Cancer Care Ontario

Transition to Fecal Immunochemical Testing (FIT)

Frequently Asked Questions for Endoscopists

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Ontario
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Overview

Ontario will be transitioning from the guaiac fecal occult blood test (gFOBT) to the fecal immunochemical test (FIT) in for people at average risk of developing colorectal cancer screening in late 2018. To support this transition, a list of frequently asked questions (FAQs) have been developed to provide endoscopists with information regarding changes to the ColonCancerCheck program and the transition's impact on endoscopy.

Since work to support the transition is ongoing, this list of FAQs does not address all questions that endoscopists may have. Additional FAQs will be developed in spring 2018. In the meantime, please contact screenforlife@cancercare.on.ca for more information.

Below is a glossary of standard terms used throughout the FAQs.

FIT: fecal immunochemical test

gFOBT: guaiac fecal occult blood test

FIT collection device: consists of the probe (grooved plastic stick) used to collect the stool and the vial (tube) where the probe is stored; also includes a small amount of buffer solution used to stabilize the sample

Inoculated device: term used to refer to the collection device once it contains a stool sample

FIT kit: term used to refer to the entire package that the laboratory/laboratories will send to the screen-eligible participants, including the FIT collection device and package components (e.g., instructions, return mailing materials). The participating laboratory or laboratories have not yet been finalized.

About the fecal immunochemical test and why it is being introduced in Ontario

1. What is the fecal immunochemical test (FIT)?

- FIT is a safe and painless stool-based test used for screening people at average risk of developing colorectal cancer*.
- Specifically, FIT checks for the presence of occult blood in the stool, which can be an early sign of colorectal cancer and/or pre-cancerous lesions.

* As outlined in ColonCancerCheck's screening recommendations, "average risk" refers to people ages 50 to 74 with no first-degree relatives who have been diagnosed with colorectal cancer, and with no personal history of inflammatory bowel disease (i.e., Crohn's disease or ulcerative colitis) or pre-cancerous colorectal polyps requiring surveillance.

2. Why is Ontario switching from the guaiac fecal occult blood test (gFOBT) to the fecal immunochemical test (FIT)?

Ontario is switching from gFOBT to FIT for several reasons:

- FIT is a more sensitive screening test than gFOBT, which means that it is better at detecting colorectal cancer and advanced adenomas. (1,2)
- FIT is specific for human hemoglobin, which means it will not mistake dietary sources of blood or other substances for human blood.
- Research has shown that people prefer screening with FIT over gFOBT, leading to increases in colorectal cancer screening participation. The benefits of FIT which are expected to lead to increased participation include:
    - the enhanced 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 stool sample needed;
    - no dietary restrictions, including vitamin C; and
    - no medication restrictions.
- FIT processing will be automated at a laboratory/laboratories*, which makes the interpretation of test results more consistent.

* The participating laboratory or laboratories have not yet been finalized.

3. Compared to the guaiac fecal occult blood test (gFOBT), how effective is the fecal immunochemical test (FIT) for screening average risk people?

- **FIT is a more accurate screening test than gFOBT for detecting a cancer or pre-cancer in average risk people**. Results from systematic reviews suggest that FIT is more sensitive (i.e., better at detecting a cancer in people who have the disease) than gFOBT (82 percent vs. 47 percent, after one-time FIT vs. one-time gFOBT). (1,2) FIT has also been shown to detect twice as many advanced adenomas and cancers as gFOBT (relative risk [RR], 2.15; 95 percent confidence interval [CI], 1.58 to 2.94). (3) Despite this much higher sensitivity, FIT only has a slightly lower specificity (i.e., proportion of positive test results correctly identified as not having the disease) than gFOBT (94 percent vs. 96 percent). (1,2)

- A recent systematic review also found that **people are more likely to participate in screening when FIT is used compared to gFOBT** (RR, 1.16; 95 percent CI, 1.05 to 1.28). (3) This may be due to the fact that FIT has no dietary or medication restrictions and sampling is easier.
- This combination of better test accuracy and higher participation than the gFOBT makes FIT a better screening test for people at average risk for colorectal cancer.

4. How does screening with the fecal immunochemical test (FIT) compare to average risk colonoscopy?

- Currently, there is limited evidence in terms of colorectal cancer mortality directly comparing FIT to colonoscopy for colorectal cancer screening in people at average risk of developing colorectal cancer. There are several large, randomized controlled trials (RCTs) underway to address this question, including an RCT in Spain with over 50,000 participants invited to be screened, but the final results for colorectal cancer mortality will not be available until the 2020s.

Cancer and pre-cancer detection:

- In 2012, the large RCT currently underway in Spain published results from the first round of screening, which provides some initial information about the effectiveness of FIT vs. colonoscopy. (4) **In the first round of screening, FIT was as good as colonoscopy at detecting colorectal cancer** (33 cancers vs. 30 cancers; *P* value = not significant) on an "intention to screen" basis (i.e., analyses are based on all participants initially randomized to that arm, regardless of whether or not they comply with or withdraw from the study—this approach better reflects practice and improves generalizability of study findings). While the study found that colonoscopy was significantly better at detecting advanced adenomas than the one-time use of FIT (514 vs. 231; *P* value = <0.001), this benefit may not be sustained over time because people in the FIT group will be recalled for screening four more times over the course of the study. Although these preliminary findings are of considerable interest, the final results will provide a more comprehensive answer about how colonoscopy compares to FIT.

Participation:

- **People tend to prefer the less invasive FIT to colonoscopy**. In the Spanish RCT described above, screening participants were given the option to switch their screening test from FIT to colonoscopy, or colonoscopy to FIT. While 23 percent of people invited for colonoscopy opted to switch to FIT, only one percent of people invited for FIT opted to switch to colonoscopy. Additional studies comparing participation between fecal-based tests and colonoscopy are described in the *Colorectal Cancer Screening in Average Risk Populations: Evidence Summary.* (3) While the quality of these studies varies, there is a general trend showing that people prefer fecal-based testing over colonoscopy.

Complications:

- In the Spanish RCT described above, among those who screened with FIT, one colorectal cancer was detected for every 18 FIT-positive people who underwent a colonoscopy, compared to one colorectal cancer being detected for every 191 people who screened with colonoscopy. (3) **Therefore, screening with FIT reduces the number of people who need a colonoscopy and ensures that only those who are most likely to benefit from the procedure are exposed to its rare, but serious, complications.**
- In the Spanish RCT, the risk of complications was statistically significantly lower in the FIT arm than in the colonoscopy arm (0.1 percent vs. 0.5 percent; *P* value = < 0.001). The complications experienced by participants in the FIT group occurred in those with a positive FIT result and who underwent a follow-up diagnostic colonoscopy.
- 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 and the use of sedation. Possible colonoscopy-related complications include (but are not limited to) perforation, post-polypectomy bleeding, cardiac events, syncope/hypotension, and death (in rare cases). (6,7) A

Canadian study found that out of approximately 68,000 people in Ontario who had an outpatient colonoscopy in 2002–2003, 101 were admitted to hospital with bleeding and 40 with perforations; five colonoscopies resulted in death. (6)

5. Are there any limitations to the fecal immunochemical test (FIT)?

- The FIT collection device has a shorter shelf life (12 to 18 months) than the guaiac fecal occult blood test (gFOBT) card (three years). Therefore, to manage device inventory and avoid the inadvertent distribution of expired devices, a laboratory/laboratories* will mail FIT kits to participants upon request from their primary care physician.
- Once a stool sample has been collected using the FIT collection device, the specimen is less stable than a gFOBT specimen on a card. Therefore, **ColonCancerCheck recommends processing FIT devices within 14 days of sample collection** (vs. 21 days for gFOBT). ColonCancerCheck will be working with the selected laboratory/laboratories* to support timely return of completed tests from participants in all regions across Ontario.

* The participating laboratory or laboratories have not yet been finalized.

Changes that can be expected with the implementation of the fecal immunochemical test for screening people at average risk of getting colorectal cancer in Ontario

6. Will the eligibility criteria for colorectal cancer screening change with the fecal immunochemical test (FIT)?

- No. Eligibility criteria to screen with FIT will be the same as it is for screening with the guaiac fecal occult blood test (gFOBT). The ColonCancerCheck eligibility includes persons who meet the following criteria:
    - ages 50 to 74*;
    - at average risk for colorectal cancer†;
    - asymptomatic‡;
    - not having screened for colorectal cancer with gFOBT or FIT in the past two years;
    - not having screened for colorectal cancer with colonoscopy or flexible sigmoidoscopy in the past 10 years; and
    - valid Ontario Health Insurance Plan (OHIP) coverage.
- Eligibility for screening with FIT will continue to be assessed by primary care providers. In addition, the laboratory/laboratories§ processing requisitions will confirm eligibility based on key parameters, such as age and, where possible, previous fecal test screening status.
  To learn more about the current ColonCancerCheck screening recommendations and eligibility criteria please visit the Resources for Primary Care Providers website (https://cancercare.on.ca/pcresources).

* 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. 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.

† "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 disease or ulcerative colitis) or pre-cancerous colorectal polyps requiring surveillance.

‡ There are no physical symptoms during the early stages of the disease. As colon cancer develops over time, someone might experience:

- unexplained anemia that is caused by a lack of iron;
- blood (either bright red or very dark) in the stool;
- unexplained weight loss;
- new and persistent diarrhea, constipation or feeling that the bowel does not empty completely;
- stools that are narrower than usual; and/or
- new and persistent stomach discomfort.

§ The participating laboratory or laboratories have not yet been finalized.

7. What is the screening interval for the fecal immunochemical test (FIT)?

- The screening interval for people at average risk* of colorectal cancer will not change after the switch from guaiac fecal occult blood testing (gFOBT) to FIT in Ontario. ColonCancerCheck will recommend screening with FIT every two years for people at average risk.

* "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 disease or ulcerative colitis) or pre-cancerous colorectal polyps requiring surveillance.

8. What changes will primary care providers, processing laboratory/laboratories and the public experience with the introduction of the fecal immunochemical test (FIT)?

- There will be two changes with the introduction of FIT: how primary care providers request a FIT for their patients and how the FIT kit is distributed to eligible Ontarians (refer to Appendix A for a summary). These changes are motivated by 1) the shorter shelf life of the FIT collection device (which expires within 12 to 18 months), and 2) the desire to reduce the number of mislabeled collection devices (which will reduce the number of rejected tests and the number of participants not receiving results). The information below provides more detail about these changes.

Primary care providers:

- will determine patient eligibility for screening with FIT;
- will no longer maintain an inventory of, or distribute, colorectal cancer screening tests (e.g., guaiac fecal occult blood test and FIT);
- will complete a FIT requisition form and send it directly to the processing laboratory/laboratories*;
- will be required to validate patient address information before completing the requisition form and sending it to the processing laboratory/laboratories*—this **validation is critical** to ensure that the laboratory/laboratories* and ColonCancerCheck have up-to-date participant mailing information, so the privacy of patients is **not compromised**, and they can receive their FIT kit and test result notification;
- will be able to specify in the requisition where the FIT kit should be sent, even if it's somewhere other than the patient's home or mailing address, as necessary; and
- will be responsible for ensuring that patients with a FIT-positive result receive timely follow-up—ColonCancerCheck recommends follow-up with a colonoscopy within eight weeks of a positive FIT result. Ensuring timely follow-up of a positive FIT result is particularly important due to the greater likelihood of abnormal findings associated with FIT-positive colonoscopies.

Processing laboratory/laboratories*:

- will mail the patients' FIT kits to the address on the requisition—each FIT kit will include the FIT collection device, instructions for completing the FIT and materials for mailing it back to the laboratory/laboratories*;

- may need to check with the primary care provider regarding completeness and/or accuracy of information on FIT requisitions; and
- before mailing FIT kits, will apply a barcode label (including participant identifiers) to each FIT collection device (reducing the likelihood of repeat tests due to labelling errors) and mail the kits directly to participants.

Participants:

- will be required to return their inoculated device to the laboratory/laboratories* by mail or by dropping it off at a specimen collection centre associated with the processing laboratory/laboratories†—inoculated devices should be returned to the laboratory/laboratories* as soon as possible after the stool is collected and the laboratory/laboratories* will contact participants if their collection date needs clarification.

* The participating laboratory or laboratories have not yet been finalized.

† The participating laboratory or laboratories have not yet been finalized. The option to drop specimens off at collection centres will depend on the participating laboratory/laboratories and will be confirmed at a later date.

9. Why does the current method of distribution for the guaiac fecal occult blood test (gFOBT) have to change with the fecal immunochemical test (FIT)?

- A centralized distribution approach is being adopted for screening with FIT. The processing laboratory/laboratories* will receive FIT requisitions from primary care providers and mail FIT kits directly to participants.
- Centralized distribution of FIT kits from the laboratory/laboratories* (instead of from physicians and pharmacies) has several advantages for patients, including:
    - 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, which is particularly important because FIT has a much shorter shelf life; and
    - reducing inappropriate use of FIT because the processing laboratory/laboratories* will confirm the patient's eligibility before mailing out each FIT kit.
- Centralized distribution for 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).

* The participating laboratory or laboratories have not yet been finalized.

Understanding how the implementation of the fecal immunochemical test in Ontario will impact colonoscopy services

10. What is the anticipated impact of the fecal immunochemical test (FIT) on colonoscopy services?

- FIT-positive colonoscopies are expected to be more challenging procedures than colonoscopies performed for most other indications, with a higher burden of colonic polyps. Compared to ColonCancerCheck's current screening test, the guaiac fecal occult blood test, FIT is expected to have higher participation rates and detect twice as many clinically-relevant lesions, including advanced adenomas and colorectal cancers. (3)

- In addition, FIT will result in the identification of larger and more challenging polyps. Therefore, the proportion of polypectomies required is expected to increase, as well as the proportion of procedures requiring a surgical referral. Because the FIT-positive lesions tend to be more challenging to remove, it is necessary to ensure endoscopists performing FIT-positive colonoscopies, and nurses who are assisting in these procedures, have the advanced skill sets to avoid and manage complications, to ensure patient safety and to avoid re-referrals for additional procedures. (5)

11. Given the increased procedure complexity, how will fecal immunochemical test (FIT) positive colonoscopies be reimbursed?

- Cancer Care Ontario is working with the Ministry of Health and Long-Term Care to validate and refine funding related to FIT-positive colonoscopies.

12. What supports are available to understand the recommended level of endoscopist/nurse expertise and facility set-up to perform fecal immunochemical test (FIT) positive colonoscopies?

- Cancer Care Ontario is planning to introduce FIT as part of Ontario's population-based colorectal cancer screening program (ColonCancerCheck). The use of FIT is expected to result in a higher volume of follow-up colonoscopies and greater procedure complexity. A guidance document titled FIT-Positive Colonoscopy: Facility-Level Guidance was developed to assist facilities in ensuring that the appropriate mechanisms are in place for safe, timely, high-quality follow-up colonoscopies for patients with a positive FIT result.
- While the Quality Management Partnership between Cancer Care Ontario and the College of Physicians and Surgeons of Ontario has established minimum standards for colonoscopy in Ontario, this document provides guidance in addition to these standards, to address the increased complexity of FIT positive colonoscopies.
- The principal goals of the guidance document are to:
  - **Support patient flow:** Patients with FIT-positive results should be referred to and undergo colonoscopy within eight weeks of an abnormal result.
  - **Assist facilities in ensuring procedures are safe and complete:** The guidance will help ensure access to the necessary equipment and expertise to manage the complexity of FIT-positive colonoscopies. The facility-level guidance will also help to maximize patient safety and reduce the need for repeat procedures.
- The FIT-Positive Colonoscopy: Facility-Level Guidance document is now available on Cancer Care Ontario's FIT Hub resource page at https://cancercare.on.ca/FITHub.

13. What if my facility does not meet the recommendations in the FIT-Positive Colonoscopy: Facility-Level Guidance?

- The criteria outlined in FIT-Positive Colonoscopy: Facility-Level Guidance are intended to serve as guidance. The guidance provided in the document was informed by screening and colonoscopy experts and draws from the experiences of other jurisdictions that currently use FIT in their population-based screening programs. As such, the guidance is intended to provide information on best practices and highlights key considerations for facilities when planning for the implementation of FIT. The goal here is to facilitate the smooth implementation of FIT-based colorectal cancer screening across the province.
- Outlined in this document are the skills and practices necessary for endoscopists to provide access to safe and high-quality FIT-positive colonoscopies. Endoscopists who intend to perform FIT-positive colonoscopies should consider whether their competencies align with the guidance and plan to expand their skill set, if necessary.

14. What if I do not meet the recommendations in the FIT-Positive Colonoscopy: Facility-Level Guidance?

- Endoscopists who intend to perform FIT-positive colonoscopies but do not currently meet the criteria outlined in the facility-level guidance can choose to participate in supplemental training opportunities, such as courses from the Skills Enhancement for Endoscopy (SEE) © program offered by the Canadian Association of Gastroenterology (cag-acg.org/education/see-program; the SEE courses are available at a reduced rate for gastroenterologists who are members of the Ontario Association of Gastroenterology).

15. What are other provinces doing to manage the impact of the fecal immunochemical test (FIT) on colonoscopy services?

- FIT is being used in eight provinces in Canada, excluding Ontario. Mechanisms to ensure high quality FIT-positive colonoscopies in these provinces are varied and range from the provision of guidelines to the credentialing or enrollment of endoscopists to participate in the screening program.
- Cancer Care Ontario has drawn from best practices in these jurisdictions to inform the FIT-Positive Colonoscopy: Facility-Level Guidance, reviewing quality initiatives for endoscopy practice from British Columbia, Newfoundland and Nova Scotia and quality assurance guidelines and credentialing programs from England, Netherlands, and the European guidelines. Input was also provided by six endoscopy experts who are currently using FIT in their provincial screening programs in Canada.

Availability of the fecal immunochemical test in Ontario

16. When will Ontario be switching to the fecal immunochemical test (FIT)?

- Cancer Care Ontario is working to make changes to the ColonCancerCheck program for the transition to screening with FIT. Once these changes are completed in 2018, FIT will be available for screening average risk people in Ontario.
- Cancer Care Ontario will be communicating with physicians regularly leading up to the launch of FIT. Over the course of 2017 and 2018, Cancer Care Ontario will be presenting at conferences, sharing communications with professional associations and Regional Cancer Programs, and posting resources and updates on the FIT resource hub (https://cancercare.on.ca/FITHub).
- Until FIT is launched in late 2018, the guaiac fecal occult blood test (gFOBT) remains the recommended colorectal cancer screening test in Ontario for people at average risk of getting colorectal cancer.
- FIT is not yet covered by the Ontario Health Insurance Plan (OHIP) and people are advised to continue using gFOBT until FIT becomes available through the ColonCancerCheck program. While FIT is available as a user-pay test from one laboratory in Ontario, Cancer Care Ontario recommends against screening people outside the program. As part of its organized screening program, ColonCancerCheck provides people with additional benefits, including letters inviting and reminding them to participate in screening and notification of results.

17. Why won't the fecal immunochemical test (FIT) be available for colorectal cancer screening until late 2018?

- Transitioning from the use of the guaiac fecal occult blood test (gFOBT) to FIT for colorectal cancer screening requires a number of large-scale changes to the ColonCancerCheck program and its supporting infrastructure.
- To ensure a successful transition from gFOBT to FIT, Cancer Care Ontario will have to make changes to the ColonCancerCheck program that impact FIT kit distribution, information technology, quality assurance, provider education and communications.

References

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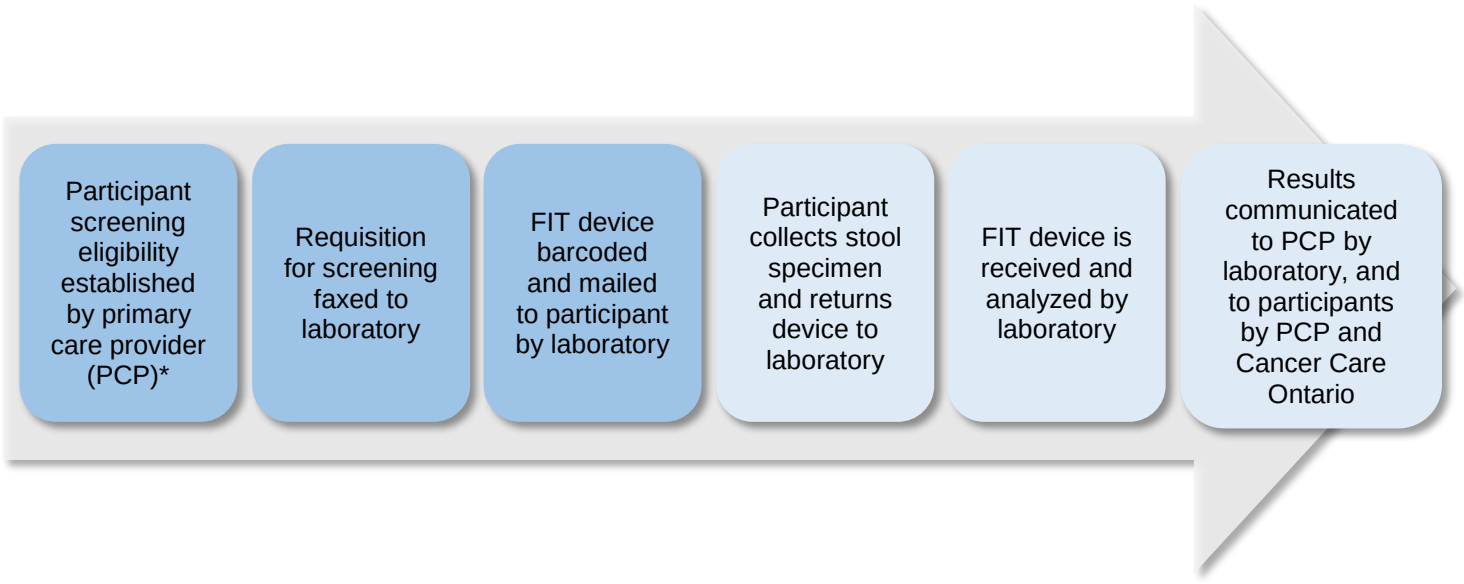
Appendix A: Fecal immunochemical test (FIT) screening pathway



ORDERING AND DISTRIBUTION

- PCPs will continue patient counselling and recruitment
- **NEW:** PCPs will no longer provide kit to their patients or maintain test kit inventory
- **NEW:** FIT requisition faxed directly to laboratory (central intake)
- **NEW:** Laboratory will validate participant eligibility and requisition completeness
- **NEW:** Centralized distribution of FIT kit by laboratory

*People without a PCP can get a requisition from Telehealth Ontario or a mobile screening coach

RECEIVING, TESTING AND REPORTING

- Completed kits returned to laboratory by mail
- **NEW:** Drop-off within 7–14 days when returning completed kit to laboratory
- **NEW:** Laboratory will refrigerate specimen upon receipt
- **NEW:** Laboratory will contact participant if collection date requires clarification
- **NEW:** Testing to be completed within 2 calendar days