Cancer Care Ontario

Time to get “FIT”

Fecal immunochemical test (FIT): A non-invasive test for colorectal cancer screening
SPEAKING NOTES

Disclaimer:

The intended users of these materials are regional primary care leads and regional aboriginal care leads employed by Cancer Care Ontario. For other individuals who wish to present, or otherwise use these materials, please contact:
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Ontario
Cancer Care Ontario

After this presentation, you will be able to:

- Understand the Burden of Colorectal Cancer (CRC) in Ontario
- Order the Fecal Immunochemical Test (FIT) and Counsel your Patients
- Compare CRC Screening Tests for Average Risk Patients
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- Describe Learnings from Other Jurisdictions
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Question 1

Slide Objective: Understand the burden of colorectal cancer in Ontario

Background:
Answer (C)
It is estimated that about 11,595 people in Ontario (about 6,376 men and 5,218 women) will be diagnosed with colorectal cancer in 2018[1]
Colorectal cancer is the second most commonly diagnosed cancer in Ontario among men (following prostate), and third most commonly diagnosed cancer among women (following breast and lung cancers)
Additional Information: Incidence in 2018
Prostate: 8,828
Breast: 11,762
Lung and bronchus: 11,396

Sources:
Cancer Care Ontario. Ontario Cancer Statistics 2018 Report. Toronto, ON: Cancer Care Ontario; 2018. [cited 2018 Jun 22]. Available from: https://www.cancercareontario.ca/sites/ccocancercare/files/assets/OCS2018_2.pdf

Question 2

Slide Objective: Understand the burden of colorectal cancer in Ontario

Background:
Answer (a)
Regular screening increases the chances of detecting colorectal cancer early (stage 1)
If identified during stage 1, individuals with colorectal cancer have a 9 out of 10 chance of being disease free at five years[1]

Sources:
CSQI National Cancer Institute [Internet]. National Cancer Institute. SEER stat fact sheets: colon and rectum cancer. Bethesda (MD): National Cancer Institute. [cited 2017 Jun 12]. Available from: http://seer.cancer.gov/statfacts/html/colorect.html

Question 3

Slide Objective: Understand the burden of colorectal cancer in Ontario

Background:
Answer (d)
It is estimated that approximately 3,359 people in Ontario (1,811 men and 1,548 women) will die of colorectal cancer in 2018
Colorectal cancer is the second leading cause of cancer deaths in men (following lung) and the third leading cause of cancer deaths in women (following lung and breast). Colorectal cancer accounts for 11% of all cancer deaths

Sources:
Cancer Care Ontario. Ontario Cancer Statistics 2018 Report. Toronto, ON: Cancer Care Ontario; 2018. [cited 2018 Jun 22]. Available from: https://www.cancercareontario.ca/sites/ccocancercare/files/assets/OCS2018_2.pdf

Burden of CRC in Ontario

Slide Objective: Review burden of CRC in Ontario

Additional Information:

- In 2018, it is estimated that approximately 6,376 men will be diagnosed with colorectal cancer and approximately 1,811 will die from it
  - Second leading cause of cancer deaths
- In 2018, it is estimated that approximately 5,219 women will be diagnosed with colorectal cancer and approximately 1,548 will die from it
  - Third leading cause of cancer deaths

Sources:

Cancer Care Ontario. Ontario Cancer Statistics 2018. Toronto: Cancer Care Ontario; 2018.
https://www.cancercareontario.ca/sites/ccocancercare/files/assets/OCS2018_2.pdf
Data sources: Ontario Cancer Registry (January 2017), CCO; Statistics Canada. Table 102-0564 - Leading causes of death, total population, by sex, Canada, provinces and territories (age standardization using 2011 population), annual, CANSIM (database); Statistics Canada.
Table 051-0001 - Estimates of population, by age group and sex for July 1, Canada, provinces and territories, annual (persons unless otherwise noted), CANSIM (database).

CRC & CRC Screening Among Indigenous Populations

Slide Objective: Review trends in incidence and mortality among First Nations, Inuit and Metis populations

Speaking Notes:

Trends in incidence and mortality:

- Incidence of CRC increasing over time more rapidly among FN men and women and survival from CRC is significantly poorer compared to non-FN in ON (1)
- Among Inuit, increases in CRC cancer over time – 1989-2008 (not limited to Canadian Inuit) (2)
- Among Metis, data doesn't show the same trends re: incidence and survival (among women, rates are significantly lower, and for men, no significant differences in cancer rates; no differences in survival (5)

Screening rates:

- There is data to suggest that Inuit are less likely to be up to date with CRC screening than non-Inuit populations (National data – regions with large Inuit populations have lower screening rates); Estimates from Inuit populations in Ottawa suggest that screening rates are much lower than rest of Ottawa population (2)
- Metis in Ontario are less likely to be up to date with CRC screening than general population (3)
- Among First Nations in Ontario living off-reserve, rates of CRC screening are comparable to the non-Indigenous population (4, 6)

Sources:

1. Chiefs of Ontario, Cancer Care Ontario and Institute for Clinical Evaluative Sciences. Cancer in First Nations People in Ontario. Toronto, 2016. Available at: http://www.snhs.ca/FNCancerInFirstNationsReportCOOCCO.PDF
2. Tungasuvvingat Inuit and Cancer Care Ontario. Cancer Risk Factors and Screening Among Inuit in Ontario and Other Canadian Regions. Toronto, 2017. Available at: https://www.cancercareontario.ca/sites/ccocancercare/files/assets/InuitRiskFactorsReport.pdf
3. Métis Nation of Ontario and Cancer Care Ontario. *Cancer in the Métis people of Ontario: Risk Factors and Screening Behaviours*. Ottawa, 2015. Available at: http://www.metisnation.org/media/653628/mno-cco-report-screen.pdf
4. Chiefs of Ontario and Cancer Care Ontario. Cancer in First Nations in Ontario: Risk Factors and Screening. Toronto, 2016 https://www.cancercareontario.ca/sites/ccocancercare/files/assets/CCOFNIMRiskFactorsReport2016.pdf
5. Mazereeuw et al. (2017). Cancer incidence and survival among Métis adults in Canada: results from the Canadian census follow-up cohort (1992–2009). CMAJ. *In Press*
6. Withrow DR, Amartey A, Marrett LD. Cancer risk factors and screening in the off-reserve First Nations, Metis and non-Indigenous populations of Ontario. Chronic Dis Inj Can. 2014;34(2-3):103-21.

CRC Incidence Rate for All Ages in Status First Nations Populations

Slide Objective: Review burden of CRC in First Nations communities

Background information:

- Limited data exists on national cancer incidence and mortality rates for First Nations communities
- Information on ethnicity is not captured by most health information databases, making it difficult to research the impact of cancer on different populations
- Despite these challenges, studies have been conducted that have shown cancer incidence has risen in each of the FNIM populations over the past few decades

Challenges within the health system in Ontario

- Lack of awareness and understanding of cultural elements that can reduce the effectiveness of treatment
- A lack of healthcare resources in communities.
- Poor coordination of care across the continuum of care, which can undermine follow up

Sources:

Sources: Chiefs of Ontario, Cancer Care Ontario and Institute for Clinical Evaluative Sciences. Cancer in First Nations People in Ontario. Toronto, 2016. Available at: http://www.snhs.ca/FNCancerInFirstNationsReportCOOCCO.PDF

Marrett and Chaudhry. 2003. Cancer incidence and mortality in Ontario First Nations, 1968-1991 (Canada). Cancer Causes and Control . 14:259–268.

CRC Incidence Rate for All Ages in Inuit Populations

Slide Objective: Review burden of CRC in Inuit communities

Background information:

- Nunangat refers to the traditional Inuit homeland, which is made up of: Inuvialuit (includes northern parts of Yukon Territory and the Northwest Territories), Nunavut, Nunavik (includes northern parts of Quebec), and Nunatsiavut includes northern parts of Newfoundland and Labrador)
- Limited data exists on national cancer incidence and mortality rates for Inuit communities
- Information on ethnicity is not captured by most health information databases, making it difficult to research the impact of cancer on different populations
- Despite these challenges, studies have been conducted that have shown cancer incidence has risen in each of the FNIM populations over the past few decades

Challenges within the health system in Ontario

- Lack of awareness and understanding of cultural elements that can reduce the effectiveness of treatment
- A lack of healthcare resources in communities
- Poor coordination of care across the continuum of care, which can undermine follow up

Sources:

Carrière et al. (2012). Cancer patterns in Inuit Nunagat: 1998-2007. Int J Circumpolar Health; 71:18581

CRC Incidence Rate for All Ages in Métis Populations

Slide Objective: Review burden of CRC in Metis communities

Background information: Metis people

- Limited data exists on national cancer incidence and mortality rates for Metis communities
- Information on ethnicity is not captured by most health information databases, making it difficult to research the impact of cancer on different populations
- Despite these challenges, studies have been conducted that have shown cancer incidence has risen in each of the FNIM populations over the past few decades

Challenges within the health system in Ontario

- Lack of awareness and understanding of cultural elements that can reduce the effectiveness of treatment
- A lack of healthcare resources in communities
- Poor coordination of care across the continuum of care, which can undermine follow up

Sources:

Mazereeuw et al. (2017). Cancer incidence and survival among Métis adults in Canada: results from the Canadian census follow-up cohort (1992–2009). CMAJ. *In Press*

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Question 4

Slide Objective: Understand the importance of average risk colorectal cancer screening

Background:

Answer (c)

- Research shows that almost 70 percent of people diagnosed with colorectal cancer have no family history of the disease (i.e., they have no first-degree relative with colorectal cancer) This is why it is important that all eligible men and women aged 50 to 74 years get screened every two years with FIT

Sources:

Cotterchio M, Manno M, Klar N, McLaughlin J, Gallinger S. Colorectal screening is associated with reduced colorectal cancer risk: a case-control study within the population-based Ontario Familial Cancer Registry. Cancer Causes and Control. 2005; 16(7):865–75.

Ontario’s ColonCancerCheck (CCC) Program

Slide Objective: Brief overview of the CCC program

Speaker Notes:

- CCC is Ontario’s organized CRC program
- It was the first in Canada, launched in 2008
- Individuals at average risk screen every two years using the guaiac fecal occult blood test (gFOBT) until the fecal immunochemical test (FIT) is available in Ontario
- Individuals can choose to be screened with flexible sigmoidoscopy every 10 year
- Individuals at increased risk (includes those with one or more first degree relatives with CRC) screen every 10 years with colonoscopy

gFOBT vs. No Screening

Slide Objective: Brief overview of gFOBT vs. no screening

Speaker Notes:

- Currently, in Ontario, the CCC screening program recommends gFOBT for CRC screening in average risk persons
- A meta-analysis conducted by CCO found a 13% reduction overall in CRC death among those screened with gFOBT compared to no screening, but no difference in CRC incidence

Sources:

Tinmouth J, Vella E, Baxter N, Dubé C, Gould M, Hey A, et al. Colorectal Cancer Screening in Average Risk Populations: Evidence summary. Toronto (ON): CCO; 2015 October 30. Program in Evidence-based Care Evidence Summary No.: 15-14.

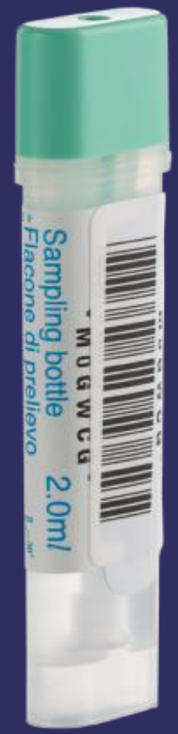
Organized CRC Screening in Canada

Slide Objective: Brief overview of organized CRC screening in Canada

Speaker Notes:

- Ontario was the first organized CRC screening program in Canada, launching with gFOBT
- gFOBT was selected because, at the time, there was insufficient evidence to support use of FIT
- More recently, greater evidence in support of FIT has become available, and many programs that were established later than CCC launched with FIT

CCC is implementing FIT as the recommended screening test for people at average risk of CRC



gFOBT vs. FIT Lab Parameters

Slide Objective: Compare lab parameters for FIT vs. gFOBT

Speaker Notes:

- Both gFOBT and FIT check for blood in the stool, but FIT uses antibodies specific for the globin component of human hemoglobin e.g. ug hemoglobin/ g feces
- FIT is not affected by diet or medications (including vitamin C, NSAIDs, oral anticoagulants)

Additional Information:

- For further information related to screening with FIT for patients on oral anticoagulants, reference case study #6 on slide 50

Sources:

1. Tinmouth J, Lansdorp-Vogelaar I, and Allison JE. Faecal immunochemical tests versus guaiac faecal occult blood tests: what clinicians and colorectal cancer screening programme organisers need to know. Gut. 2015 Aug;64(8):1327-37.

gFOBT vs. FIT Lab Parameters

Slide Objective: Compare lab parameters for FIT vs. gFOBT

Additional Information:

Inventory management: Unused FIT devices have a shorter shelf-life than gFOBT; given the greater challenges with inventory management, FIT devices will not be stocked in primary care provider offices. Instead, FIT kits will be distributed to patients (by mail) directly from the lab.

Sample stability: Unlike gFOBT, FIT specimens (ie once the stool sample has been added) are not as stable at high temperatures and over time.

Lab Process:

- FIT samples in Ontario will be analyzed using automated systems in the laboratory
- FIT analyzers provide a numerical result and the positivity threshold (“cut-off”), which used to define an abnormal test, can be customized
- Other FIT kits are qualitative and have pre-specified cut-off points used to define an abnormal result and similar to gFOBT, the result is visually interpreted

Sources:

Tinmouth J, Baxter N, Paszat L, Rabeneck L, Randell E, Sutradhar R, et al. Report on pilot evaluation of fecal immunochemical test (FIT) in Ontario. The Ontario FIT pilot. Final report submitted July 5 2013. Revised Jan 29, 2014.

Catomeris P, Baxter NN, Boss SC, Paszat LF, Rabeneck L, Randell E, et al. Effect of Temperature and Time on Fecal Hemoglobin Stability in 5 Fecal Immunochemical Test Methods and One Guaiac Method. Arch Pathol Lab Med. 2018;142:75–82.

FIT Usability for Participants

Slide Objective: Brief overview of FIT

Speaker Notes:

- FIT is an easy to complete at-home stool test
- FIT requires a single stool sample (rather than three in the current gFOBT)
- FIT is designed for easy sampling including;
  - grooved stick attached to cap of the FIT collection device; and
  - collection paper to keep stool from being submerged in the toilet water
- Unlike gFOBT, for which vitamin C should be avoided before/during the test, FIT requires no dietary or medication restrictions
  - Patients taking NSAIDs or oral anti-coagulants (OACs) can complete FIT without discontinuing their use of these medications

Sources:

Tinmouth J, Vella E, Baxter N, Dubé C, Gould M, Hey A, et al. Colorectal Cancer Screening in Average Risk Populations: Evidence summary. Toronto (ON): CCO; 2015 October 30. Program in Evidence-based Care Evidence Summary No.: 15-14.

Accuracy for CRC: One-Time Test

Slide objective: Discuss FIT accuracy

Speaker Notes:

- In asymptomatic adults, FIT has a much improved sensitivity (82% vs 38%) with minimal loss of specificity (94% vs 96%)
- Game Changer: with FIT, CRC screening is now on par with other well accepted screening tests: mammography and Pap test

Additional Information:

- Estimates of FIT sensitivity and specificity were based on a good quality systematic review by Lee et al. that compared one time FIT to colonoscopy. Median sensitivity and specificity of gFOBT (Hemoccult II) was provided in the meta-analysis by the Canadian Task Force on Prevention Health Care.
- Estimated sensitivity and specificity of mammograms and Pap tests
  - Mammograms: 86% sensitivity; 93% specificity
  - Pap: as high as 78% sensitivity (as low as 44%) and 91%–96% specificity

Sources:

1. Lee JK, Liles EG, Bent S, Levin TR, Corley DA. Accuracy of fecal immunochemical tests for colorectal cancer: systematic review and meta-analysis. Ann Intern Med 2014;160:171-181.
2. Canadian Task Force on Preventive Health Care. Screening for Colorectal Cancer [Internet]. Ottawa, Canada: Canadian Task Force on Preventive Health Care; 2014. Available from: http://canadiantaskforce.ca/guidelines/published-guidelines/colorectal-cancer/

FIT vs. gFOBT: Clinical Implications

Slide Objective: Compare participation rate and CRC/ advanced adenoma detection for FIT vs. gFOBT

Speaker Notes:

- FIT is 2x more accurate
- Also, participation is higher: RR 1.16 (16% improvement)

*RCTs = randomized control trial
*RR = relative risk
*CI = 95% confidence interval

Sources:

Tinmouth J, Vella E, Baxter NN, Dubé C, Gould M, Hey A, et al. Colorectal cancer screening in average risk populations: Evidence summary. Toronto (ON): CCO; 2015 November 11. Program in Evidence-based Care Evidence Summary No.: 15-14.

Adenoma to Cancer

Slide Objective: Compare detection of CRC and HRAs with FIT vs gFOBT

Additional Information:

- FIT is more sensitive for the detection of CRCs and unlike gFOBT, also detects high risk (advanced) adenomas
- Some polyps, ie. high risk adenomas, are more likely to become cancer than others (ie. low risk adenomas)
  - Low risk adenoma: 1-2 tubular adenomas <10mm in diameter with no high grade dysplasia.
  - High risk adenoma: Tubular adenoma ≥ 10mm, 3 or more adenomas, adenoma with villous histology or adenoma with high grade dysplasia.
- Time from low risk diminutive adenoma to cancer is estimated to be 26 years (5 years for larger adenomas)

Sources:

Chen et al. A case-cohort study for the disease natural history of adenoma-carcinoma and *de novo* surveillance of colon and rectum after polypectomy: implication for efficacy of colonoscopy. Br J Cancer. 2003:Vol 88(12), 1866-1873.

Cost Effectiveness of FIT

Slide objective: Review findings that assess the cost effectiveness of different CRC tests

Additional Information on CES using Canadian costs:

Heitman et al. (2010)

- Economic evaluation assessed FIT annually at various test performance characteristics
- Also assessed cost effectiveness of gFOBT, fecal DNA, flexible sigmoidoscopy, colonoscopy and computed tomography colonography
- Outcomes of interest: number of cancers, cancer-related deaths, quality-adjusted life-years gained, incremental cost-utility ratios
- FIT was more effective and less costly compared to all other strategies (including no screening)

Goede et al. (2017)

- Used modeling to estimate health benefits and costs of gFOBT and FIT screening (compared to no screening) in average risk Ontarians
- FIT is more effective and less costly than gFOBT and cost-saving compared to no screening
- FIT is as effective as, and less costly than, colonoscopy

<u>Sources:</u>

1. Heitman S, Hilsden R, Au F, Dowden S, Manns B. Colorectal Cancer Screening for Average-Risk North Americans: An Economic Evaluation. PLoS Medicine. 2010;7(11):e1000370.
2. Goede S, Rabeneck L, van Ballegooijen M, Zauber A, Paszat L, Hoch J et al. Harms, benefits and costs of fecal immunochemical testing versus guaiac fecal occult blood testing for colorectal cancer screening. PLOS ONE. 2017;12(3):e0172864.

Cost Effectiveness of FIT

Slide objective: Review findings that assess the cost effectiveness of different CRC tests

Sources:

1. Heitman S, Hilsden R, Au F, Dowden S, Manns B. Colorectal Cancer Screening for Average-Risk North Americans: An Economic Evaluation. PLoS Medicine. 2010;7(11):e1000370.

2. Goede S, Rabeneck L, van Ballegooijen M, Zauber A, Paszat L, Hoch J et al. Harms, benefits and costs of fecal immunochemical testing versus guaiac fecal occult blood testing for colorectal cancer screening. PLOS ONE. 2017;12(3):e0172864

FIT vs. Colonoscopy for Average Risk Screening

Systematic Review: Average Risk Screening for CRC (slide 27)

Slide objective: Compare availability and strength of evidence for average risk screening across multiple modalities, which informed program recommendations; review evidence supporting use of FIT

Additional Information:

- Three large-scale RCTs are underway comparing FIT to colonoscopy:
- (COLONPREV, CONFIRM study, SCREESCO- screening of Swedish Colons study).
- So far, only the results of the first round of screening in COLONPREV have been published, and are presented in the next few slides.

COLONPREV

- See notes on slide 31 for high level summary
- ClinicalTrials.gov Identifier: NCT00906997

CONFIRM (Colonoscopy vs. Fecal Immunochemical Test in Reducing Mortality from Colorectal Cancer - US)

- 50-75 years old, average risk
- Annual FIT vs. colonoscopy
- Primary endpoint is CRC mortality at 10 years (secondary endpoints include CRC incidence & complications of screening colonoscopy & association between colonoscopists' characteristics and key outcomes)
- Estimated study completion in 2021
- ClinicalTrials.gov Identifier: NCT01239082

(slide 27) continued

SCREESCO (Screening of Swedish Colons)

- 59-62 years old invited through mail
- Biennial FIT vs. colonoscopy
- Primary endpoint: CRC mortality at 15 years (results estimated in 2029)
- Secondary endpoints include (but are not limited to): CRC incidence, screening program compliance, factors associated with adherence, emotional impact of screening, quality control
- Estimated study completion in 2034 (includes completion of all endpoints)
- ClinicalTrials.gov Identifier: NCT02078804
- In addition, there is an ongoing RCT examining the impact of screening with colonoscopy vs. no screening on CRC mortality and incidence:

NordICC – Northern-European Initiative on CRC

- Multinational (Netherlands, Norway, Poland, Sweden)
- 55-64 years old
- Primary endpoints are cumulative CRC-specific death and CRC incidence at 15 years following colonoscopy (interim incidence and mortality to be analyzed at 10 years)
- Secondary endpoints: all-cause mortality, screening participation, changes in lifestyle patterns in screened group, control group, and among non-attendees
- Estimated study completion: 2036 (primary completion in 2026)
- ClinicalTrials.gov Identifier: NCT00883792

Sources:

1. Quintero E, Castells A, Bujanda L, Cubiella J, Salas D, Lanas Á, et al. Colonoscopy versus fecal immunochemical testing in colorectal cancer screening. The New England Journal of Medicine. 2012; 366(8): 697-706.
2. Dominitz JA, Robertson DJ, Ahnen DJ, Allison JE, Antonelli M, Boardman KD et al., Colonoscopy vs fecal immunochemical test in reducing mortality from colorectal cancer (CONFIRM): rationale for study design. Am J Gastroenterol. 2017 Nov;112(11):1736-1746. doi: 10.1038/ajg.2017.286. Epub 2017 Oct 10.
3. Tinmouth J, Vella E, Baxter NN, Dubé C, Gould M, Hey A, et al. Colorectal cancer screening in average risk populations: Evidence summary. Toronto (ON): CCO; 2015 November 11. Program in Evidence-based Care Evidence Summary No.: 15-14.
4. Kaminsky MF, Bretthauer M, Zauber AG, Kuipers EJ, Adami H, van Ballegooijen M, et al. The NordICC study: Rationale and design of a randomized trial on colonoscopy screening for colorectal cancer. Endoscopy. 2012. 44(7):695-702.
5. SCREESCO: https://clinicaltrials.gov/ct2/show/NCT02078804

Quintero et al.: FIT vs. Colonoscopy

Slide objective: Provide high-level overview of first publication of RCT results comparing FIT to colonoscopy

Speaker Notes:

- The study (COLONPREV) was designed to assess the efficacy of biennial FIT and one-time colonoscopy for reducing the rate of death from CRC at 10 years. Over 26,000 invited in each arm for FIT and colonoscopy.
- Large RCT in Spain
- Ages 50 – 69 years old
- Biennial FIT versus one-time colonoscopy
- Mailed invitation to participate
- Primary outcome: CRC-death at 10 years
- Secondary outcome: compliance rate, complication rate, colorectal cancer incidence, adherence rate, advanced colorectal neoplasm detection rate
- ClinicalTrials.gov Identifier: NCT00906997

This publication reflects only the first round results → outcomes include participation, CRC and adenoma detection, and complications (1 round of FIT, and baseline colonoscopy)

Sources:

Quintero E, Castells A, Bujanda L, Cubiella J, Salas D, Lanas Á, et al. Colonoscopy versus fecal immunochemical testing in colorectal cancer screening. The New England Journal of Medicine. 2012; 366(8): 697-706.

Quintero et al.: Patients Prefer FIT

Slide objective: Present evidence suggesting that people prefer FIT over colonoscopy when given a choice (based on the between-group differences in rates of participation for FIT vs. colonoscopy).

Speaker Notes:

- Over 26,000 people invited in each arm for FIT and colonoscopy
- Among those who were invited to do FIT, 36% responded and attended that screening arm compared to 28% in the colonoscopy arm.
- The study design allowed for crossover between the two study groups
  - Participants in each arm were given information about BOTH tests, including the test to which they were assigned, and were given the option to switch to the other test.
- At the appointment in the colonoscopy arm, just under one quarter who were offered colonoscopy actually opted to do FIT instead.
- By comparison, only 1% of those offered FIT opted for colonoscopy.

Conclusion: FIT has higher rates of participation than colonoscopy, when participants are offered a choice in screening test. (Note that participants invited into the FIT arm were also more likely to agree to participate (36% response rate) in the study than those invited into the colonoscopy arm (28% response rate).

Sources:

Quintero E, Castells A, Bujanda L, Cubiella J, Salas D, Lanas Á, et al. Colonoscopy versus fecal immunochemical testing in colorectal cancer screening. The New England Journal of Medicine. 2012; 366(8): 697-706.

Quintero et al.: Diagnostic Yield – Intention to Screen

Slide objective: To demonstrate that, on an intention-to-screen basis, FIT is as good as colonoscopy in detecting CRC, and that FIT allows for better use of colonoscopy resources and limits risks.

Additional Information:

Detection

- While a significant difference in detection was noted for advanced adenomas, this represents only the 1st round of FIT screening.
- There was no difference in cancer detection between colonoscopy and FIT during the 1st round
- The full impact will be better understood over time as the final study results become available. In contrast, the only round of colonoscopy screening is complete and therefore, the results from the colonoscopy group cannot improve further.

Number needed to scope

- The numbers of patients who needed to undergo colonoscopy to find 1 CRC were 191 in the colonoscopy group and 18 in the FIT group; the latter represents those who underwent colonoscopy as a follow-up to an abnormal FIT. This means that we need to scope far fewer people to find 1 CRC and therefore, FIT allows for better use of colonoscopy resources (high yield procedure) as well as limits risks.

Complications

- While patients undergoing FIT+ colonoscopies were exposed to complications, far fewer people require colonoscopy to find 1 CRC; therefore, screening with FIT means that exposure to risk associated with colonoscopy is limited to only those patients who are most likely to benefit from this procedure.

Sources:

Quintero E, Castells A, Bujanda L, Cubiella J, Salas D, Lanas Á, et al. Colonoscopy versus fecal immunochemical testing in colorectal cancer screening. The New England Journal of Medicine. 2012; 366(8): 697-706.

Colonoscopy Associated Complications: Calgary, Alberta

Slide Objective: Review data for colonoscopy-related adverse events

Additional Information:

- Study objectives were to determine the associations between quality indicators and the detection of screen relevant lesions, adverse events, and post-colonoscopy cancers.
- Study cohort included 18,456 patients who underwent 1 or more screening colonoscopies at the Colon Cancer Screening Centre (CCSC) in Calgary, Alberta from January 1, 2008 to December 31, 2010. One colonoscopy per patient was included in the analysis.
- Patients between the ages of 40 to 74 were included in the study if they had a primary screening colonoscopy for an indication of either average risk for CRC or were at increased risk because of family history of CRC or polyps. Patients undergoing post- polypectomy surveillance or diagnostic colonoscopy for an abnormal fecal occult blood test were excluded.
- Events were deemed to have been caused by the colonoscopy if it occurred within 30 days of the procedure and was clearly an adverse event of the colonoscopy or when the event may or may not have been directly caused by the colonoscopy, but the decision of the patient to present to the emergency department was likely influenced by the preceding colonoscopy (1).
- Adverse events that were related or possibly related to the colonoscopy were classified as mild, intermediate or severe.
- While colonoscopy is a generally safe exam, complications can occur, including those related to the bowel preparation (e.g., falls, injuries and electrolytic abnormalities) and the use of sedation.

*Post-polypectomy syndrome is an uncommon complication from polypectomy with electrocautery and is characterized by a transmural burn of the colon wall. This typically occurs between 12 hours to seven days post-polypectomy. Most patients present with abdominal pain or tenderness near the polypectomy site. Others may present with fever, leukocytosis, peritoneal inflammation and tachycardia in the absence of frank perforation after a polypectomy with electrocoagulation[2].

Sources:

1. Hilsden RJ, Dube C, Heitman SJ, Bridges R, McGregor SE, Rostom A. The association of colonoscopy quality indicators with the detection of screen-relevant lesions, adverse events, and postcolonoscopy cancers in an asymptomatic Canadian colorectal cancer screening population. Gastrointest Endosc. 2015 Nov; 82(5):887-94.
2. Cash BD, Saltzman JR, Robson KM. Postpolypectomy electrocoagulation syndrome Postpolypectomy electrocoagulation syndrome. Postpolypectomy electrocoagulation syndrome.

Screening with Colonoscopy vs. FIT

Slide Objective: To compare relative diagnostic yield for screening with FIT vs Colonoscopy

Speaker Notes:

- This slide shows the relative diagnostic yield of FIT compared to colonoscopy assuming 100,000 individuals were scoped with each screening modality.
  - This is comparable to the average number of colonoscopies performed in Ontario annually (~79,000), but rounded up for ease of demonstration.

For the same number of colonoscopies:

- FIT increases the number of CRCs detected by 20 times;
- FIT increases the number of high risk adenomas detected by 4.5 times;
- FIT increases the number of people screened by 13 times;
  - compared to average risk screening with colonoscopy
- Therefore, many more individuals could be screened for every 100,000 scopes, maximizing use of colonoscopy resources and minimizing risk to patients.

Additional Information:

- Diagnostic yield = number of scopes x positive predictive value (PPV)*
- CRC – PPV =0.4% (scope); 8% (FIT)
- HRA– PPV = 10% (scope); 45% (FIT)
- Next, the number required to screen was calculated in order to get 100,000 scopes (100,000/positivity rate (5.5%)** = 1.8 million)

*Assumption used for PPV (CRC & AA) for FIT and average risk colonoscopy was drawn from estimates from the Dutch bowel cancer screening program

** Positivity rate for FIT reflects a quantitative positive FIT threshold that allows Ontario to reap the benefits associated with a more sensitive fecal-based test, while also mitigating the risk of over demand and under supply of colonoscopy volumes in the system when FIT is launched.

FIT vs. Colonoscopy: Summary

Slide Objective: Summarize the benefits of FIT vs colonoscopy

Case Study 1 - Part 1

Speaker notes: Answer (e)

Benefits of FIT

- When speaking with Rahm, emphasize that FIT is the recommended colorectal cancer screening test for Ontarians, and highlight factors associated with the ease of use, including:
  - the design of the collection device, which is easy to use and reduces the amount of contact people have with their stool when collecting it;
  - only one sample needed;
  - no dietary restrictions, including vitamin C; and
  - no medication restrictions.
- You may wish to note that FIT is a more sensitive screening test than the guaiac fecal occult blood test (gFOBT), which means that it is better at detecting colorectal cancer and advanced adenomas[1,2]. In addition, FIT is specific for human hemoglobin, which means it will not mistake dietary sources of blood or other substances for human blood.

Sources:

1. Lee JK, Liles EG, Bent S, Levin TR, Corley DA. Accuracy of Fecal Immunochemical Tests for Colorectal Cancer: Systematic Review and Meta-analysis. Ann Intern Med. 2014; 160(3):171-181.
2. Canadian Task Force on Preventive Health Care. Screening for Colorectal Cancer [Internet]. Ottawa, Canada: Canadian Task Force on Preventive Health Care; 2014. [cited 2017 May]. Available from: http://canadiantaskforce.ca/guidelines/published-guidelines/colorectal-cancer/

Case Study 1 - Part 2

Speaker Notes: Answer (e)

- There is insufficient direct evidence to support the use of colonoscopy to screen people at average risk for colorectal cancer[1]. For average risk patients with no family history of colorectal cancer, Cancer Care Ontario recommends screening with the FIT.

Risks and Limitations Associated with Colonoscopy:

- When discussing colorectal cancer testing with patients, it is important to emphasize that the FIT is a safe, non-invasive screening test.
- While colonoscopy is a generally safe exam, complications can occur, including those related to the bowel preparation (e.g., falls, injuries and electrolytic abnormalities) and the use of sedation. In addition, possible colonoscopy-related complications include (but are not limited to) perforation, post-polypectomy bleeding, cardiac events, syncope/hypotension, and death (in very rare cases) [2, 3]. A Canadian study found that out of 67,632 people of screen eligible age in Ontario who had a colonoscopy in 2002-2003, rates of colonoscopy-related bleeding, perforation, and death were 1.49/1000 (101 cases) , 0.591/1000 (40 cases) and 0.074/1000 (5 cases) respectively[2]. Of the five deaths, two were confirmed to be colonoscopy related and the remainder were possibly colonoscopy related[2].

References:

1. Tinmouth J, Vella E, Baxter NN, Dubé C, Gould M, Hey A, et al. Colorectal cancer screening in average risk populations: Evidence summary. Toronto (ON): CCO; 2015 November 11. Program in Evidence-based Care Evidence Summary No.: 15-14.
2. Rabeneck L, Paszat L, Hilsden R, Saskin R, Leddin D, Grunfeld E, et al. Bleeding and Perforation After Outpatient Colonoscopy and Their Risk Factors in Usual Clinical Practice. Gastroenterology. 2008; 135(6):1899-1906.

Case Study 2

Speakers Notes: Answer (e)

- Danielle has iron deficiency anemia, which may be indicative of colorectal cancer, and should be thoroughly examined and referred for specialist evaluation. It is not sufficient to simply prescribe iron supplements for Danielle. Following a comprehensive physical examination and bloodwork, referral for specialist evaluation is warranted to investigate the cause of iron deficiency anemia and assess for sources of obscure occult GI bleeding, which could be caused by diseases of the colon. Danielle should also be examined for causes of iron malabsorption (i.e., celiac disease).
- Both gFOBT and FIT are strictly screening tests to be used in asymptomatic individuals and are not to be used to investigate disease. It is not advised, and is potentially counterproductive, to test Danielle's stools for occult blood, as the result of the test (whether abnormal or normal) will not change the fact that Danielle needs to have her iron deficiency anemia investigated.
- In addition, Danielle should be prescribed iron supplements and counselled on dietary sources of iron to treat her symptoms in the interim period between specialist referral and evaluation.
- As per the Canadian Association of Gastroenterology Consensus Group on wait time, the Colorectal Cancer Referral Expert Panel and the Colorectal Cancer Diagnosis Pathway Map[1-3], patients presenting with unexplained iron deficiency anemia require an urgent referral to a specialist competent in endoscopy or to a Colorectal Cancer Diagnostic Assessment Program[1,2], and should expect to be seen by a specialist and, if indicated, endoscoped within eight weeks[1-3].

References:

1. Colorectal Cancer Pathway Maps – Colorectal Cancer Diagnosis [Internet]. Toronto: Cancer Care Ontario [updated 2016 Mar; cited 2017 Jul]. Available from: https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=353574
2. The Colorectal Cancer Referral Expert Panel. Referral of patients with suspected colorectal cancer by family physicians and other primary care providers. Del Giudice L, Yao X, Kellett S, reviewers. Toronto (ON): Cancer Care Ontario; 2012 Apr 24 [Endorsed 2017 April 10]. Program in Evidence-based Care Evidence-Based Series No.: 24-1 Version 2 ENDORSED.
3. Paterson WG, Depew WT, Paré P, Petrunia D, Switzer C, Veldhuyzen van Zanten SJ, et al. Canadian consensus on medically acceptable wait times for digestive health care. Can J Gastroenterol. 2006; 20(6): 411-423.

After this presentation, you will be able to:

- Understand the Burden of Colorectal Cancer (CRC) in Ontario
- Order the Fecal Immunochemical Test (FIT) and Counsel your Patients
- Compare CRC Screening Tests for Average Risk Patients
- Select Appropriate Follow-Up: Screening Interval and Surveillance
- Describe Learnings from Other Jurisdictions
- Integrate Cancer Care Ontario Tools to Support your Practice

Colorectal Cancer CRC Screening in Calgary, Alberta

Slide Objective: Brief overview of the transition to FIT in Alberta

Speaker Notes:

- AB screening program exists since 2009; recommended gFOBT every 2 years as in ON
- PCPs initiate screening in Alberta, similar to Ontario
- In 2013, prior to the FIT screening program launch, approximately 23.5% of adults in the Calgary Zone had completed a gFOBT in the prior two years.
- FIT was launched in November 2013
- In 2014, approximately, 30% of the target age group (50 – 74 years) completed a FIT

Sources:

Alberta Health Services. First Year Experience with the Fecal Immunochemical Test. June 2015

FIT Roll Out: Impact on Colonoscopy in Calgary, Alberta

Slide Objective: Brief overview of the transition to FIT in the Calgary zone – Alberta (monthly referral for colonoscopy)

Speaker Notes:

- Colorectal Cancer Screening Centre (CCSC) provides majority of CRC screening-related colonoscopies in Calgary zone, which comprises about 35% of Alberta population
-
- CCSC performs nearly 20,000 colonoscopies per year
- Monthly referral volumes for those at average risk for CRC and those with an abnormal occult blood test are shown
- FIT was implemented in November 2013
- The number of referrals for colonoscopy in individuals at average risk for CRC decreased by 51% from 15,635 referrals in 2013 to 7,615 referrals in 2014
- Referrals for individuals with an abnormal occult blood test increased by 527% from 766 referrals in 2013 with the gFOBT to 4,801 in 2014 with FIT
- There were substantial changes in referral volumes during the first six months of 2014, but volumes stabilized in the second half of the year, and were maintained in subsequent years

Sources:

Alberta Health Services. First Year Experience with the Fecal Immunochemical Test. June 2015.

Calgary: Lesions Detected at Colonoscopy

Slide objective: Brief overview of the transition to FIT in the Calgary zone – Alberta (yield of FIT + colonoscopy vs average risk colonoscopy)

Speaker Notes:

- FIT+ colonoscopy yields more cancers and more screen-relevant polyps than average risk colonoscopies
- Screen-relevant lesions includes cancers and high risk adenomas that are considered cancer precursors
- In this slide, high risk adenomas (HRAs) include all high risk lesions, i.e., adenomas 1cm or greater, tubulovillous adenomas, adenomas with high grade dysplasia and sessile serrated polyps and have a higher risk of progressing to cancer
- Up to a third of FIT+ colonoscopies will have high risk adenomas, compared to 8% of average risk colonoscopies

Sources:

Alberta Health Services. First Year Experience with the Fecal Immunochemical Test. June 2015.

After this presentation, you will be able to:

- Understand the Burden of Colorectal Cancer (CRC) in Ontario
- Order the Fecal Immunochemical Test (FIT) and Counsel your Patients
- Compare CRC Screening Tests for Average Risk Patients
- Select Appropriate Follow-Up: Screening Interval and Surveillance
- Describe Learnings from Other Jurisdictions
- Integrate Cancer Care Ontario Tools to Support your Practice

ColonCancerCheck (CCC) Eligibility Criteria for FIT

Slide Objective: To review CCC's eligibility criteria for FIT

Speaker Notes:

- The eligibility criteria for FIT will not be changing.
- Ages 50-74
- Asymptomatic
- No first-degree relative diagnosed with CRC
- No personal history of CRC, Crohn's colitis or ulcerative colitis
- No colorectal polyps needing surveillance

Additional Information:

- Although the CCC program does not recommend regular screening for people over age 74, someone may choose to get screened after age 74 if the benefits of screening outweigh the risks. Therefore, primary care providers will be able to order FIT kits for people ages of 75 to 85 who they deem eligible and appropriate for screening

Is your patient symptomatic?

- Important manifestations of possible CRC include iron deficiency anemia and rectal bleeding, among others
- Refer to specialist for evaluation

Do not use FIT for symptomatic patients

Case Study 3

Speakers Notes: Answer (a)

- For patients experiencing rectal bleeding, it is important to perform a digital rectal examination as part of a thorough physical examination. Endoscopic evaluation is warranted to investigate the cause of the bleeding. This evaluation may include a colonoscopy or flexible sigmoidoscopy, given that this patients' presentation points to bleeding from the distal colon/rectum or rectal outlet source.
- Patients experiencing symptoms should be referred for evaluation. It is not appropriate to screen symptomatic patients with the FIT or guaiac fecal occult blood test (gFOBT).
- If colonoscopy or flexible sigmoidoscopy results are reported as normal and the investigated is resolved, Jamieson should be screened with the FIT or flexible sigmoidoscopy in ten years.

Case Study 4

Speakers Notes: Answer (c)

- ColonCancerCheck recommends that average risk people age 50 – 74 screen for colorectal cancer with the FIT* every two years. **It is important to note that when not actively bleeding, the presence of hemorrhoids is not a contraindication to complete a FIT.**
- If desired by the patient, a flexible sigmoidoscopy every ten years would also be an appropriate colorectal cancer screening test.

Case Study 5

Speakers Notes: Answer (a)

- There are no medication restrictions for completing a FIT. Therefore, Jessica should screen with a FIT at ages 72 and 74. ColonCancerCheck recommends that people ages 50 to 74 who have no symptoms and are at average risk of getting colon cancer get screened with the FIT every two years.
- Although the ColonCancerCheck program does not recommend regular screening for people over age 74, someone may choose to get screened after age 74 if the benefits of screening outweigh the risks.
- “Average risk” refers to people ages 50 to 74 with no first-degree relative who has been diagnosed with colorectal cancer, and with no personal history of inflammatory bowel disease (i.e., Crohn’s colitis or ulcerative colitis) or pre-cancerous colorectal polyps requiring surveillance.
- Should Jessica receive an abnormal FIT result, appropriate management of her anticoagulants will be required at the time of colonoscopy.

Ordering FIT: Steps for Providers

How to Order FIT for Patients

Slide Objective: Introduce FIT screening pathway – how to order FIT for patients

Speaker Notes:

NEW:

- PCPs will no longer maintain kit inventory in their office
- PCP to validate patient mailing address information
- PCP to explain to patient how to complete FIT

NEW:

- FIT screening as part of the CCC program is supported by LifeLabs
- FIT requisition is sent directly to lab through fax and EMRs
  - PCPs should not give the requisition directly to their patient
- Lab will assess requisition completeness and verify eligibility
  - Age
  - Date of last FIT, gFOBT or colonoscopy

NEW:

- LifeLabs will mail pre-labelled FIT kit to preferred mailing address

Requisition Changes

Slide Objective: Introduce changes to FIT requisition – MOHLTC Laboratory requisition no longer valid for ordering screening tests in the CCC program

Speaker Notes:

- The current MOHLTC lab requisition will no longer be a valid option for ordering CRC screening tests in the CCC program.
- gFOBT will be removed as an option from the MOHLTC lab requisition
- Writing FIT in the “Other tests” box will not be a valid way of ordering FIT

New FIT Requisition

Slide Objective: Introduce changes to FIT requisition – CCC has a new requisition just for FIT

Speaker Notes:

- Send FIT requisition to LifeLabs
- Requisitions are valid for six months
  - After six months, your patient's health status may have changed and screening may no longer be appropriate.
  - Completed FIT kits will be rejected if they arrive after the FIT requisition has expired. The laboratory will issue a laboratory report to the requester with the reason for rejection and recommended next steps.
- FIT kits that are misplaced, damaged or not received within 6 months can be replaced by LifeLabs without requiring a new requisition, within the six month period following the original requisition.
  - Encourage your patient to call the lab for a replacement kit if they have misplaced, damaged or did not receive their FIT kit
- In addition, the FIT requisition has a 'copy-to' field, to allow results to be sent to another provider

New FIT Requisition

Slide Objective: Introduce changes to FIT requisition – CCC has a new requisition just for FIT

Speaker Notes:

- The new FIT requisition contain eligibility requirements and information on patients who should not screen with FIT
- This will help reduce the number of kits rejected due to patient in-eligibility

Ensure Your Patients Get Their FIT

Slide Objective: Introduce changes to FIT requisition – two address fields

Speaker Notes:

- **FIT requisition provides an option for kit delivery to an alternate address (e.g., health center, nursing station)**
- PCPs will be able to specify in the requisition where the FIT kit should be sent
- Patient's primary mailing address (OHIP registration address) will be used for correspondence

Ensure Your Patients Get Their FIT

Slide Objective: Introduce changes to FIT requisition – two address fields

Speaker Notes:

- **FIT requisition provides an option for kit delivery to an alternate address (e.g., health center, nursing station)**
- PCPs will be able to specify in the requisition where the FIT kit should be sent
- Patient's primary mailing address (OHIP registration address) will be used for correspondence

Preparing Your Practice for FIT: Requisition

Slide Objective: Review tips to prepare your practice for the change to FIT requisition

Additional Information:

- FIT requisition will be available at cancercareontario.ca/pcscreeningprograms once FIT is available
- The FIT requisition will be made available prior to FIT go-live on the FIT hub: cancercareontario.ca/FIThub

FIT Kit

Slide Objective: Introduce the new FIT kit patients will receive

Additional Information:

- LifeLabs mails a patient a FIT kit within two days of receiving a fully complete and accurate FIT requisition from you.
- It is very important to take time to check a patient's address information for accuracy before submitting (e.g., faxing) the FIT requisition to LifeLabs to avoid mailing delays. LifeLabs will use an address cleansing service to ensure that the patient addresses provided on FIT requisitions meet Canada Post's criteria for "mailability".
- If your patient's address information is incomplete, inaccurate or does not meet Canada Post's mailing criteria, LifeLabs will make at least three attempts to contact you (e.g., by phone or fax) to confirm or retrieve information. If the information cannot be retrieved by the third contact attempt, LifeLabs will let you know that the requisition has not been accepted.
- Once mailed from LifeLabs, in general, most participants can expect to receive their FIT kit from Canada Post, generally within five to 10 days (standard local mail).

Why Centralized Distribution?

Slide Objective: Explain rationale for change to centralized distribution with FIT

Speaker Notes:

- Current program design challenges include:
- High rate of mislabelled tests; in 2017, mislabeling accounted for an average of 69% of all rejected tests
- Rejection of expired cards and expired specimens
  - Expired cards account for an average of 10% of all rejected tests
  - Expired specimens account for an average of 14% of all rejected tests
- Combined, un-labelled & expired gFOBTs contribute to ~94% of rejected tests
- FIT program central distribution benefits include:
- Centralized distribution of FIT kits from LifeLabs (instead of from providers and pharmacies) will help to address the shorter shelf life and minimize rejected tests through:
  - barcode labelling of FIT collection devices with patient identifiers, which reduces the information patients have to provide themselves (failure to provide this information can lead to test rejections)
  - improved inventory management, so patients do not receive expired kits, given the shorter shelf life of the FIT collection device (which expires within 12 to 18 months)
  - centralized distribution also allows for LifeLabs' confirmation of patient eligibility before mailing out each FIT kit (which will help to reduce inappropriate use of FIT); and
  - centralized distribution of gFOBT and FIT kits is common practice in many jurisdictions (Nova Scotia, Saskatchewan, Manitoba, New Brunswick, Prince Edward Island, Newfoundland, England, Australia and the Netherlands).

Challenges with FIT:

- Patient is still required to write date of specimen collection on the device
- FIT has a shorter device shelf life (12–18M)

Why Centralized Distribution?

Slide Objective: Explain current program challenges with gFOBT

Speaker Notes:
Current program design challenges include:
- High rate of mislabelled tests; in FY 2017/18, mislabeling accounted for an average of 59% of all rejected tests
- Rejection of expired cards and expired specimens
  - Expired cards account for an average of 10.1% of all rejected tests
  - Expired specimens account for an average of 10.5% of all rejected tests
- Centralized distribution eliminates almost 90% of causes for rejected tests

Additional Information:
- Includes reasons for rejected tests only (re-tests comprise both rejected (5.5%) and indeterminate (6.1%) tests

Ordering FIT for Unattached Patients

Slide Objective: Highlight the differences between ordering a FIT for attached and unattached

Cancer Care Ontario

Completing FIT: Steps for Patients

Completing FIT: 3 Steps for Patients

Slide Objective: Introduce FIT screening pathway – 3 steps for patients

Speaker Notes:

- Patients are required to confirm accuracy of label information and clearly record the date of specimen collection on the FIT tube
- Reminder that mislabelling of the device is a major reason for test rejection (accounting for 69% of all rejected gFOBTs in 2017)

NEW: Patients must mail or drop off completed FIT to the lab **as soon as possible.**

Because hemoglobin degrades over time, even at ambient temperatures, timely return of completed samples to the lab is critical for ensuring samples are viable for testing. The CCC program recommends that patients mail or drop off their completed FIT to the lab as soon as possible, ideally within 2 days, to ensure it arrives at the lab within 14 days. This will help to reduce the risk of sample degradation over time.

Supporting Patients

Slide Objective: Highlight that CCC program correspondence will be updated for FIT

Speaker Notes:

- Patients will continue to receive CCC program correspondence, which will be updated for FIT
- To increase screening participation, opt in to physician-linked correspondence, which will include your name in your rostered patients' screening invitation letters
- Research has shown that people who receive a personal recommendation from their family physician are more motivated to get screened for cancer than those who do not
- The ColonCancerCheck program conducted a 2-phase pilot in 2009 to evaluate the feasibility and effectiveness of physician-linked correspondence
- Screening participation with gFOBT was higher during the 6-month study period in the group that received physician-linked letters (22%) than in the group that was not invited by mail (8%)
- This means that for every 7 physician-linked letters sent, 1 additional person was screened

Source:

Tinmouth J, Baxter NN, Paszat L, Sutradhar R, Rabeneck L, Yun L. Using physician-linked mailed invitations in an organised colorectal cancer screening programme: effectiveness and factors associated with response. BMJ. 2014 Mar 12;4(3):e004494. doi: 10.1136/bmjopen-2013-004494

Evidence Supporting CCC Correspondence

Slide Objective: Highlight evidence supporting CCC correspondence

Speaker Notes:

- To increase screening participation, opt in to physician-linked correspondence, which will include your name in your rostered patients' screening invitation letters
- Research has shown that people who receive a personal recommendation from their family physician are more motivated to get screened for cancer than those who do not
- The ColonCancerCheck program conducted a 2-phase pilot in 2009 to evaluate the feasibility and effectiveness of physician-linked correspondence
- Screening participation with gFOBT was higher during the 6-month study period in the group that received physician-linked letters (22%) than in the group that was not invited by mail (8%)
- This means that for every 7 physician-linked letters sent, 1 additional person was screened
- In phase 2 (2012), screening participation was higher among those who received PLC invites (16.9%) compared to those that received non-PLC (unlinked) invites (9.2%)
- CCC correspondence letters draw from qualitative research conducted internally and consultation with health behaviourists
- CCC has also introduced male specific invitation letters, which include messaging that has been shown to improve participation among men compared to standard letters that use different messaging

Source:

1. *Tinmouth J, Baxter NN, Paszat L, Sutradhar R, Rabeneck L, Yun L. Using physician-linked mailed invitations in an organised colorectal cancer screening programme: effectiveness and factors associated with response. BMJ. 2014 Mar 12;4(3):e004494. doi: 10.1136/bmjopen-2013-004494*
2. *Llovet D, Tinmouth J, Hershfield L, Bravo C, Bronstein T, Paszat L. Improving the quality of colorectal cancer screening correspondence: Results from an expert assessment. Cancer Care Ontario. (2013)*
3. *Llovet D, Tinmouth J, Hershfield L, Bravo C, Ginieniewicz J, Ekanayake S, Murzin K, Bronstein T, Paszat L. Towards evidence-based colorectal cancer screening correspondence: Recommendations for invitation and abnormal FOBT result letters. Cancer Care Ontario. (2013)*

Supporting Patients

Slide Objective: Highlight the new correspondence insert that will inform patients of the transition to FIT

Additional Information:

- This is a new correspondence insert that will be included in invitations to screen and recall letters to inform people who have just completed a gFOBT that the next time they screen, it will be with FIT
- It will be included in the invitation to screen and recall correspondence for 2 years after FIT launch

Supporting Patients

Slide Objective: To introduce the FIT instructions

Speaker Notes:

- Illustrated FIT instructions have been developed.
- The instructions are word-light, relying primarily on visual depictions of the steps required to successfully complete a FIT.
- The FIT instructions will be available in both English and French in the FIT kits, and will also be available online in 20+ languages.
- To view or print a copy of the FIT instructions visit the FIT hub
- PCPs will receive a copy of the instructions and are encouraged to walk through instructions with patients

Supporting Patients- Lab Label TBC

Slide Objective: To introduce the FIT device label

Cancer Care Ontario

FIT Return

Slide Objective: To review return options for FIT

Speaker Notes:

- Ideally within 2 days, to ensure it arrives to the lab within 14 days of specimen collection
  - Unlike gFOBT, FIT specimens are not as stable at high temperatures and over time.
  - Due to stability concerns, the return time has been shortened from 21 days, to 14 days
- People who live on a first nation reserve can call their nursing station or health centre

Patient Service Centre (PSC) Locations

Slide Objective: To provide a link to a location finder for patient service locations to drop off a completed FIT

Presenter Instructions:

Presenter may put in LHIN location into the PSC finder and provide a list of the PSCs for the audience

FIT Results and Follow-Up by Primary Care Provider (PCP)

Slide Objective: Introduce FIT screening pathway → how results are shared and next steps for patients

Speaker Notes:

- Important to follow-up an abnormal result with a colonoscopy within 8 weeks
- Patients with an abnormal FIT are more likely to have a cancer or a high risk adenoma therefore abnormal results require an urgent referral
- If the test result is invalid or the FIT collection device is rejected, a new requisition will be required for the lab to send a new kit to your patient. The provider will receive a lab report with the reason for the invalid test result or rejected FIT collection device, and recommended actions, which will include completing and submitting a new FIT requisition for the patient.

Additional Information:

FIT kits that are misplaced, damaged or not received will be replaced by the laboratory at the request of a provider or patient, without a new requisition provided that the FIT requisition is still valid (requisitions are valid for 6 months after they are first received by the lab).

The Patient Perspective

Slide Objective: Review tips on how to communicate abnormal results to patients

Speaker Notes:

- Receiving an abnormal FIT result can be stressful for your patient and their family
- Speak with your patient at the time of ordering the test about what an abnormal FIT can mean

Additional Information:

- Data from the Ambulatory Oncology Patient Satisfaction Survey (AOPSS) shows that patients think wait times are too long for a number of events along the cancer journey including receiving the results of a test and having an appointment scheduled with a specialist (e.g.: time from abnormal FOBT/FIT to colonoscopy)
    - Respondents emphasized how waiting increases anxiety.
- For patient-facing materials explaining an abnormal FIT result, visit: https://www.cancercareontario.ca/en/types-of-cancer/colorectal/screening/abnormal-fobt-result-faq

Case Study 6

Speakers Notes: Answer (d)

- Counsel Anna on the importance of a follow-up colonoscopy and refer her promptly for colonoscopy to determine if the abnormal FIT was caused by colorectal cancer or an advanced polyp.
- When speaking with Anna, emphasize the importance of a follow-up colonoscopy within eight weeks[1], and counsel her on what to expect before, during and after the examination to relieve any anxiety she may have. Explain to Anna that an abnormal FIT result necessitates additional testing with colonoscopy, as only colonoscopy can determine if colorectal cancer is present.
- A follow-up colonoscopy is required to inspect the colon for possible colorectal neoplasia. Even if your patient insists that their bleeding may have caused a false abnormal FIT result, or you suspect the bleeding is from a benign source (e.g., anal fissure), you should emphasize the importance of finding out whether the abnormal FIT result was caused by cancer or an advanced polyp. Regardless of whether you suspect the bleeding is benign, it's important to remember that the FIT is specific to bleeding from the distal gut (i.e., colon and rectum). It's possible that a patient could be bleeding from both a benign source and potentially malignant source.

Case Study 6 (continued)

- Cancer Care Ontario recommends that participants with an abnormal FIT result follow up with colonoscopy within eight weeks. Following an abnormal FIT result, a prompt colonoscopy is required. This is because there is a higher likelihood that the patient has colorectal cancer compared to those who are referred to colonoscopy for average risk screening or most of those who are referred with symptoms. Diagnostic delays following an abnormal FIT result could allow the disease to progress to a more advanced stage, and may lead to delays in receiving treatment. In addition, prompt follow-up is important to address patient anxiety with respect to abnormal screening results. The eight week benchmark was set by the Canadian Association of Gastroenterology Wait Time Consensus Group[2], and aligns with recommendations set by the Canadian Partnership Against Cancer's National Colorectal Cancer Screening Network[3].

Take Home Message:

An abnormal FIT is a abnormal FIT regardless of the circumstances leading up to or during sampling time that may or may not have impacted the test result. Patients with either an abnormal FIT or abnormal gFOBT have an increased risk of colorectal cancer. In the Spanish RCT described in the previous case study, one colorectal cancer was detected for every 18 participants (5.6%) who underwent colonoscopy following an abnormal FIT[4].

References:

1. Screening Guidelines – Colon Cancer [Internet]. Toronto: Cancer Care Ontario [updated 2016 Aug 18; cited 2017 Jun]. Available from: https://www.cancercare.on.ca/pcs/screening/coloscreening/cccstandardsguidelines/
2. Paterson WG, Depew WT, Paré P, Petrunia D, Switzer C, Veldhuyzen van Zanten SJ, et al. Canadian consensus on medically acceptable wait times for digestive health care. Can J Gastroenterol. 2006; 20(6): 411-423.
3. Canadian Partnership Against Cancer. Quality Determinants and Indicators for Measuring Colorectal Cancer Screening Program Performance in Canada. Toronto: The Partnership, 2012.
4. Quintero E, Castells A, Bujanda L, Cubiella J, Salas D, Lanas Á, et al. Colonoscopy versus fecal immunochemical testing in colorectal cancer screening. The New England Journal of Medicine. 2012; 366(8): 697-706.

Receiving and Interpreting Lab Reports

Slide Objective: Review how FIT results will be displayed/communicated to providers

Speaking notes:

- Lab reports for providers will include the test result and recommended next steps, including follow-up
- Providers are encouraged to become familiar with the result categories
- The table displayed provides an example of draft lab reports for normal and abnormal FIT results.

Receiving and Interpreting Lab Reports

Slide Objective: Review how FIT results will be displayed/communicated to providers

Speaking notes:

- If the test result is ***invalid*** or if the FIT collection device was ***rejected***, lab reports will include the specific reason for the invalid result or rejected FIT collection device and recommended actions, which may require completing a new FIT requisition
- The table displayed provides an example of draft lab reports for an invalid FIT result and rejected FIT collection device

Additional Information:

Possible reasons for an invalid FIT result include:

- Result below positivity cut-off, specimen 15 – 30 days old
- Result below positivity cut-off, no specimen date
- Too much sample (instrument cannot read)

Possible reasons for a rejected FIT collection device include:

- Requisition expired (patient did not return the FIT collection device within 6 months of the lab receiving the FIT requisition **or** patient returned the FIT collection device more than 6 months after the FIT requisition was received at the lab)
- FIT collection device not opened (no sample)
- Reduced buffer
- Device lot number expired
- Damaged device
- Participant declined to complete FIT
- Specimen leaking
- Specimen too old to be tested

Receiving and Interpreting Lab Reports

Slide Objective: Review how FIT results will be displayed/communicated to providers

Speaking notes:

- If the FIT requisition was rejected or if the lab was unable to mail out the FIT kit (e.g., address information did not meet Canada post requirements for mailing), the lab report will clearly identify the issue under the ***result*** column of the lab report, along with recommended next steps in the comments column
- The table displayed provides an example of draft lab reports for a rejected FIT requisition

Additional Information:

- Possible reasons for a rejected FIT requisition include:
  - Patient is not age-eligible
  - Patient is not eligible due to recent screening with FIT in the last two years (for normal or abnormal results only)
  - Patient is not covered by OHIP

Note:

Repeating the FIT after an abnormal FIT or gFOBT is not appropriate and can lead to delays in diagnosis and treatment. Requests to repeat FIT after an abnormal result will not be accepted by the lab.

Discontinuation of CCC gFOBT in Ontario

Slide Objective: To highlight the key milestones of discontinuing the use of gFOBT

Speaker Notes:

- Prior to FIT being available in Ontario, reduce the inventory of gFOBT in your office, and the amount you order for resupply
- Once FIT is available, remove any gFOBT inventory from your office and do not distribute gFOBT
  - Once the fecal immunochemical test (FIT) becomes available as the average risk screening test for colorectal cancer, ColonCancerCheck (CCC) gFOBT laboratory providers will arrange to remove unused CCC gFOBT kits from primary care provider offices, pharmacies, and Cancer Care Ontario mobile screening coaches. If you have any questions, contact your CCC gFOBT laboratory provider for more information.
- FIT screening data will begin to be available in your SAR one month after FIT is available
- Until FIT is available through the CCC program, providers should continue to screen eligible patients when they are due for screening with gFOBT Decommissioning of gFOBT will be a period of 6 months
- Once the gFOBT is decommissioned by the CCC program, participants who complete a gFOBT will not be considered up to date for screening and therefore will not be excluded from receiving a FIT

Disposing of CCC gFOBT Kits in Ontario

Slide Objective: To highlight how to dispose of gFOBT inventory once FIT is available

Cancer Care Ontario

After this presentation, you will be able to:

- Understand the Burden of Colorectal Cancer (CRC) in Ontario
- Order the Fecal Immunochemical Test (FIT) and Counsel your Patients
- Compare CRC Screening Tests for Average Risk Patients
- Select Appropriate Follow-Up: Screening Interval and Surveillance
- Describe Learnings from Other Jurisdictions
- Integrate Cancer Care Ontario Tools to Support your Practice

Follow-Up of guaiac fecal occult blood test (gFOBT)

Slide Objective: Highlight the current challenges with follow-up in Ontario in 2016/2017

Speaking Notes:

- Follow-up of abnormal gFOBT results is sub-optimal
  - only 48% receive a colonoscopy within the recommended eight week benchmark
  - approximately 20% are considered lost to follow-up at six months

Additional Information:

Lost to follow-up = did not undergo colonoscopy within 6 months of abnormal gFOBT result

Ensure Timely Follow-Up

Slide Objective: Emphasize importance of timely follow-up

- Data from the Ambulatory Oncology Patient Satisfaction Survey (AOPSS) shows that patients think wait times are too long for a number of events along the cancer journey including receiving the results of a test and having an appointment scheduled with a specialist (e.g.: time from abnormal FOBT/FIT to colonoscopy)
  - Respondents emphasized how waiting increases anxiety.

Importance of Timely Follow-Up

Slide Objective: Underscore the importance of timely follow-up of FIT+ results

Additional Information:

Study details:

- Main finding: Steady rate of CRC diagnosis (about 3%) between 0-6 months
- Compared to patients who had a colonoscopy within 8 to 30 days following their result, those who had their colonoscopy after 10 months had a higher risk of CRC and advanced-stage disease at diagnosis.
- Compared with patients who received follow up within 8 to 30 days (reference group) after an abnormal FIT result, there was no significant increase in risk of CRC outcomes for examinations within 6 months.
- For follow up at 7-9 months, there was a higher risk of stage II CRC
- For follow up at 10-12 months, the risk was higher for any CRC, advanced stage disease, stage II CRC and stage IV CRC
- For exams at more than 12 months, the risk was higher for advanced adenomas, any CRC, advanced stage disease, stage II CRC, stage III CRC and stage IV CRC
- Since the Ontario program screens every 2 years, it is likely that the impact of diagnostic delay would be apparent sooner than that observed in a program that screens yearly

Sources:

Corley et al. JAMA 2017; 317(16): 1631-1641.

Importance of Follow-Up

Slide Objective: Underscore the importance of follow-up of FIT+ results

Additional Information:

Study details:

- n=59,389 FIT positive individuals in Taiwan, age 50-69 (positivity threshold 20ugHb/g)
- 2004-2009
- Primary endpoint (CRC mortality) monitored until end of 2012
- 1.63-fold (95% CI:1.32-2.04) increased risk for CRC death for non-colonoscopy group compared to colonoscopy group

Sources:

1. Lee et al., Association Between Colorectal Cancer Mortality and Gradient Fecal Hemoglobin Concentration in Colonoscopy Noncompliers. J Natl Cancer Inst (2017) 109(5): doi: 10.1093/jnci/djw269

Case Study 7

Speakers Notes: Answer (a)

- Katya should be scoped within eight weeks. Following an abnormal FIT result, a prompt colonoscopy is required and should be completed within eight weeks of the abnormal result[1].
- Cancer Care Ontario recommends that participants with an abnormal FIT result follow up with colonoscopy within eight weeks. This benchmark was set by the Canadian Association of Gastroenterology Wait Time Consensus Group[2], and aligns with recommendations set by the Canadian Partnership Against Cancer's National Colorectal Cancer Screening Network[3].
- It is important to consider that patients with an abnormal FIT result have a higher likelihood of an underlying colorectal cancer compared to those who are referred to colonoscopy for average risk screening or most of those who are referred with symptoms. Diagnostic delays following an abnormal FIT result could allow the disease to progress to a more advanced stage, and may lead to delays in receiving treatment.
- Furthermore, patients with abnormal FIT results are likely to feel anxious and concerned as they wait for their follow-up. To help manage anxiety, primary care providers should ensure timely access to colonoscopy and promptly refer patients for colonoscopy so that the procedure can be completed within the eight week benchmark.
- Be aware of any regional strategies to ensure timely access to colonoscopy for your patients with a positive (i.e., abnormal) FIT. A list of facilities funded by Cancer Care Ontario to provide colonoscopies for patients with an abnormal FIT result will be available at cancercareontario.ca/FITcolonoscopy when FIT is launched. If the colonoscopy is normal, re-screen with FIT in 10 years.
- If colonoscopy is abnormal, surveillance should be initiated as per surveillance guidelines[4]. Following a normal colonoscopy within the average risk population, there is no reason to continue to re-screen with colonoscopy, and the patient should return to screening with the FIT in 10 years.

References:

1. Screening Guidelines – Colon Cancer [Internet]. Toronto: Cancer Care Ontario [updated 2016 Aug 18; cited 2017 Jun]. Available from: https://www.cancercare.on.ca/pcs/screening/coloscreening/cccstandardsguidelines/
2. Paterson WG, Depew WT, Paré P, Petrunia D, Switzer C, Veldhuyzen van Zanten SJ, et al. Canadian consensus on medically acceptable wait times for digestive health care. Can J Gastroenterol. 2006; 20(6): 411-423.
3. Canadian Partnership Against Cancer. Quality Determinants and Indicators for Measuring Colorectal Cancer Screening Program Performance in Canada. Toronto: The Partnership, 2012.
4. Winawer SJ, Zauber AG, Fletcher RH, Stillman JS, O'Brien MJ, Levin B, et al. Guidelines for Colonoscopy Surveillance After Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer and the American Cancer Society. Gastroenterology. 2006; 130:1872-1885.

Strategies to Reduce Lost to Follow-Up Rates

Slide Objective: Identify strategies to reduce lost to follow-up

Additional Information:

- Contact OntarioMD (OMD) Peer Lead for help with your EMR
- Note: Your FIT lab reports will contain recommended follow-up and next steps
- Find out where FIT-positive colonoscopies are performed in your region and keep central FIT colonoscopy referral fax number handy

Carefully Consider Where Follow-Up Occurs

Slide Objective: Highlight the complexity of FIT+ colonoscopies – underscore the importance of carefully considering where follow-up occurs.

Speaker Notes:

- Since FIT+ colonoscopies detect twice as many screen-relevant lesions, including CRCs and high risk adenomas, FIT+ procedures will be more complex, lengthier and resource intensive due to the greater polyp burden.
- Regions are currently working to identify facilities that will be equipped and ready to perform fit procedures
- Refer to facilities with appropriate resources and expertise
- Contact your Regional Cancer Program (RCP) for your region’s FIT colonoscopy referral process

FIT+ Guidance

Slide Objective: Introduce CCO's FIT-positive guidance for facilities – to further underscore the importance of carefully considering where follow-up occurs, and what is expected of facilities providing FIT-positive colonoscopies.

Speaker Notes:

- Cancer Care Ontario published the FIT-positive guidance in 2017 to support facilities in ensuring that FIT-positive procedures are safe, complete, and timely, recognizing that these procedures will be more complex, lengthier, and more resource intensive.
- Key examples provided in the guidance document include:
- Facilities should have a booking management plan in order to ensure adequate time and expertise is available for these procedures. Suggestions for achieving these recommendations include:
  - Use of a standardized referral sheet
  - Protected slots for booking FIT-positive colonoscopies
  - Careful consideration of the number of FIT-positive procedures (including order and timing) to minimize endoscopist fatigue
- Endoscopists performing FIT-positive colonoscopies should have cognitive, integrative and technical competencies to safely and proficiently remove polyps up to two centimeters in diameter. Endoscopists performing FIT-positive colonoscopies should also be able to:
  - Manage post-polypectomy bleeding
  - Identify complex polyps that require adjudication to determine best management
  - (refer to FIT-positive guidance document for complete list)
- Facilities should provide access to all the necessary tools and equipment, including access to appropriate referral channels for complex cases
  - This recommendation acknowledges that referral to dedicated therapeutic endoscopists may be required for advanced/complicated polyps

Sources:

Cancer Care Ontario. Fecal immunochemical test (FIT)-positive colonoscopy facility-level guidance. 2017. Available at: www.cancercare.on.ca/FIThub

Impact of FIT

Slide Objective: To highlight the impact of FIT and that FIT requires better use of follow-up colonoscopy

Cancer Care Ontario

Colonoscopy Surveillance Recommendations

Surveillance

Slide Objective: Review background information on colonoscopic surveillance

Speaker Notes:

- Some people are at higher than average risk of CRC due to a personal history of colorectal adenomas or sessile serrated polyps. Surveillance is required in those people to decrease CRC incidence and subsequent mortality by removing incident adenomas (pre-cancerous polyps)
- While CCC has endorsed the USMSTF 2006 guidelines since 2008, CC has recently developed revised recommendations for post-polypectomy surveillance, which reflect the most recent available evidence.

Additional Information:

- Individuals with a personal history of pre-cancerous polyps are at increased risk of developing CRC (1,2). In such individuals, that risk may be decreased through colonoscopy surveillance, which refers to subsequent colonoscopy(ies) performed following an initial colonoscopy that showed high risk colorectal polyps (high risk adenomas and sessile serrated polyps)
- The future risk of CRC in people with a history of polyps is linked to the histological characteristics, size, and number of those polyps
- The purpose of post-polypectomy colonoscopy surveillance is therefore to decrease the incidence of CRC in individuals with a personal history of noncancerous colorectal neoplasia

<u>Sources:</u>

1. Atkin W, Wooldrage K, Brenner A, Martin J, Shah U, Perera S, et al. Adenoma surveillance and colorectal cancer incidence: a retrospective, multicentre, cohort study. The Lancet Oncology. 2017;18(6):823-34.
2. Lieberman DA, Rex DK, Winawer SJ, Giardiello FM, Johnson DA, Levin TR. Guidelines for colonoscopy surveillance after screening and polypectomy: a consensus update by the US Multi-Society Task Force on Colorectal Cancer. Gastroenterology. 2012;143(3):844-57.

Background

Slide Objective: To provide background on the purpose of CCC's post polypectomy surveillance recommendations

CCC's Approach for Developing New Recommendations

Slide Objective: Describe CCC's approach to developing new surveillance recommendations

Additional Information:

- More details on the polyp nomenclature are provided in the next slide
- Systematic review and meta-analysis of the risk of high risk (advanced) adenomas (HRAs), CRC, and/or CRC-related death among individuals with low risk adenomas (LRAs)
- This systematic review found that, compared with the general population, people with LRAs have significantly lower risks of CRC and CRC-related mortality. However, compared to those with a normal initial colonoscopy, there is a small statistically significant increase in the risk of HRAs in people with LRAs; the clinical importance of this observation is uncertain. However, the cumulative incidence of HRAs remained low and comparable in both groups, indicating that while the difference is statistically significant, it is not a clinically relevant finding.
- Additional evidence supporting the new recommendations (published following the systematic review) will be highlighted in the following slides

Sources:

1. Lieberman DA, Rex DK, Winawer SJ, Giardiello FM, Johnson DA, Levin TR. Guidelines for colonoscopy surveillance after screening and polypectomy: a consensus update by the US Multi-Society Task Force on Colorectal Cancer. Gastroenterology. 2012;143(3):844-57.
2. Leddin D, Enns R, Hilsden R, Fallone CA, Rabeneck L, Sadowski DC, et al. Colorectal cancer surveillance after index colonoscopy: guidance from the Canadian Association of Gastroenterology. Canadian journal of gastroenterology. 2013;27(4):224-8.
3. Dubé C, Yakubu M, McCurdy BR, Lischka A, Kone A, Walker MJ, et al. Risk of Advanced Adenoma, Colorectal Cancer, and Colorectal Cancer Mortality in People With Low-Risk Adenomas at Baseline Colonoscopy: A Systematic Review and Meta-Analysis. The American journal of gastroenterology. 2017;112(12):1790-801.

Developing Surveillance Recommendations

Slide Objective: Considerations in developing CCC's new surveillance recommendations

Speaker Notes:

- CCC's updated post-polypectomy surveillance recommendations:
- Account for future probability of CRC, based on size and histology of the most advanced screen-relevant polyp (low risk adenoma, high risk adenoma)
- Designed to ensure that surveillance colonoscopies are performed on individuals who are likely to benefit from the procedure, while not exposing those who don't stand to benefit to the risks and inconvenience of a colonoscopy
- Assume baseline colonoscopy was complete, of high quality, and polypectomy was complete
- Recommendations are provided based on the findings of the initial and subsequent surveillance colonoscopy (if applicable), and include the suggested test/procedure and interval.

Polyp Types and CRC Risk

Slide Objective: Provide overview of polyp nomenclature

Speaker Notes:

- Not all polyps are linked to CRC; only those which are linked with CRC are considered “screen relevant”
- Non screen relevant polyps:
  - Those which are not neoplastic and/or do not convey any increase in future risk of advanced neoplasia. Best example of this are small hyperplastic polyps in the rectum. Such polyps are very common; they have a typical appearance (sessile, whitish with lacy vascular pattern) and do not need to be removed nor to require surveillance.
- Screen relevant polyps:
  - Neoplastic polyps, either adenomas or sessile serrated polyps
  - Can be “low risk” or “high risk”
    - Low risk polyps= low risk adenomas

High risk polyps= high risk adenomas, large (>=10mm) sessile serrated polyps and sessile serrated polyps with dysplasia. It is uncertain whether small (<10mm) sessile serrated polyps are low risk or high risk at the moment. Pending further information, CCC categorizes those polyps as high risk.

Low Risk Adenomas- Screen Relevant

Slide objective: To define and show the appearance of low risk adenomas

Speakers Notes:

- Low risk adenoma(s) (LRAs) are defined as 1 to 2 tubular adenomas <10mm in diameter with no high-grade dysplasia.
- Of note, 30% of people >50 undergoing colonoscopy will have LRAs – these are very common

High Risk Adenomas- Screen Relevant

Slide Objective: To define and demonstrate the appearance of high risk adenomas

Speakers Notes:
High risk adenoma(s) (HRAs) are defined as either tubular adenoma ≥10mm, 3 or more adenomas, adenoma(s) with villous histology or adenoma with high-grade dysplasia.
Note that sessile serrated polyps >=10mm or sessile serrated polyps with dysplasia are also considered high risk polyps, but they are not high risk “adenomas”

NEW: Recommendations for Post-Polypectomy Surveillance

Slide Objective: To introduce CCC's new recommendations for post-polypectomy surveillance and highlight how these recommendations differ from previous recommendations

Speaker Notes:
- CCC has recently released new recommendations for post-polypectomy surveillance
- It is important to be aware of some of the key elements of these recommendations, including:
- Patients with small hyperplastic polyps in the rectum or sigmoid do NOT require surveillance
- These patients are considered to have had a normal colonoscopy and should next screen with FIT in 10 years

Additional Information:
These recommendations refer to FIT only; assumption is that by the time patients need to return to screening, FIT will be available in the CCC program
This tool is unique in bringing together recommendations for initial and subsequent colonoscopy results (where findings are high risk)

NEW: Recommendations for Post-Polypectomy Surveillance (continued)

GLOSSARY:

- Low risk adenoma(s): 1 to 2 tubular adenomas <10mm in diameter with no high-grade dysplasia.
- High risk adenoma(s): Tubular adenoma ≥10mm, 3 or more adenomas of any size, adenoma(s) with villous histology or adenoma with high-grade dysplasia.
- Sessile serrated polyp: Either sessile serrated polyps (SSPs) (also called “sessile serrated adenoma” [SSA] or “sessile serrated adenoma/polyp” [SSA/P]) or traditional serrated adenoma (TSA). Most serrated polyps will not have any dysplasia; serrated polyps with dysplasia are considered advanced. Traditional serrated adenomas are uncommon, and are often pedunculated and left-sided. For more classification information, please refer to the National Colorectal Cancer Screening Network Classification of Benign Polyps.(2)
- Serrated polyposis syndrome: At least 5 serrated polyps proximal to the sigmoid colon, with 2 or more being >10mm; any number of serrated polyps, proximal to the sigmoid colon in someone who has a first-degree relative with serrated polyposis; or 20 or more serrated polyps of any size, but distributed throughout the colon.(3)

<u>Sources:</u>

Dubé C, Yakubu M, McCurdy BR, Lischka A, Kone A, Walker MJ, et al. Risk of Advanced Adenoma, Colorectal Cancer, and Colorectal Cancer Mortality in People With Low-Risk Adenomas at Baseline Colonoscopy: A Systematic Review and Meta-Analysis. The American journal of gastroenterology. 2017;112(12):1790-801.

National Colorectal Cancer Screening Network. Classification of benign polyps. Pathology Working Group Report. June 2011.

Snover D, Ahnen D, Burt R, Odze R. Serrated polyps of the colon and rectum and serrated polyposis. In: Bosman F, Carneiro F, Hruban R, Theise N, editors. WHO classification of tumours of the digestive system. Lyon: IARC; 2010.

https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/38506 There is a mix of language in the 2 hyperplastic is a lot of text, and not new. Maybe simplify to state. ‘Patients with no or hyperplastic polyps as described should screen with FIT in 10 years, and not have colonoscopy surveillance’

Risk of CRC & CRC Mortality After Colonoscopy

Slide Objective: Demonstrate that there is no significant difference in CRC risk or CRC-related death between people with low risk (non-advanced) adenomas and no adenomas at initial colonoscopy, therefore colonoscopic surveillance not required

Speaking notes:

- CRC incidence rates per 10 000 person-years of observation were 20.0 (95%CI, 15.3-24.7; n = 70) for advanced adenoma, 9.1 (95%CI, 6.7-11.5; n = 55) for nonadvanced adenoma, and 7.5 (95%CI, 5.8-9.7; n = 71) for no adenoma.
- Participants with advanced adenoma were significantly more likely to develop CRC compared with participants with no adenoma (rate ratio [RR], 2.7 [95%CI, 1.9-3.7]; P < .001).
- There was no significant difference in CRC risk between participants with nonadvanced adenoma compared with no adenoma (RR, 1.2 [95% CI, 0.8-1.7]; P = .30).
- Compared with participants with no adenoma, those with advanced adenoma were at significantly increased risk of CRC death (RR, 2.6 [95%CI, 1.2-5.7], P = .01), but mortality risk in participants with non-advanced adenoma was not significantly different (RR, 1.2 [95%CI, 0.5-2.7], P = .68).
- For the purposes of discussing this slide;
- non-advanced adenomas = low risk adenoma,
- advanced adenoma = high risk adenoma
-

Risk of CRC & CRC Mortality After Colonoscopy (continued)

Additional Information:

- Non-advanced adenomas are defined as: as any number of tubular polyps <10 millimeters without high grade dysplasia
- This study is particularly relevant as it uses people with normal colonoscopy findings as the comparator, rather than the general population and fills an important gap in the evidence (most studies compared to the general population in the systematic review). Furthermore, this study used a longer follow up time (15 years) than previous studies.
-

Figure title:

- Cumulative Colorectal Cancer Incidence by Adenoma Status among Participants 55-74 Years Enrolled in the Prostate, Lung, Colorectal, and Ovarian Cancer Randomized Clinical Trial
- Figure footnote:
- Error bars indicate 95% CIs at the given time point. Median time of follow-up was 13.6 years (interquartile range [IQR], 10.3-15.0) for advanced adenoma, 13.1 years (IQR, 9.9-15.0) for non-advanced adenoma, and 12.5 years (IQR, 9.7-15.0) for no adenoma. P values for pairwise comparisons (log-rank test) were P < .001 for advanced adenoma vs no adenoma, P < .001 for advanced adenoma vs non-advanced adenoma, and P = .32 for non-advanced adenoma vs no adenoma.

Sources:
Click B, Pinsky PF, Hickey T, Doroudi M, Schoen RE. Association of colonoscopy adenoma findings with long-term colorectal cancer incidence. JAMA 2018; 319(19):2021-2031.

Risk of CRC Death After Colonoscopy

Slide Objective: Demonstrate that the risk of CRC death is lower among those who had a low risk adenoma removed, compared to those who had a high risk adenoma removed at follow-up colonoscopy, and compared to the general population.

Additional Information:

- 25% significant relative risk reduction in CRC mortality of LRA vs. general population
- Standardized mortality ratio = 0.75 (95% CI: 0.63–0.88)
- By contrast to the Click study presented earlier, CRC-mortality is compared to people from the general population; as a reminder, in Click's study, the comparator was people with a normal colonoscopy at baseline
- Figure Title:
- Colorectal-Cancer Mortality in a Cohort of Patients Who Underwent Removal of Adenomas and in the General Population. In this study, people underwent polypectomy at initial colonoscopy and did not undergo surveillance.

Figure Footnote:

- The graph shows the risk of death from colorectal cancer after a median follow-up of 7.7 years (maximum, 19) in the general population (dashed line) and in the cohort of patients with adenomas that were removed, which included patients who had high-risk adenomas and those who had low-risk adenomas. Error bars indicate 95% confidence intervals.

Sources:
Bretthauer M, Loberg M, Kalager M. Long-term colorectal-cancer mortality after adenoma removal. The New England journal of medicine. 2014;371(21):2036-7.

NEW: Recommendations for Post-Polypectomy Surveillance

Slide Objective: To introduce CCC's new recommendations for post-polypectomy surveillance and highlight how these recommendations differ from previous recommendations

Speaker Notes:
Patients with low risk adenomas should screen next with FIT, not colonoscopy; these patients should screen with FIT in 5 years (*NEW*)

Additional Information:
- These recommendations refer to FIT only; assumption is that by the time patients need to return to screening, FIT will be available in the CCC program
- This tool is unique in bringing together recommendations for initial and subsequent colonoscopy results (where findings are high risk)
- No evidence to support surveillance in people with LRAs
- People with LRAs have lower risk of CRC and CRC mortality compared to the general population
- Small increase in relative risk for high risk adenomas at 4-10 years compared to those with normal colonoscopy

NEW: Recommendations Following the FIRST Surveillance Colonoscopy

Slide objective: To introduce CCC's new recommendations for post-polypectomy surveillance and highlight how these recommendations differ from previous recommendations

Speaker Notes:

- Another key feature of CCC's new recommendations for post-polypectomy surveillance is the inclusion of recommendations for not only of the initial surveillance colonoscopy, but also the subsequent surveillance colonoscopy; recognizing that the approach to surveillance needs to be adjusted over time according to the findings of each subsequent procedure.
    - For example, a subsequent surveillance colonoscopy is recommended where a high risk adenoma(s) has been found at the initial colonoscopy. In this case, depending on whether no/low risk adenoma(s) or high risk adenoma(s) are found at the second colonoscopy, a subsequent colonoscopy is recommended in 5 or 3 years, respectively.

Additional information:

These recommendations refer to FIT only; assumption is that by the time patients need to return to screening, FIT will be available in the CCC program

Sources:

1. *Dubé C, Yakubu M, McCurdy BR, Lischka A, Kone A, Walker MJ, et al. Risk of Advanced Adenoma, Colorectal Cancer, and Colorectal Cancer Mortality in People With Low-Risk Adenomas at Baseline Colonoscopy: A Systematic Review and Meta-Analysis. The American journal of gastroenterology. 2017;112(12):1790-801.*
2. *National Colorectal Cancer Screening Network. Classification of benign polyps. Pathology Working Group Report. June 2011.*

Post-Polypectomy Surveillance in People With a Family History of CRC

Slide Objective: Review implications of post-polypectomy surveillance recommendations for recall intervals in people with a family history of CRC in a first degree relative

Speaker Notes:

- What about individuals at increased risk of colorectal cancer?
- Among individuals with a family history of CRC (i.e., a first-degree relative with the disease), surveillance following a normal colonoscopy should be based on family history or surveillance recommendations, whichever occurs first.
- As a reminder, if a patient's colonoscopy is normal and they have a family history of CRC, the recommendations are:
- Colonoscopy should be repeated every five years if their first-degree relative with CRC was diagnosed at <60 years old
- Colonoscopy should be repeated every 10 years if their relative was diagnosed at ≥60 years old

Primary Care Provider Role in Post Polypectomy Surveillance

Slide Objective: To highlight the importance of providing endoscopists with a copy of prior colonoscopy and pathology reports when available

Speaker Notes:

- Primary care providers provide an important role in supporting appropriate post-polypectomy surveillance for their patients
- When referring a patient for surveillance, primary care providers should provide endoscopists with a copy of the prior colonoscopy and pathology report, if available
- The endoscopist can determine if surveillance is indicated at that time

Considerations

Slide Objective: Review considerations for CCC's surveillance recommendations

Speaker Notes:

- While it is important to be familiar with CCC's surveillance recommendations, you may encounter a scenario in which the endoscopist's recommendations do not align with CCC's surveillance recommendations.
- In this case, be aware that:
- endoscopist recommendations may be influenced by other factors not captured in the surveillance guidelines (e.g., the quality of the previous colonoscopy may not have been sufficient)
- the endoscopist's recommendations may have been made prior to the availability/awareness of the more recent evidence available
- Primary care providers' awareness of CCC's surveillance recommendations can be used to support discussions with endoscopists

Case Study 8 - Part 1

Speakers Notes: Answer (b)

- As per ColonCancerCheck Surveillance Guidelines, average risk people with hyperplastic polyps in the rectum or sigmoid colon should re-screen in ten years with a FIT. Following a normal colonoscopy, people at average risk of colorectal cancer do not need to continue to re-screen with colonoscopy, and the patient should return to screening with the FIT in ten years.
- As outlined within ColonCancerCheck Screening Recommendations[2], people ages 50-74 without a family history of colorectal cancer could choose to be screened with flexible sigmoidoscopy every 10 years instead of FIT.

Case Study 8 - Part 2

Speakers Notes:

- It is good practice to be aware of ColonCancerCheck's recommended surveillance guidelines, which can be used to facilitate discussion with endoscopists. If you are concerned with the recommended screening interval on the colonoscopy report and feel comfortable, it is reasonable to reach out to the respective endoscopist to discuss the rationale for the recommendation. The endoscopists recommendation may differ from the surveillance guidelines due to concerns with respect to the quality of the colonoscopy.
- A number of factors may have contributed to this recommendation, including poor bowel preparation, inadequate examination of the colonic mucosa and/or incomplete colonoscopy (i.e. cecum was not reached). As outlined within the Canadian Association of Gastroenterology consensus guidelines on safety and quality indicators in endoscopy, endoscopists should be explaining the reasons for recommendations which differ from consensus guidelines[2].

Case Study 9

Speakers Notes: Answer (d)

- As Mildred will be 75 in 10 years, her return to screening in 10 years should be based on an assessment that considers the benefits and risks of screening in her situation. There are a number of things to consider when deciding whether to screen older adults for colorectal cancer including how long someone is expected to live, their other medical conditions and screening history, their risk of dying from cancer and whether or not they are well enough to do follow-up tests (i.e., colonoscopy).
- The ColonCancerCheck program does not recommend regular screening for people over age 74. Decisions to screen those between the ages of 75-85 years should include an assessment of risks and benefits, and take into consideration health, life expectancy, and prior screening history. Someone may choose to get screened after age 74 if the benefits of screening outweigh the risks. Generally speaking, people over age 74 do not benefit as much and are at more risk of having complications when they get screened for colorectal cancer. People who are younger than age 75 who have severe medical conditions may also experience more risks than benefits from screening. It is generally accepted that someone who is expected to live less than five years should not get screened1. There may be times when a healthy older adult wants to be screened after age 74. Some people over age 74 may benefit from screening, especially those who are very healthy or who have never had colon cancer screening. However, ColonCancerCheck does not recommend screening in persons over the age of 85.

After this presentation, you will be able to:

- Understand the Burden of Colorectal Cancer (CRC) in Ontario
- Order the Fecal Immunochemical Test (FIT) and Counsel your Patients
- Compare CRC Screening Tests for Average Risk Patients
- Select Appropriate Follow-Up: Screening Interval and Surveillance
- Describe Learnings from Other Jurisdictions
- Integrate Cancer Care Ontario Tools to Support your Practice

Tools that Support Colorectal Cancer (CRC) Screening: ColonCancerCheck Screening Recommendation Summary

Copies can be found at: cancercareontario.ca/pcresources

Tools that Support CRC Screening: Physician Linked Correspondence

Slide Objective: Review the benefits of signing up for physician linked correspondence

Additional Information:

Slide Objective: Highlight that CCC program correspondence will be updated for FIT

Speaker Notes:

- Patients will continue to receive CCC program correspondence, which will be updated for FIT
- To increase screening participation, opt in to physician-linked correspondence, which will include your name in your rostered patients' screening invitation letters
- Research has shown that people who receive a personal recommendation from their family physician are more motivated to get screened for cancer than those who do not
- The ColonCancerCheck program conducted a 2-phase pilot in 2009 to evaluate the feasibility and effectiveness of physician-linked correspondence
- Screening participation with gFOBT was higher during the 6-month study period in the group that received physician-linked letters (22%) than in the group that was not invited by mail (8%)
- This means that for every 7 physician-linked letters sent, 1 additional person was screened

Source:

Tinmouth J, Baxter NN, Paszat L, Sutradhar R, Rabeneck L, Yun L. Using physician-linked mailed invitations in an organised colorectal cancer screening programme: effectiveness and factors associated with response. BMJ. 2014 Mar 12;4(3):e004494. doi: 10.1136/bmjopen-2013-004494

Tools that Support CRC Screening: FIT Resource Hub

Slide Objective: Review what content is available on the FIT resource hub

Speakers Notes:

- The FIT resource hub contains updates, changes and tools relevant to PCP practice and stakeholders
- Resources such as FIT FAQs, Screening Recommendations Summary and FIT instructions can be found on the FIT resource hub
- The FIT FAQs cover topics such as;
  - FIT eligibility
  - Ordering FIT for patients
  - How FIT kits will be distributed
  - Follow-up guidance

Tools that Support CRC Screening: Screening Activity Report (SAR)

Slide Objective: Review the benefits of registering for the screening activity report

Speaking Notes:

- Signing up for Cancer Care Ontario's SAR can help you identify screen-eligible patients and monitor FIT result that may require follow-up
- The SAR reports on patients who are overdue for screening, had a normal FIT, had an abnormal FIT or have had colonoscopy

Tools that Support CRC Screening: eLearning Modules

Slide Objective: Review the available eLearning courses on the First Nations, Inuit and Metis health landscape

Speaking Notes:

- Cancer Care Ontario offers multiple eLearning modules for you to earn continuing education credits
- The modules focus on First Nations, Inuit and Metis history, culture, health landscape and improving person centred care within cancer screening

Clinical Pearls for Average Risk Screening

Use FIT, not colonoscopy

Centralized FIT kit distribution will minimize errors

FIT+ colonoscopy needed within 8 weeks

Screen with guaiac fecal occult blood test (gFOBT) until FIT is available

Post Quiz

Question 1

Slide Objective: Review key concepts related to average risk colorectal cancer screening with FIT

Answer (b)

- People with an abnormal FIT result should be have a follow-up colonoscopy within eight weeks[1]
- Cancer Care Ontario recommends that participants with an abnormal FIT result follow up with colonoscopy within eight weeks. Following an abnormal FIT result, a colonoscopy is urgently required as there is a relatively high likelihood that the patient has a CRC and diagnostic delays could allow for the progression of the disease to a more advanced stage. In addition, prompt follow-up is important to address patient anxiety with respect to abnormal screening results. The eight week benchmark was set by the Canadian Association of Gastroenterology Wait Time Consensus Group[1], and aligns with recommendations set by the Canadian Partnership Against Cancer's National Colorectal Cancer Screening Network[2].

Sources:

1. Paterson WG, Depew WT, Paré P, Petrunia D, Switzer C, Veldhuyzen van Zanten SJ, et al. Canadian consensus on medically acceptable wait times for digestive health care. Can J Gastroenterol. 2006; 20(6): 411-423.
2. Canadian Partnership Against Cancer. Quality Determinants and Indicators for Measuring Colorectal Cancer Screening Program Performance in Canada. Toronto: The Partnership, 2012.

Question 2

Answer (a)

- The screening interval for average risk screening will not change after the switch from gFOBT to FIT in Ontario. ColonCancerCheck will recommend screening with FIT every two years for asymptomatic people ages 50 to 74 without a family history of CRC[1].

Sources:

1. Screening Guidelines – Colon Cancer [Internet]. Toronto: Cancer Care Ontario [updated 2016 Aug 18; cited 2017 Jun]. Available from: https://www.cancercare.on.ca/pcs/screening/coloscreening/cccstandardsguidelines/

Question 3

Slide Objective: Review key concepts related to average risk colorectal cancer screening with FIT

Answer (c)

- The FIT is a fecal based CRC screening test. Use of FIT is not appropriate for patients experiencing symptoms or for investigation of disease. Patients experiencing symptoms should be referred to a specialist for evaluation.
- Presentations that may be indicative of CRC include iron deficiency anemia, blood in the stool, new and persistent diarrhea, constipation, or feeling that the bowel does not completely empty, narrower stools, new and persistent stomach discomfort, and unexplained weight loss.
- Cancer Care Ontario does not recommend the use of the FIT for indications other than CRC screening (e.g., for diagnostic use or for point-of-care testing). Fecal based testing has low sensitivity for the diagnosis of CRC in patients with symptoms[1, 2]. Furthermore, the use of fecal based testing as a diagnostic tool has been shown to lead to diagnostic delays and inefficiencies[3, 4, 5].

Sources:

1. Farag A, Barkun AN, Martel M. The Utility of Fecal Occult Blood Testing for Clinical Indications of Suspected Gastrointestinal Blood Loss Outside a Setting of Colorectal Cancer Screening: A Systematic Review. Poster session presented at: Digestive Disease Week; 2016 May 22 – 24; San Diego, CA.
2. Pochapin MB, Fine SN, Eisorfer RM, Rigas B. Fecal occult blood testing in hospitalized patients. J Clin Gastroenterol. 1994; 19(4):274-277.
3. Narula N, Ulic D, Al-Dabbagh R, Ibrahim A, Mansour M, Balion C, et al. Fecal occult blood testing as a diagnostic test in symptomatic patients is not useful: A retrospective chart review. Can J Gastroenterol Hepatol. 2014; 28(8): 421–26.
4. van Rijn AF, Stroobants AK, Deutekom M, Lauppe C, Sturk A, Bossuyt PMM, et al. Inappropriate use of the faecal occult blood test in a university hospital in the Netherlands. Euro J of Gastroenterol and Hepatol. 2012; 24(11):1266-69.
5. Ip S, Sokoro AA, Kaita L, Ruiz C, McIntyre E, Singh H. Use of fecal occult blood testing in hospitalized patients: results of an audit. Can J Gastroenterol Hepatol. 2014; 28(9): 489-94.

Question 4

Slide Objective: Review key concepts related to average risk colorectal cancer screening with FIT

Answer:

- Advise Jenny that she is not eligible to complete a FIT at this point in time, as she has recently screened with a flexible sigmoidoscopy. Counsel Jenny about the eligibility criteria for FIT
- Upon the transition to FIT, CCC eligibility criteria to screen with FIT will be the same as it is currently for screening with the gFOBT. The CCC eligibility criteria are:
  - being age 50 to 74;
  - being at average risk for CRC;
  - being asymptomatic;
  - not having screened for CRC with gFOBT or FIT* in the past two years;
  - not having screened for CRC with colonoscopy or flexible sigmoidoscopy in the past 10 years; and
  - having a valid Ontario Health Insurance Plan (OHIP) number.
- After 10 years when Jenny is due for CRC screening, she can decide if she would like to screen with the FIT or flexible sigmoidoscopy[1].

Sources:

Screening Guidelines – Colon Cancer [Internet]. Toronto: Cancer Care Ontario [updated 2016 Aug 18; cited 2017 Jun]. Available from: https://www.cancercare.on.ca/pcs/screening/coloscreening/cccstandardsguidelines/