, implementation of community-based development initiatives, and CRC screening in home healthcare-related visits.

Rationale

- The success and effectiveness of a population-based screening program depends upon high participation rates.
- Recruitment is an important function of the program and therefore the ability to identify and reach the target population is done most efficiently through the provincial health plan (AHCIP).
- Letters of invitation are not likely sufficient for the entire eligible population due to cultural, ethnic, educational, economic or other factors.

Implementation Guidelines

- Alberta residents are invited for screening when they become eligible i.e. meet criteria, for the provincial program.
- Alberta Health provides access to an updated list of people in the target population to AHS/Cancer Services for recruitment, planning and monitoring purposes.
- Invitational letters, using program letterhead are issued through the provincial program and currently provided in FIT kits. Mailed invitations may be considered in the future.
- The content of the invitational or other correspondence (letters) is developed based on literature findings and experience of existing screening programs and is ideally focus tested for acceptability and comprehension. The content includes but is not limited to:
 - Eligibility criteria
 - Information on colorectal health and the availability of screening access
 - Information that eligible population may access FIT screening through their family physician (or through self-referral-future phase of program)
 - Information on the possibility of further testing in the event of an abnormal screening result

Program Education and Promotion

Standard

- Promotion and recruitment maximizes participation of the target population. This will occur primarily through clinician champions who support CRC screening and an organized program approach for their patients and the population, and direct recruitment of clients.
- A number of strategies will be used to meet this standard including:
 - i. Public and provider education materials in various mediums
 - ii. Recruitment letters to target population
 - a.) Invitation
 - b.) Recall
 - c.) Reminder
 - iii. Awareness and education working group (to guide, monitor and evaluate strategies)
 - iv. Social marketing strategyCRC Screening Clinical Practice Guideline (partnership with TOP)

Rationale

- Evidence from existing UK, Australia and other international CRC screening programs and/or pilots have demonstrated increased uptake of the target population following a structured program education and promotion program component (IARC, 2010).
- Personal invitations, specifically letters of invitation, have been shown to be the most efficient and cost effective method of recruitment, achieving the highest screening rates. Studies have shown that reminder letters increase participation rates when sent within three to six weeks of the first invitation (Wagner T.H., 1998).

Implementation Guidelines

The following key activities are under consideration for future phases of program implementation:

- Provided current evidence supports correspondence and funding is secured, infrastructure will be developed to support province-wide engagement in CRC screening including:
 - Invitation
 - Recall
 - Reminder
- Continued use of other evidence-based engagement strategies i.e. social marketing, physician recommendation
- Ongoing development of program educational materials for the public and health care professionals
- Formation of partnerships with stakeholders as required i.e. gastroenterologists, other specialists and general practitioners, Alberta Medical Association, Primary Care Networks, and AHS health facilities/services/operations to promote organized CRC screening
- Conducting pilot recruitment strategies (2008-2010) i.e. mailing of positive results letters, test kits and invitation
- Developing and implementing recruitment and retention strategies for the target population
- Ongoing collaboration and capacity building with partners

Target Population Primary Screening Process

Primary Screening Fecal Immunochemical Test (FIT) and Frequency

Standard

- i. At this time a Fecal Immunochemical Test (FIT) has been selected as the population health approach primary screening tool for men and women aged 50-74 at average risk.
- ii. The average risk population will be screened at least biennially or preferably annually as long as they continue to have negative screening results with fecal testing.
- iii. For the ACRCSP, one FIT stool sample is required to test for traces of blood that are not visible to the naked eye.
- iv. Early detection of colorectal cancer using FIT annually would be expected to generate a cure rate of over 90% cancers detected at stage I, and downstage tumours detected at later stages (i.e. II to IV) where there is only a 5-year survival rate of about 10%.
- v. Two laboratories in Alberta will provide processing services for FIT and will adhere to relevant standards established by their respective lab quality control protocols.

Rationale

- According to the Report of the Ontario Expert Panel on Colorectal Cancer Screening (Cancer Care Ontario, Sept 2004), an estimated two-thirds of colorectal cancers bleed over the course of one week and 90% will bleed at some point over several years.
- The sensitivity of the FIT for CRC and advanced adenomas will vary depending on the positivity threshold selected by the program. Sensitivity at threshold values of 50, 75 and 100 ng/ml has been reported in the literature. Currently the program will use one sample at 75ng/ml (ACRCSP and Zone medical lead consensus). The studies to date report sensitivity at 75ng/ml is between 61 and 81% for CRC and specificity for CRC is reported to be between 93 and 98%. Sensitivity for CRC at 100ng/ml to be between 77-84% and specificity 95-97% for CRC. Sensitivity at 50ng/ml is between 68 and 89% and specificity at 50ng/ml is between 89 and 97% (IARC, 2010).
- Positivity threshold of FIT can be adjusted to find the most effective balance for sensitivity/specificity while managing screen positive follow-up demand on endoscopy services.
- Evidence supporting early detection, reduction of morbidity and mortality include Mandel et al., 2000, and Mandel et al., 1993.
- International Standardization Organization. Medical laboratories – particular requirements for quality and competence: ISO 15189:2003. Geneva: ISO; 2003.

Implementation Guidelines

- The FIT has been funded for CRC screening use only and is available throughout Alberta for the average risk target population. One sample will be required.
- Successful FIT kit completion requires easy to read and understand stool collection instructions (preferably diagrams), adequate documentation area for patients to enter personal information on the vial, and an adequate number of

community laboratory FIT drop-off points or in Zones where not available, other processes such as postal services will be used.

- The FIT is the preferred entry level screening test for average risk given its higher sensitivity. It has replaced the current guaiac-FOBT and all guaiac-FOBT Standards in this document.

Obtaining and Returning the FIT Kit

Standard

- i. A newly recruited targeted individual can obtain a FIT kit via a lab requisition from a primary care provider (the preferred point of access), walk-in clinic or a PCN.
- ii. The option to include FIT will be added on to the general lab community requisition (i.e. there will not be a dedicated FIT requisition).
- iii. FIT may be obtained directly from a health provider in some Zones i.e. North Zone where access to community collection sites are limited. Processes will be in place for FIT sample drop-off.
- iv. Use of the FIT will be limited to screening purposes only. All lab requisitions in the province will state the following criteria for ordering a FIT: for average risk CRC screening only, asymptomatic, 50 to 74 year old. For logistical reasons, the lab will accept requisitions for a wider age range than the target population. The program will monitor the use of FITs outside of the target age range and in future, a clinical mechanism will be required to address the use of the FIT in lower than 40 and beyond 74 year age groups.
- v. At this time, given the extreme temperatures in Alberta and instability of the FIT in high temperatures, mailing completed kits is not an option. Patients will be expected to return completed FIT kits to their local community laboratory collection sites or whatever lab process is established for those communities with limited access to lab.

Rationale

- Evidence for increased FOBT kit uptake strongly supports direct mail to target population (UK, Australia Bowel Cancer Screening Programs and other national and international programs).
- There are some exceptions to screening with a FIT between the ages of 50 to 74. For example, patients with a family history that includes a first degree relative with CRC over the age of 60, who may choose to screen with a FIT starting at the age of 40. As well, some patients over 74 may have a life expectancy exceeding 10 years and in optimal health, may choose to continue screening for CRC.

Implementation Guidelines

- It is expected that the majority of individuals will be able to access a FIT kit via requisition through their primary care providers and, where necessary, with local lab and provider arrangements, direct access to FIT kits may occur in PCNs, clinics and/or other local arrangements.
- A toll-free provincial CRC screening program telephone number and a program website (screeningforlife.ca) have been established for providing specific information to the target population regarding available screening methods and centers across the province.
- The Cancer Screening Program's toll-free information telephone line and/or Health Link can also assist those targeted persons requiring a primary care provider.
- A single manufacturer provides standardized custom FIT kits and there is a process in place for FIT kit distribution to all Zones.

Collection of the FIT Specimen

Standards

- i. Patients will obtain a province-wide standardized FIT kit using the appropriate lab requisition for FIT from a designated lab community collection site or other local lab process for access to FIT as specified. The requisition must be signed by a physician or physician's clinic staff on behalf of the physician.
- ii. All FITs are to be completed by the patient using the FIT kit. There is no recommended time of day or day of week to complete the FIT. The FIT should not be completed at the lab or in a physician's office during a digital rectal exam or physical exam.
- iii. The FIT kit will contain: one sealed FIT vial, a patient information label, an ACRCSP Introduction Letter, standardized FIT instructions and an absorbent pad in a clear plastic biohazard bag.
- iv. Dietary restrictions are not necessary for the participants before or during the collection of stool samples for the FIT kit.
- v. Participants should not discontinue the oral intake of any medications, including aspirin, iron or anticoagulants, prior to or during the collection of the sample.

Rationale

- The FIT is a home test for asymptomatic individuals and should be completed at home as per the TOP CPG (every one to two years), or as per ACRCSP every year, as part of a regular health seeking behaviour.

Implementation Guidelines

In April 2013 a project team was reconvened to implement FIT testing across the province. The project team implemented FIT testing as a primary screening test for asymptomatic patients between the ages of 50-74 years. Key deliverables included:

- Developing the Request for Proposal for instrument acquisition
 - Instrument and reagent contracts
 - Staff training
 - Standard Operational Procedures(SOP) development
- Establishing the instrument interface to Netcare and ACRCSP
- Work-up of new analyzers and delivery of instruments and supplies to performing labs
 - Polymedico Diana OC analyzers worked up at both testing sites.
 - Work-up data reviewed and approved by respected medical leads in accordance with College of Physicians and Surgeons of Alberta's(CPSA) accreditation requirements
- Training for laboratory staff responsible for performing FIT testing
 - Initial training provided by vendor representative
 - Three webinars offered to provide front-line staff with background information about the FIT testing and answer their questions about the new processes and testing guidelines
- Requisition revisions in all Zones to remove FOBT on community requisitions and replace with FIT (asymptomatic 50-74 years)

ACRCSP Requirements for Laboratory Implementation of the FIT

Standard

Program Specifications for the FIT

1) Screening

- Based on evidence and clinical judgment the program recommends as a starting point:
 - One sample collection
 - 75ng/ml = positive FIT test (threshold)

2) Product specifications

- Contents in each kit= 1 FIT vial (sample), instructions for use, program information letter, plastic (biohazard) envelope for sample return, standardized labels (for vial, envelope)
- Bar code (future consideration)
- Standardized instructions
 - Different languages as per the AHS policy on translated resources
 - Include diagrams for low literacy

3) Product procurement and inventory management

- Inventory management - labs to determine most effective and efficient approach

FIT Dissemination, Collection and Processing

1) Point of FIT kit dissemination

- Standard community collection site requisitions for general lab tests
- Requisitions for the FIT completed by MD, RN or any of the primary care team in PCN, etc.
- Patient instructions created, finalized and provided by ACRCSP
- Option to distribute kits to doctors' offices/hospitals/clinics/other if necessary in remote communities. In cities and towns where patients have access to lab services, a FIT must be obtained from a lab via requisition

2) Collection

- Lab has a process for checking returned samples to ensure patients have correctly completed labeling of the FIT sample
- Lab will process all requisitions for FITs regardless of age-based eligibility given the extenuating circumstances i.e. use of FIT in 40-49 year old individual,

that are at higher risk for CRC but can screen with FIT earlier than 50 years old, and older than 75 year old individuals. The ACRCSP will monitor and address issues associated with eligibility for FIT kit (age-based eligibility)

- Lab has a process to facilitate patient drop-off of completed kit
- Lab has a process to record length of time from specimen sampling to analysis and specimen drop off to analysis

3) Transport

- Length of time of specimen transportation – lab to determine based on stability studies
- Temperature control during transportation – lab to determine based on stability studies

4) Processing - Lab to develop detailed process

- There are two designated FIT processing centres: Dynalife in Edmonton and Calgary Lab Services (CLS) in Calgary
 - Lab standards and protocols are developed based on lab quality control and usual procedures to ensure:
 - Temperature & specimen adequacy for processing
 - Definition and resolution of an inadequate sample or result
- Instrumentation (mirror instrumentation)
- Contingency plan for instrument failure

5) Kit wastage –Lab responsibility:

- Managing inventory and expired kits

6) Quality Control/Quality Assurance procedures in place

Health Care Workers Education and Communication

1) Physician communication

- The FIT should be used for CRC screening only according to program standard criteria: 50-74, male or female, average risk for CRC, asymptomatic. Criteria are stated on lab requisition.
- The gFOBT was phased out province wide January 1st 2014 with the exception of acute care and emergency departments where gFOBT will continue to remain available for point of care testing and will be considered for discontinuation at a later date. FOBT results will not be tracked by the ACRCSP.
- The FIT will not be used as a replacement for diagnostic gFOBT.

- The ACRCSP medical leadership will provide the communication and plan regarding ineligible FIT requests and inappropriate use of FIT i.e. as a diagnostic tool.

2) Laboratory and pathology communication plan → pathology services will eventually be impacted by increased number of biopsies resulting from increased adenoma detection from FIT.

3) Communication with the public → strategies to encourage patient compliance with testing.

4) Staff training required initial set up and will be ongoing as per lab policies for staff training.

Reporting and Data Management

1) Standardized data elements - list of data elements (Appendix 1)

Rationale

Program Specifications

1) Product performance (Minimum requirements)

- Sensitivity, specificity, positivity rate for average risk, and stability to be monitored on a quarterly basis.
- 75ng threshold based on evidence and clinical judgment recommended as a starting point.
- Promote compliance of patients by decreasing number of samples required i.e. from 2 samples to 1 sample.

2) Product specifications

- Must be easy to use and understood by patients for use at home.
- Future: bar code will address issues with patient self-labeling and decrease rate of indeterminate tests.

FIT Dissemination, Collection and Processing

1) Point of FIT kit dissemination

- The FIT must be recognized as the entry level test for average risk screening and associated with the ACRCSP accountable for population-based screening for CRC.
- The program has responsibility for ensuring patients can successfully complete the FIT i.e. FIT instructions must be easily understood and can be followed by all Albertans taking the test regardless of reading level, reading ability and/or language spoken. Quality control for the FIT, which includes inventory control and management of expired product, requires that the FIT should be distributed

to patients from a lab facility only. Recognizing Zones are different and local lab access issues exist, some distribution of kits may occur from doctors' offices/hospitals/clinics/other i.e. in remote communities.

2) Collection

- In order to successfully screen patients, processes must be in place at collection sites to check returned samples for complete information. Samples with incomplete information require re-screening, potential non-compliance, and therefore decreased uptake of screening, and cancer/precancerous adenomas may go undetected as a result.

3) Transport

- Stability of samples affect test results therefore stability must be considered in transporting samples to processing sites.

4) Processing - Lab to develop

- There are two designated FIT processing centres: Dynalife in Edmonton and Calgary Lab Services (CLS) in Calgary necessary to manage quantity of tests that will require processing in Alberta. Also, an additional analyzer will be available at CLS to ensure there is a back-up to prevent completed FITs from delayed processing time, should there be any mechanical, human resource or procedural issues..

Health Care Workers Education and Communication

1) Physician communication - must understand appropriate use of the FIT and comply.

2) Laboratory and pathology communication required for impact on workload - higher positivity will result in greater detection of adenomas and increase number of biopsies.

3) Communication with the public to encourage screening for CRC given the evidence for population benefits from CRC screening.

4) Staff training required initial set up and should be ongoing as per lab policies for staff training to ensure quality and standardization.

Reporting and Data Management

1) Standardized data elements - list of data elements (Appendix 1) to track screening uptake and improve processes.

Implementation Guidelines

Implementation is documented in the FIT implementation project plan.

ACRCSP Communication of FIT Results

Standard

- i. The provincial program will support the communication process of FIT results by serving as a communication “safety net”. This is to ensure all individuals invited to, and accessing CRC screening will receive timely follow up on FIT results.
- ii. Standardized result categories are used to provide consistent and complete reporting at the laboratory and follow-up correspondence with the patient and physician. Physicians will receive a text result only i.e. positive/negative. The program will receive a text and numeric result to monitor numeric results.
- iii. These categories include:
 - a. Positive: one positive vial (positive = ≥ 75 ng threshold)
 - b. Negative: one vial, (negative = ≤ 74 ng threshold)
 - c. Indeterminate: unable to determine results from vial submitted and includes inadequate result: unable to process vial submitted.
- iv. Prior to the implementation of province wide invitation to CRC screening by the provincial program, patients having FIT kits processed at any lab in Alberta should have a physician identified in the data set provided to ACRCSP.
- v. The ACRCSP (as safety net) will provide follow up through correspondence with patients.
- vi. In the long term, the provincial program will provide (at appropriate time intervals) correspondence (safety net) for all results (positive, negative, indeterminate results), and have a process in place for ongoing monitoring of FITs or repeat testing respectively.
- vii. Where a primary care physician, PCN or other CRC screening program provider has not been identified in the patient data set provided by the lab, the patient will be informed of the FIT result and provided suggestions/guidance regarding those results.

In the event that the result is abnormal, the patient will be encouraged to contact his/her family physician (or health care provider responsible for distributing the FIT kit).

In the future, abnormal results may be communicated to a dedicated center in the Zone so that ordering physicians may be directly contacted for timely referral to colonoscopy services.

Rationale

- It is well established in existing CRC screening and other programs, and in the literature cited elsewhere in this document, that creation of standardized result categories and related correspondence processes will reduce confusion and provide a communication “safety net” for the patient and health care providers.
- Providing (time controlled) follow-up correspondence to the FIT positive patient may encourage them to seek further investigation from their physician.
- Providing a physician contact to the provincial program ensures correspondence can occur with the physician where a positive FIT result is found. This ensures continuity in CRC screening path of care and appropriate timely diagnostic modalities are provided.
- A reminder notification for annual FIT screening, where a negative test result is found, increases the program sensitivity of FIT as a primary screening modality.
- Other jurisdictions report program correspondence that communicate the need to repeat FIT and sending an additional kit will ensure patients with indeterminate including inadequate FIT kits have an opportunity to be retested.

Implementation Guidelines

- A standard communication (letter) and applicable next steps for each result has been developed and implemented across the province.
- All physicians, other health providers and regional stakeholders will receive adequate communication and education prior to implementing the correspondence processes.

ACRCSP Managing FIT Results

Managing Positive Results

Standard

- Ordering physician will be responsible for follow-up of abnormal FIT results
- Patients will be informed that they should have a follow-up colonoscopy within 60 days of FIT result.
- Physicians can refer patients for colonoscopy to a local CRC screening centre (if available) or a local colonoscopist.
- As a safety net the ACRCSP will provide FIT positive result letters to all patients in Alberta with a positive FIT result informing them to follow up with their physician.

Rationale

- The purpose of the result letter is to ensure patients, who have not received any follow up, are informed about their positive FIT result and to support primary care providers should there be any delay in addressing the FIT result for any reason.
- This result letter will be delayed (sent 3 weeks after the FIT result is received by the ACRCSP) to allow adequate time for the physician to provide initial follow up with their patient.

Implementation Guidelines

- As per ACRCSP and Cancer Screening Program correspondence process in place.

Managing Negative Results

Standard

- Physicians will record FIT results and take appropriate action for next screening interval with FIT (annual or at least biennial).
- Patients will be informed that they have a normal FIT result and should speak to their physician about ongoing CRC screening.

Rationale

- The purpose of the normal result letter is to ensure patients are aware of their normal result and that they understand the importance of ongoing CRC screening with the FIT.
- This result letter will be sent to patients immediately after the FIT result is received by the ACRCSP for timely and conclusive FIT result information to patients.

Implementation Guidelines

- As per ACRCSP and Cancer Screening Program correspondence process in place.

Appendices

Appendix 1 FIT Data Elements

Standardized data elements collected for each individual submitting an FIT kit

<i>Client Information</i>	<i>Description or Comment</i>
ULI	The primary client identifier that stands for Unique Lifetime Identifier
Province	Client's residential province
Gender	The gender of the client in this transaction
Client first name	First name of the client
Client middle name	Middle name of the client
Client last name	Last name of the client
Date of birth	Client's date of birth
<i>FIT information</i>	<i>Description or Comment</i>
Sending facility	The facility responsible for sending the FIT
Site of test	The facility where the FIT was observed
Exam ID	Unique identifier giving to the exam by lab
Physician first name	Ordering Provider first name
Physician middle name	Ordering Provider middle name
Physician last name	Ordering Provider last name
Date FIT test results sent	Date the FIT sent to receiving facility (ABC)
Type of FIT test	Fecal Immunochemical Test 1/ Fecal Immunochemical Test 2
Performed date	Date FIT was performed by client
Received date	Date FIT Sample received by site of test
Observation date	Date of FIT results
FIT result qualitative	Positive /Negative/No result
FIT result quantitative	Numeric value/threshold

Appendix 2 TOP Clinical Practice Guideline Revised November 2013

<http://www.topalbertadoctors.org/cpgs/30429617>

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