

Time to get "FIT"

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

DR N ZAVAGNIN MD CCFP

This **Group Learning** program has been certified by the College of Family Physicians of Canada for up to 4 Mainpro+ credits..



Faculty/Presenter Disclosure



Presenter: Dr. Nicole Zavignin

Title of Presentation:__Time to Get FIT

I have no financial or personal relationship related to this presentation to disclose.



Disclosure of Commercial Support

Commercial Support:

 This program has received financial support from Cancer Care Ontario in the form of payment for the certification of this module

Potential for conflicts of interest: None



Mitigating Potential Bias

 This program is not the opinions of the speakers, but uses evidencebased content developed by Cancer Care Ontario





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



Approximately how many new cases of CRC will be diagnosed in Ontario in 2018?

- a) 8,500
- b) 10,100
- c) 11,600
- d) 10,600





Fill in the blank: If caught early (stage 1), approximately of people with CRC will be disease free at five years?

- a) 90%
- b) 80%
- c) 35%
- d) 55%





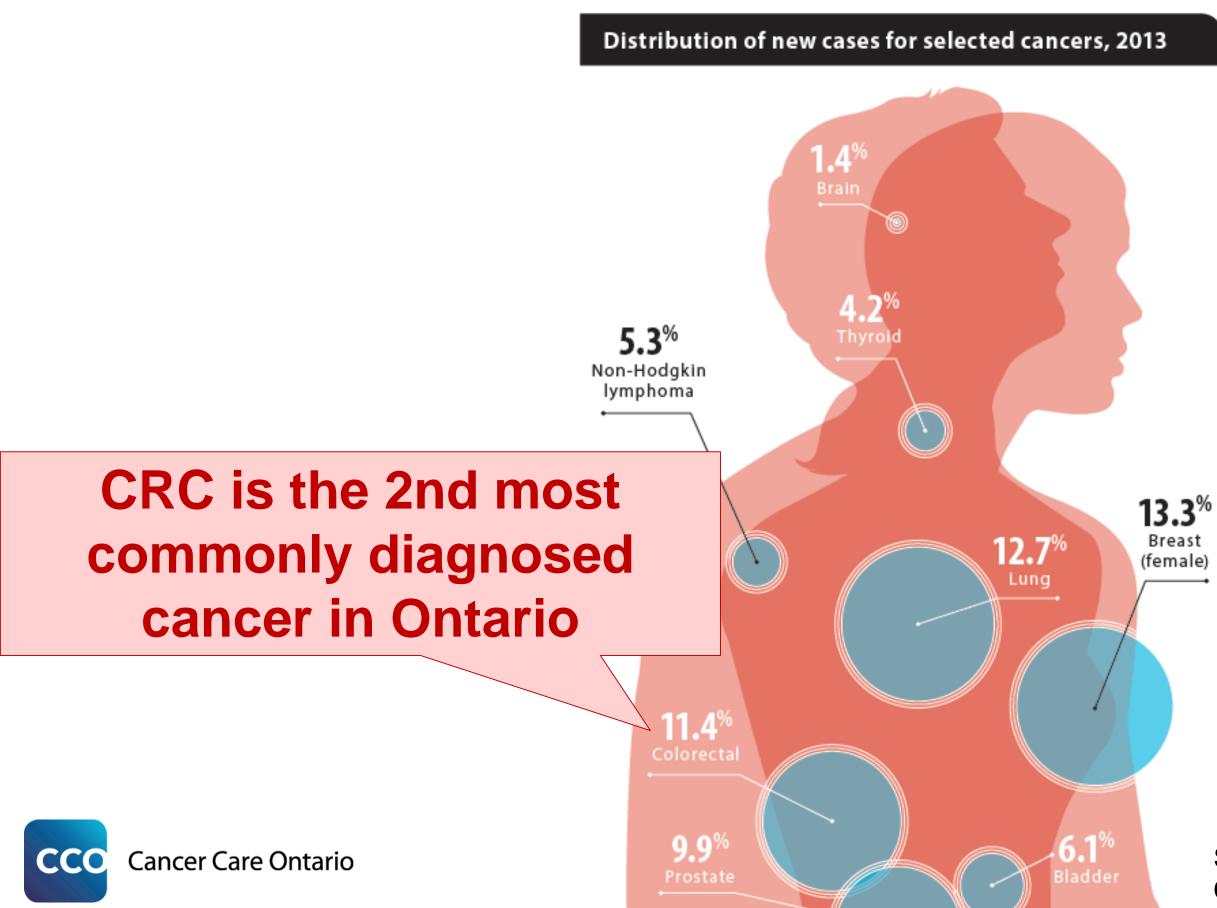
Within Ontario, approximately how many people will die from CRC annually?

- a) 5,000
- b) 10,500
- c) 19,000
- d) 3,350
- e) 700





Burden of CRC in Ontario

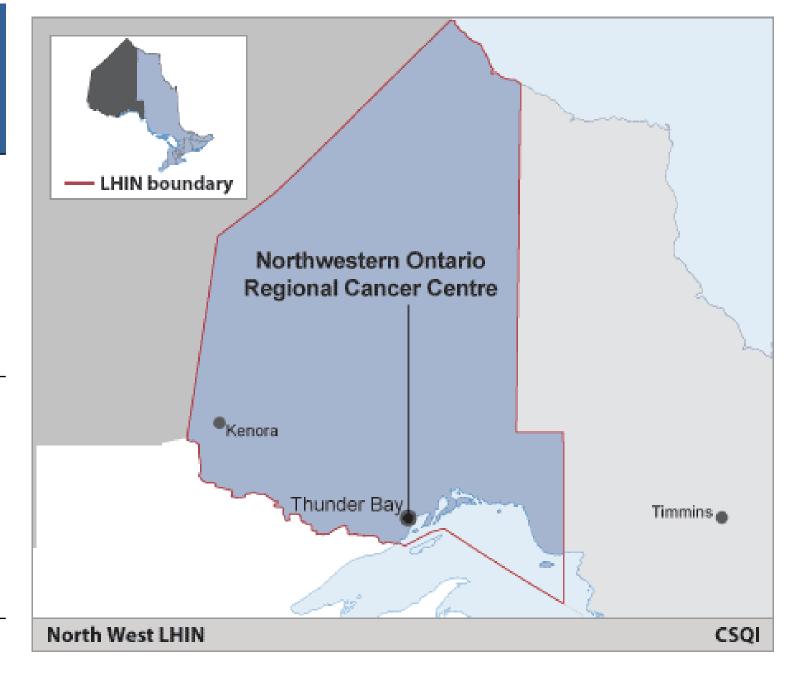


Source: Cancer Care Ontario. Ontario Cancer Statistics 2018. Toronto: Cancer Care Ontario; 2018.

North West Local Health Integration Network (LHIN)



Indicator (total population)	North West LHIN	Ontario
Age-standardized incidence of colorectal cancer (CRC) (per 100,000 people) (2017 estimate)	84.2	72.1
Age-standardized 5-year relative survival of CRC (2009–2013)	65.5%	67.5%
Percentage of people overdue for CRC screening* (2016)	42.5%	38.1%



*People are considered "overdue" if they have not had an gFOBT in 2 years, colonoscopy in 10 years, or flexible sigmoidoscopy in 10 years.





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Select Appropriate Follow-Up: Screening Interval and Surveillance

Fill in the blank: Of the individuals diagnosed with CRC, approximately ____have no family history of the disease.

- a) 50%
- b) 15%
- c) 70%
- d) 90%
- e) 25%



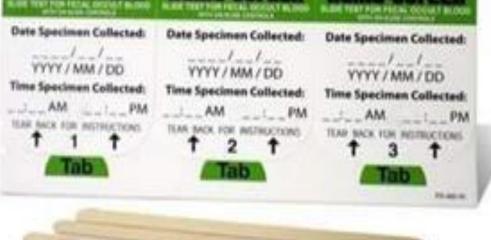


Ontario's ColonCancerCheck (CCC) Program

- Canada's first organized province-wide CRC screening program launched in 2008
- Sends letters to eligible people
- Screening offered to people ages 50–74
 - Via primary care provider
 - Average risk: guaiac fecal occult blood test (gFOBT)*
 until fecal immunochemical test (FIT) is available in Ontario
 - Increased risk (≥1 first-degree relative with CRC): colonoscopy

*Flexible sigmoidoscopy every 10 years is an acceptable screening test.





gFOBT vs. No Screening



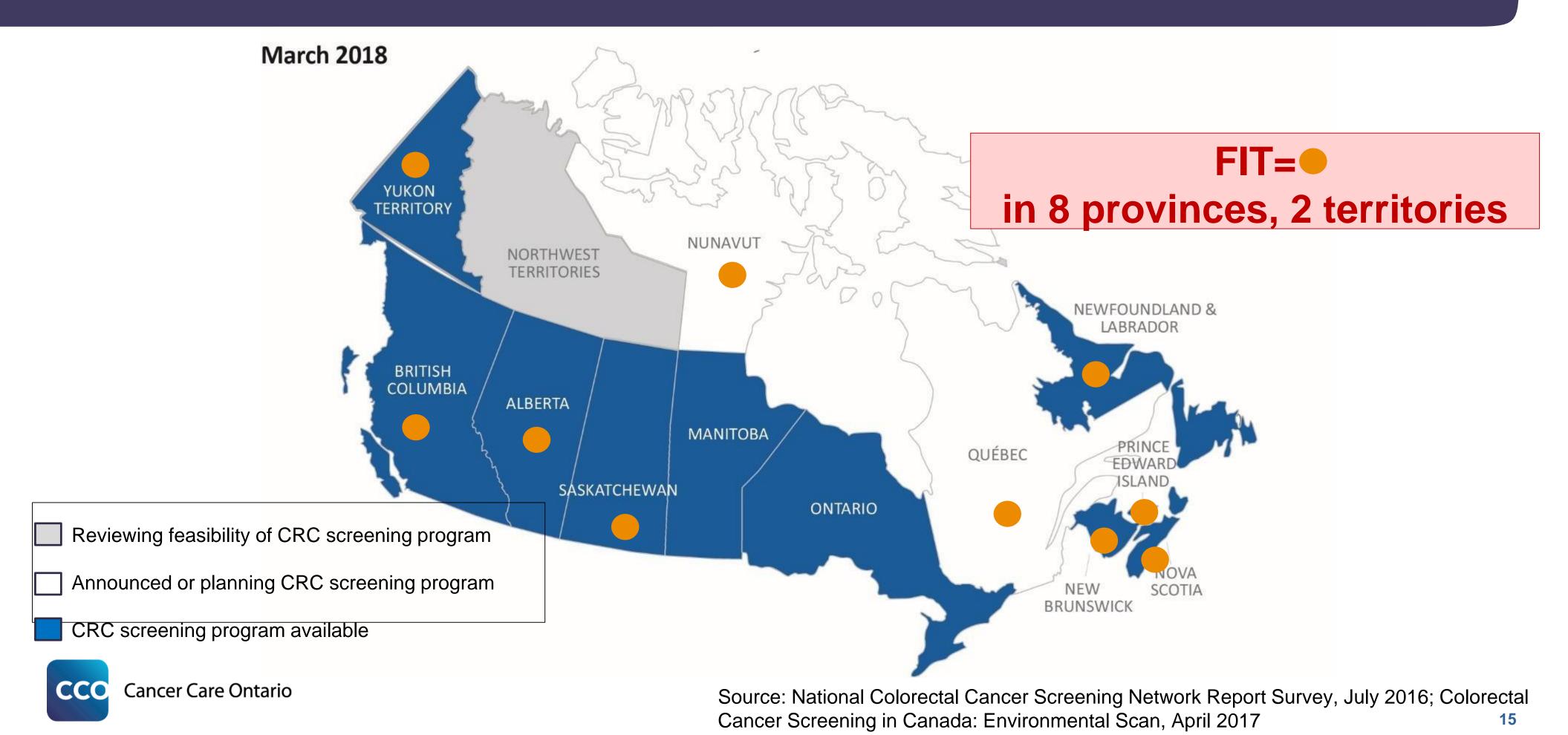
Outcomes	Relative Effect (95% CI*)	# of Person-Years [] (# 13% reduction in
CRC mortality (follow-up range: 17–30 years)	RR* 0.87[1](0.82-0.52)	
CRC incidence (follow-up range: 17–30 years)	RR 0.96[SEP](0.90–1.02)	4,866,448[sep](5 RCTs)

*CI=confidence interval, RR= relative risk, RCT= randomized control trial



Source: 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



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



gFOBT vs. FIT Lab Parameters

	gFOBT	FIT
Measures	Detects much smalle	Globin; human
Test technique	levels of blood in stoo	Immunochemical
Lower limit of blood detection	300–600 µg Hb/g*	10-20 µg Hb/g
Interference	Vitamin C, other sources of Hb	None



No dietary or medicine restrictions

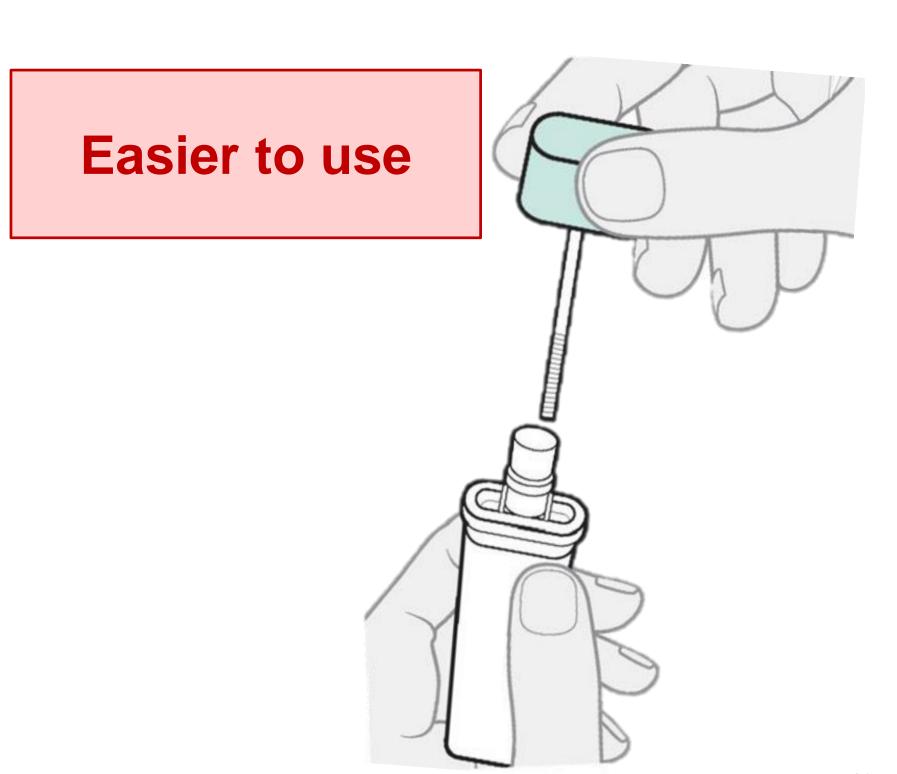
gFOBT vs. FIT Lab Parameters

		gFOBT		FIT
Shelf life		3 years		12 to 18 months
Specimen stability			Less st	able at high temperatures and over time
# of samples requi	• K	Ait inventory management		1
Lab process		it delivery and retu		Automated
Results		Qualitative	Q	Qualitative or quantitative



FIT Usability for Participants

- At-home stool sample screening test
- 1 sample
- Tube designed for easy sampling
- No dietary or medication restrictions





Accuracy for CRC: One-Time Test

	Sensitivity	Specificity
FIT (n=19 studies)	82%	94%
gFOBT (n=9 studies)	47.1%	96.1%



Sources:

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.

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

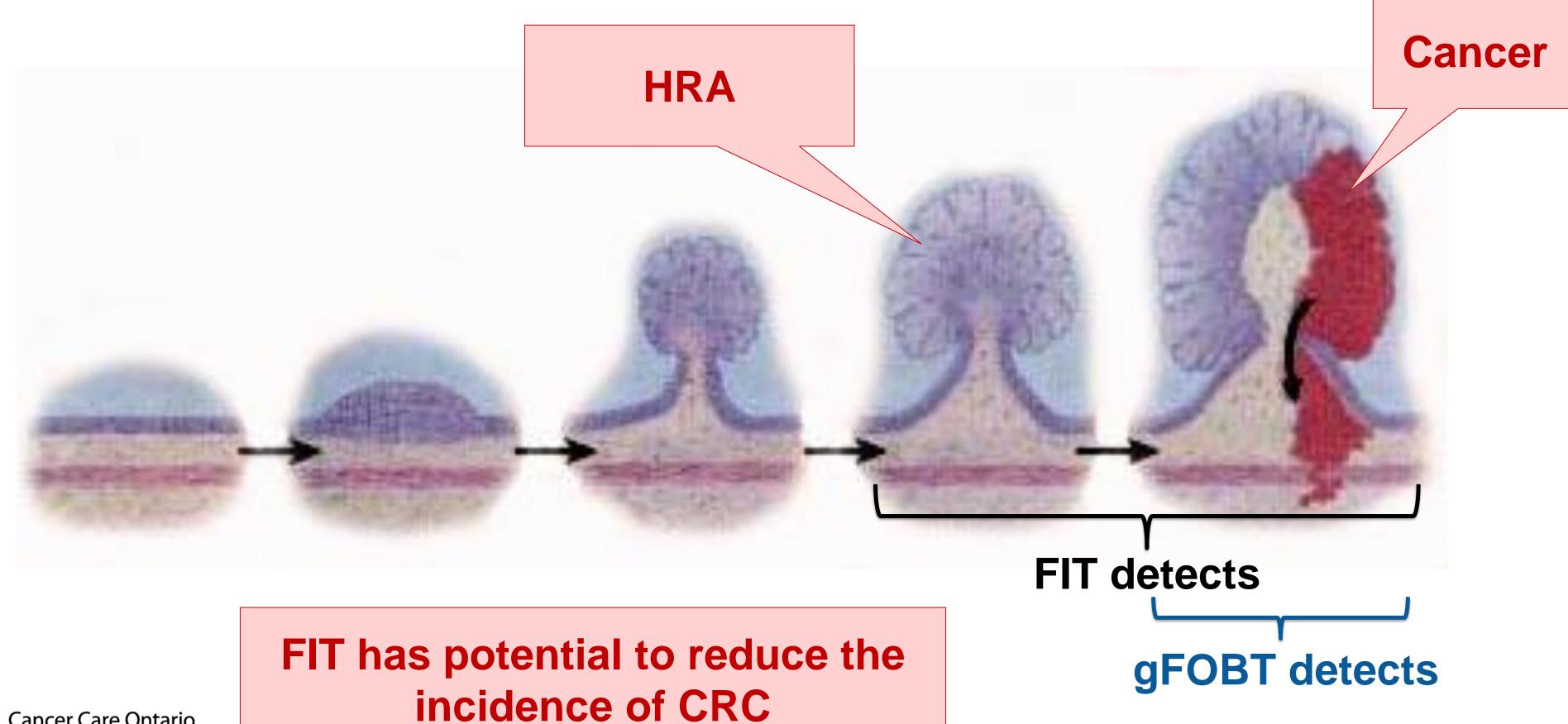
		6% increase in	
Outcomes	Relative Effe (95% CI*)	participation (# of studies)	
Participation rate	RR* 1.16 (1.05–1.28)	52,038[SEP](6 R	CT*s)
CRC and HRA* detection	RR 2.15 (1.58–2.94)	51,634[sep](5 R	CTs)

- 2X more accurate
- Detects CRC and HRA



*HRA= High risk adenoma, CI = confidence interval, RCT= randomized control trial, RR= relative risk Source: 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 21 Evidence-based Care Evidence Summary No.: 15-14.

Adenoma to Cancer



Cost Effectiveness of FIT

OPEN ACCESS Freely available online

PLOS MEDICINE

Colorectal Cancer Screening for Average-Risk North Americans: An Economic Evaluation

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fits and costs of fecal nical testing versus guaiac fecal testing for colorectal cancer

labeneck^{2,3,4}, Marjolein van Ballegooijen¹, Ann G. Zauber⁵, rey S. Hoch^{3,6}, Jean H. E. Yong⁶, Sonja Kroep¹, Jill Tinmouth^{3,7},

, Erasmus University Medical Center, Rotterdam, The Netherlands, rol, Cancer Care Ontario, Toronto, Canada, 3 Institute for Clinical Evaluative Department of Medicine, University of Toronto, Toronto, Canada, and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY, entre for Excellence in Economic Analysis Research, Li Ka Shing Knowledge I, Toronto, Canada, 7 Department of Medicine, Division of Gastroenterology, Centre, Toronto, Canada



- Modelling techniques used to estimate relative benefits and costs of FIT vs other screening approaches/no screening
- Canadian cost data used in both studies

Sources:

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. 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

Key Findings

- biennial screening with FIT is:
 - more effective and less costly than gFOBT
 - o as effective as, and less costly than, colonoscopy; and
 - cost saving compared to no screening

Sources:

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. 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

Strength Evidence **Strong evidence** Fecal tests for occult blood FIT is at least as good as gFOBT for **UCRC-related mortality** Flexible sigmoidoscopy vs. no Strong evidence screening Colonoscopy is at least as sensitive as FS but uncertain risk/benefit ratio Insufficient direct evidence Colonoscopy vs. no screening Early results are promising FIT vs. colonoscopy Strong emerging evidence *3 large-scale RCTs are underway

Quintero et al.: FIT vs. Colonoscopy

Large RCT in Spain

Ages 50-69

Biennial FIT vs. one-time colonoscopy



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Colonoscopy versus Fecal Immunochemical Testing in Colorectal-Cancer Screening

Enrique Quintero, M.D., Ph.D., Antoni Castells, M.D., Ph.D., Luis Bujanda, M.D., Ph.D., Joaquín Cubiella, M.D., Ph.D., Dolores Salas, M.D., Ángel Lanas, M.D., Ph.D., Montserrat Andreu, M.D., Ph.D., Fernando Carballo, M.D., Ph.D., Juan Diego Morillas, M.D., Ph.D., Cristina Hernández, B.Sc., Rodrigo Jover, M.D., Ph.D., Isabel Montalvo, M.D., Ph.D., Juan Arenas, M.D., Ph.D., Eva Laredo, R.N., Vicent Hernández, M.D., Ph.D., Felipe Iglesias, R.N., Estela Cid, R.N., Raquel Zubizarreta, M.D., Teresa Sala, M.D. Marta Ponce, M.D., Mercedes Andrés, M.D., Gloria Teruel, M.D., Antonio Peris, M.D. María-Pilar Roncales, R.N., Mónica Polo-Tomás, M.D., Ph.D., Xavier Bessa, M.D., Ph.D., Olga Ferrer-Armengou, R.N., Jaume Grau, M.D., Anna Serradesanferm, R.N., Akiko Ono, M.D., José Cruzado, M.D., Francisco Pérez-Riquelme, M.D., Inmaculada Alonso-Abreu, M.D., Mariola de la Vega-Prieto, M.D., Juana Maria Reyes-Melian, M.D., Guillermo Cacho, M.D., José Díaz-Tasende, M.D., Alberto Herreros-de-Tejada, M.D., Carmen Poves, M.D., Cecilio Santander, M.D., and Andrés González-Navarro, M.D., for the COLONPREV Study Investigators*

ABSTRACT

BACKGROUND

Colonoscopy and fecal immunochemical testing (FIT) are accepted strategies for colorectal-cancer screening in the average-risk population.

METHOD

In this randomized, controlled trial involving asymptomatic adults 50 to 69 years of age, we compared one-time colonoscopy in 26,703 subjects with FIT every 2 years in 26,599 subjects. The primary outcome was the rate of death from colorectal cancer at 10 years. This interim report describes rates of participation, diagnostic findings, and occurrence of major complications at completion of the baseline screening. Study outcomes were analyzed in both intention-to-screen and as-screened populations.

RESULT

The rate of participation was higher in the FIT group than in the colonoscopy group (34.2% vs. 24.6%, P<0.001). Colorectal cancer was found in 30 subjects (0.1%) in the colonoscopy group and 33 subjects (0.1%) in the FIT group (odds ratio, 0.99; 95% confidence interval [CI], 0.61 to 1.64; P=0.99). Advanced adenomas were detected in 514 subjects (1.9%) in the colonoscopy group and 231 subjects (0.9%) in the FIT group (odds ratio, 2.30; 95% CI, 1.97 to 2.69; P<0.001), and nonadvanced adenomas were detected in 1109 subjects (4.2%) in the colonoscopy group and 119 subjects (0.4%) in the FIT group (odds ratio, 9.80; 95% CI, 8.10 to 11.85; P<0.001).

CONCLUSION

Subjects in the FIT group were more likely to participate in screening than were those in the colonoscopy group. On the baseline screening examination, the numbers of subjects in whom colorectal cancer was detected were similar in the two study groups, but more adenomas were identified in the colonoscopy group. (Funded by Instituto de Salud Carlos III and others; ClinicalTrials.gov number, NCT00906997.)

N ENGL J MED 366;8 NEJM.ORG FEBRUARY 23, 2012

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Castells at the Department of Gastroenterology, Hospital Clínic, Villarroel 170, 08036 Barcelona, Spain, or at castells@clinic.ub.es; or to Dr. Quintero at the Department of Gastroenterology, Hospital Universitario de Canarias, Ctra. Ofra S/N Cuesta, 38320 La Laguna, Tenerife, Spain, or at equinter@gmail.com.

Drs. Quintero and Castells contributed equally to this article.

*The investigators in the COLONPREV study are listed in the Supplementary Appendix, available at NEJM.org.

This article was updated on April 27 2016, at NEJM.org.

N Engl J Med 2012;366:697-706. Copyright © 2012 Massachusetts Medical Society.

Mailed invitation to participate

Primary outcome: CRC death at 10 years

Reflects only first round results

697

The New England Journal of Medicine

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Quintero et al.: Patients Prefer FIT

26,599 invited for FIT



36% responded

23% offered colonoscopy opted for FIT

8,983 completed FIT

Overall FIT participation: 34.2%

26,703 invited for colonoscopy



28% responded

1% offered FIT opted for colonoscopy

4,953 completed colonoscopy

Overall colonoscopy participation: 24.6%

Quintero et al.: Diagnostic Yield – Intention to Screen

Reflects first round results only	Colonoscopy n=26,703	FIT n=26,599	P-value
	30	33	Not significant
HRA	514	231	<0.001
# needed to <u>screen</u> to find 1 CRC	191	281	
# needed to scope to find 1 CRC	191	18	
Complication rate	24	10	<0.001

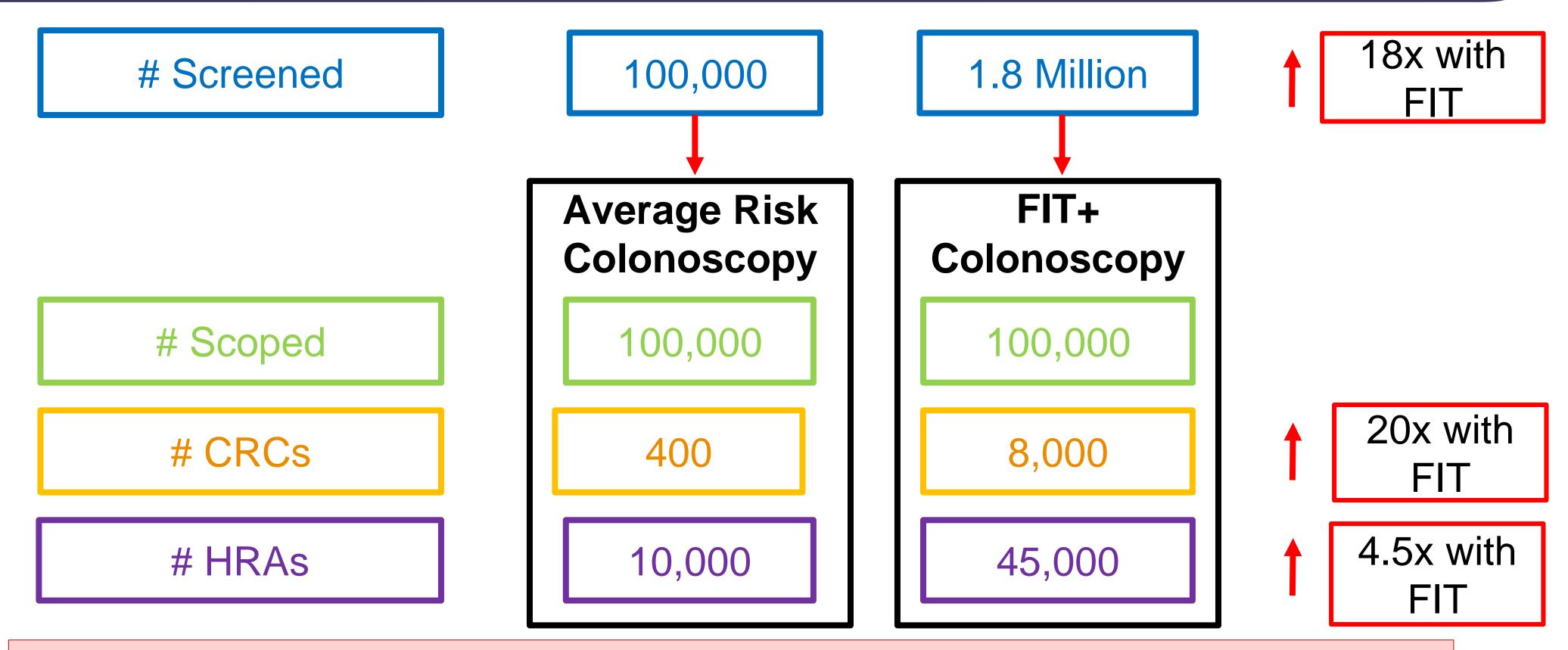


Colonoscopy Associated Complications: Calgary, Alberta

Complication N=18,456 Total # adverse events: 119	Event Rate* *per 1,000 colonoscopies
Bleeding	2.93
Perforation	0.22
Post-polypectomy syndrome	0.16
Cardiac	0.22
Syncope/hypertension	0.27
GI symptoms (minor and transient)	1.95
Splenic/hepatic hematoma	0.11
Other	0.60

Sources: Hilsden R.I. Dube C. Heitman S.I. Bridges R. McGregor S.F. Rostom A. The association of colonoscopy quality indicators with the detection of screen-relevant lesions

Screening with Colonoscopy vs. FIT



FIT: same number of colonoscopies • more people screened • more cancers detected • higher diagnostic yield

FIT vs. Colonoscopy: Summary

- Patients prefer FIT
- FIT is safer than colonoscopy
- FIT is as good as colonoscopy at detecting CRC in average risk people
- FIT-positive colonoscopy is high yield colonoscopy used in people most likely to benefit

The CCC program does not recommend screening for average risk people with colonoscopy

FIT → better risk-benefit ratio of screening



Case Study 1 - Part 1

You are discussing CRC screening with Rahm, a 52 year old man with **no** known family history of CRC. Rahm has heard about colonoscopy examination through a friend on his baseball team, and he has decided he really wants one. Rahm has heard that fecal-based testing can often miss identifying cancers. During your conversation, you are emphasizing the benefit(s) of FIT to him. Please identity the benefit(s) of the FIT.

- a) High sensitivity for CRC
- b) Detects high risk adenomas (HRAs)
- c) Easy take-home screening test (e.g., one stool sample, no dietary medication restrictions)
- d) FIT is non-invasive and safer than colonoscopy
- e) All of the above





Case Study 1 - Part 2

After you explain the benefits of FIT, your patient still feels they may want to have a colonoscopy and asks about potential risks. What are the risks associated with colonoscopy?

- a) Colonoscopy-related perforation
- b) Post-polypectomy bleeding
- c) Risks related to bowel preparation
- d) Risks related to the use of sedation
- e) All of the above





Case Study 2

Danielle, a 66 year old woman with no family history of CRC, mentions that she has been experiencing fatigue, shortness of breath, weakness and low energy for the past two months. She denies any rectal bleeding, melena, or hematemesis. You conduct a focused patient history and thorough physical examination and order routine bloodwork. Danielle's hemoglobin is reported back as 108 g/L (it was measured to be 130 g/L one year previously) and her ferritin level is 5 µg/L (reference range: 11-307 ug/L). Please identify the next appropriate course of action:

- a) Complete a FIT requisition for Danielle
- b) Have Danielle come for an in-office gFOBT
- c) Refer Danielle for specialist evaluation (including colonoscopy)
- d) Prescribe iron supplements and counsel Danielle on dietary sources of iron
- e) c and d



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ColonCancerCheck (CCC) Eligibility Criteria for FIT

Average risk



- Age 50 to 74
- Asymptomatic
- No first-degree relative diagnosed with colorectal cancer
- No personal history of colorectal cancer, Crohn's disease involving colon or ulcerative colitis
- No colorectal polyps needing surveillance
- Valid OHIP number



Eligibility criteria have not changed

Jamieson is a 52 year old patient who comes to your office indicating that he has recently noticed numerous streaks of blood on his toilet paper. You conduct a thorough physical examination, including a digital rectal exam, and note the presence of hemorrhoids but no mass. During your appointment, you note that Jamieson is due for colorectal cancer screening next month. Please identify the appropriate next course of action:

- a) Refer for endoscopic evaluation (may include colonoscopy)
- b) Order a computed tomography colonography
- c) Repeat digital rectal examination in three months
- d) Complete a FIT requisition for Jamieson
- e) Reassure Jamieson and recommend topical therapy for hemorrhoids





Your new patient Kelly is a 50 year old woman who presents to your office for a periodic health visit. Kelly has a history of hemorrhoids that were treated with rubber band ligation 10 years ago. Kelly can still feel skin tags when wiping after a bowel movement but hasn't experienced any bleeding since the banding ten years ago. Taking the above into consideration, how and when should Kelly be screened for CRC?

- a) Kelly should be screened every ten years with a colonoscopy
- b) Kelly should be screened every two years with a colonoscopy
- c) Kelly should be screened every two years with FIT
- d) Kelly should be screened every two years with flexible sigmoidoscopy
- e) None of the above



Jessica suffers from chronic atrial fibrillation and has been on dabigatran for the past year. Upon her 72nd birthday, she receives a correspondence letter from Cancer Care Ontario indicating that it's time for her to complete CRC screening. Jessica has completed a number of gFOBT in the past, with no abnormal findings. Taking the above into consideration, is it appropriate to screen Jessica for CRC with FIT?

- a) Yes
- b) No
- c) Unsure





Ordering FIT: Steps for Providers

How to Order FIT for Patients

Step 1
Confirm
mailing
address for
FIT kit,
patient
address and
date of birth*

Step 2

Explain to patient how to complete FIT

Step 3

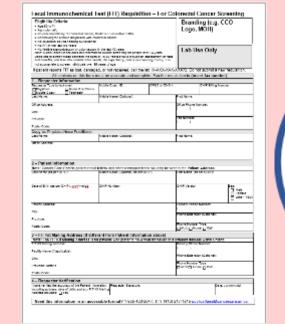
Submit completed FIT requisition to LifeLabs

Step 4

LifeLabs will mail prelabelled FIT kit to patient

*Patients who live on a First Nation reserve can contact their health centre or nursing station







Requisition Changes

MOHLTC lab requisition cannot be used to request CCC program FIT

CCC gFOBT will be removed from MOHLTC lab requisition



Ontario Ministry of Health and Long-Term Care Laboratory Requisition Requisitioning Clinician / Practitioner	Laboratory Use Only	
ddress		
	Clinician/Practitioner's Contact Number for Urgent Resul	Service Date yyyy mrn dd
inician/Practitioner Number CPSO / Registration No.	Health Number Version	Sex Date of Birth yyyy mm dd
heck (/) one:	Province Other Provincial Registration Number	Patient's Telephone Contact Number
OHIP/Insured Third Party / Uninsured WSIB		
dditional Clinical Information (e.g. diagnosis)	Patient's Last Name (as per OHIP Card)	
	Patient's First & Middle Names (as per OHIP Card)	<u> </u>
Copy to: Clinician/Practitioner ast Name First Name	Patient's Address (including Postal Code)	
ote: Separate requisitions are required for cytology, his	tology / pathology and tests performed by Bubi	lie Health (aboratory
Biochemistry		x Viral Hepatitis (check one only)
·	x Hematology CBC	1 / /
Glucose Random Fasting		Acute Hepatitis
HbA1C	Prothrombin Time (INR)	Chronic Hepatitis
Creatinine (eGFR)	Immunology	Immune Status / Previous Exposure Specify: Hepatitis A
Uric Acid	Pregnancy Test (Urine)	Hepatitis B
Sodium	Mononucleosis Screen	☐ Hepatitis C
Potassium	Rubella	or order individual hepatitis tests in the "Other Tests" section below
Chloride	Prenatal: ABO, RhD, Antibody Screen	
CK	(titre and ident. if positive)	Prostate Specific Antigen (PSA)
ALT	Repeat Prenatal Antibodies	☐ Total PSA ☐ Free PSA
Alk. Phosphatase	Microbiology ID & Sensitivities	Specify one below:
Bilirubin	(if warranted)	Insured – Meets OHIP eligibility criteria
Albumin	Cervical	Uninsured – Screening: Patient responsible for paymen
Lipid Assessment (includes Cholesterol, HDL-C, Triglycerides, calculated LDL-C & Chol/HDL-C ratio; individual lipid tests may	Vaginal	Vitamin D (25-Hydroxy)
be ordered in the "Other Tests")	Vaginal / Rectal – Group B Strep	Insured - Meets OHIP eligibility criteria:
Albumin / Creatinine Ratio, Urine	Chlamydia (specify source):	osteopenia; osteoporosis; rickets; renal disease; malabsorption syndromes;
Urinalysis (Chemical)	GC (specify source):	medications affecting vitamin D metabolism
Neonatal Bilirubin:	Sputum	Uninsured - Patient responsible for payment
Child's Age: days hours	Throat	Other Tests - one test per line
Clinician/Practitioner's tel. no.	Wound (specify source):	
Patient's 24 hr telephone no.	Urine	
Therapeutic Drug Monitoring:	Stool Culture	
Name of Drug #1	Stool Ova & Parasites	
Name of Drug #2	Other Swabs / Pus (specify source):	
Time Collected #1 hr. #2 hr.		
Time of Last Dose #1 hr. #2 hr.	Specimen Collection	
Time of Next Dose #1 hr. #2 hr.	Time Date	
hereby certify the tests ordered are not for registered in or	Fecal Occult Blook st /BT) (check one)	
ut patients of a hospital.	2002	FOBT (CCC) no other test can be ordered on this form
	Laboratory Use Only	
linician/Practitioner Signature Date		

4422-84 (2012/11) @ Queen's Printer for Ontario, 2012

New FIT Requisition

- FIT kits can be completed up to 6 months after lab receives FIT requisition
- Supports patients who opt for a different preferred FIT mailing address





Ensure Your Patients Get Their FIT

Confirm that patient address information is up to date:

- Alternate FIT kit delivery
- option

Eligibility Criteria: • Age 50 to 74 • Asymptomatic • No personal history of colorectal cancer, Crohn's or ulcerative colitis • No first degree relative diagnosed with colorectal cancer • No colorectal polyps needing surveillance			Branding Logo, MC	y (e.g. CCO DH)
No FitT in the last two years Note: ColonCancerCheck does not recommend routine screening for people over 74 years. 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. It is not appropriate to screen individuals over 85 years of age.			Lab Use	Only
	85 years of age.			
		he lab (X-XXX-XXX-	XXXX). Do not si	ubmit a new requisition.
not appropriate to screen individuals over if patient reports FIT as lost, dama		•		
not appropriate to screen individuals over if patient reports FIT as lost, dama	iged, or not received, call th	•		
not appropriate to screen Individuals over If patient reports FIT as lost, dama All sections on this form 1 — Requester Information Requester Type (check one): □ Physician □ Nurse Practitions	iged, or not received, call the must be accurate and con	•	isition to (insert	
not appropriate to screen Individuals over If patient reports FIT as lost, dama All sections on this form 1 — Requester Information Requester Type (check one): Physician Nurse Practitions	iged, or not received, call the must be accurate and con	mplete. Fax the requ	isition to (insert t	fax number).
not appropriate to screen Individuals over If patient reports FIT as lost, dama All sections on this form 1 — Requester Information Requester Type (check one): Physician	iged, or not received, call the must be accurate and con	mplete. Fax the requ	isition to (insert	fax number). IP Billing Number:
not appropriate to screen Individuals over If patient reports FIT as lost, dama All sections on this form 1 — Requester Information Requester Type (check one): Physician	iged, or not received, call the must be accurate and con	mplete. Fax the requ	isition to (insert)	fax number). IP Billing Number:

3 – FIT Kit Mailing Address (If different from Patient Inc., mation above)			
☐ Same as patient address above	Note: The FIT Kit Mailing Address is for patients who prefer to have their kit mailed to a different address within Ontario.		
FIT kit Mailing Address (include facility nat City:	ne if applicable):	Primary Phone Number:	
Province: Ontario		Phone Extension (Optional): Phone Number Type:	
Province:		Phone Extension (Optional):	
Postal Code: e Ontario		Phone Number Type: Work Home Cell	

Including Address

Need this information in an accessible format? 1-855-460-2647, TTY (416) 217-1815 publicaffairs@cancercare.on.ca.

Preparing Your Practice for FIT: Requisition

- ✓ Call LifeLabs at 1-833-676-1426 if you do not routinely receive laboratory supplies or test results from them
- ✓ Add the FIT requisition to your usual process for requesting laboratory tests
- ✓ Add the FIT requisition to your library of custom forms
- √ Add LifeLabs kit distribution contact information to your address book
 - Phone: 833-676-1426
 - Fax Requisition: 1-833-676-1427

FIT requisition can be found at: cancercareontario.ca/pcscreeningprograms

The FIT requisition will be made available before FIT launch



Why Centralized Distribution?

Program challenges

Addressing program challenges for FIT

- 11.1% of gFOBTs require re-testing
- Majority of rejected tests due to mislabelling

Pre-labelled FIT kit with patient identifiers

- gFOBT shelf-life: three years
- FIT shelf-life: 12 months

Inventory management at central laboratory

Inappropriate use of gFOBT:

- Repeating gFOBT between recommended screening intervals
- Using the test in people outside the screen-eligible age range

Laboratory verification of patient information during processing of requisition form

Why Centralized Distribution?

Program challenges

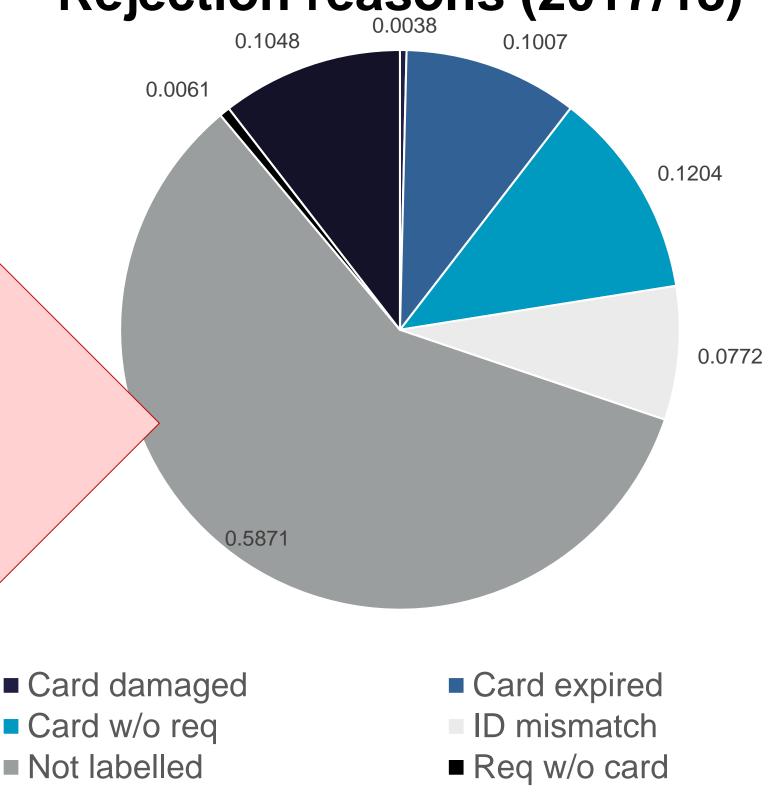
- 11.6% of gFOBTs require re-testing
- Majority of rejected tests due to mislabelling
- gFOBT
- FIT sh€

Centralized distribution eliminates almost 90% of causes for rejected tests

Inappropriate use of gFOBT:

- Repeating gFOBT between recommended screening intervals
- Using the test in people outside the screen-eligible age range

Rejection reasons (2017/18)



Ordering FIT for Unattached Patients

 Unattached patients can contact Telehealth Ontario or a mobile coach (where available) to request a FIT kit





Screening with the Fecal Immunochemical Test FIT on Mobile Screening Coaches: North West

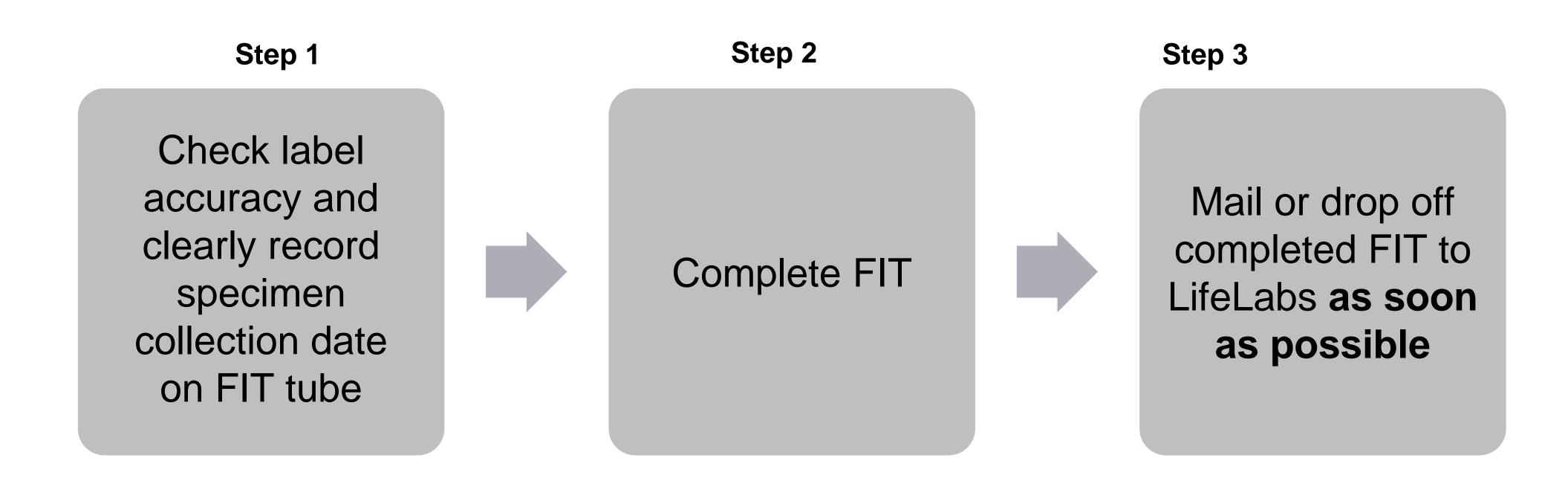
- Participants can request a FIT kit from a mobile screening coach
- The mobile screening coaches will not have gFOBT or FIT kit inventory patients will receive their FIT kit from the lab in the mail
- Check the mobile screening coaches schedule: http://tbrhsc.net/programs-services/regional-cancer-care/information-for-patients-and-families/cancer-screening/screen-for-life/travel-schedule/





Completing FIT: Steps for Patients

Completing FIT: 3 Steps for Patients





Supporting Patients





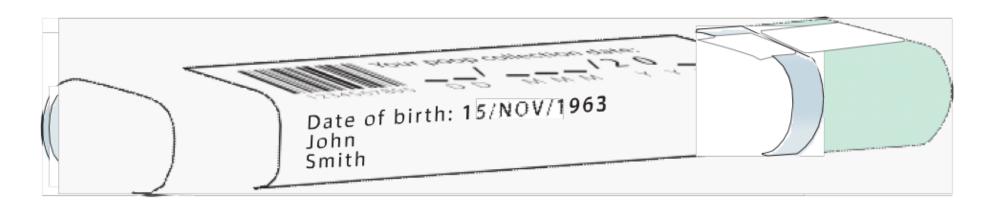
Supporting Patients

- Patient-friendly FIT materials being developed, including FIT instructions with more visuals than words
- FIT instructions will be available in 20+ languages and in accessible format online: cancercareontario.ca/FITinstructions

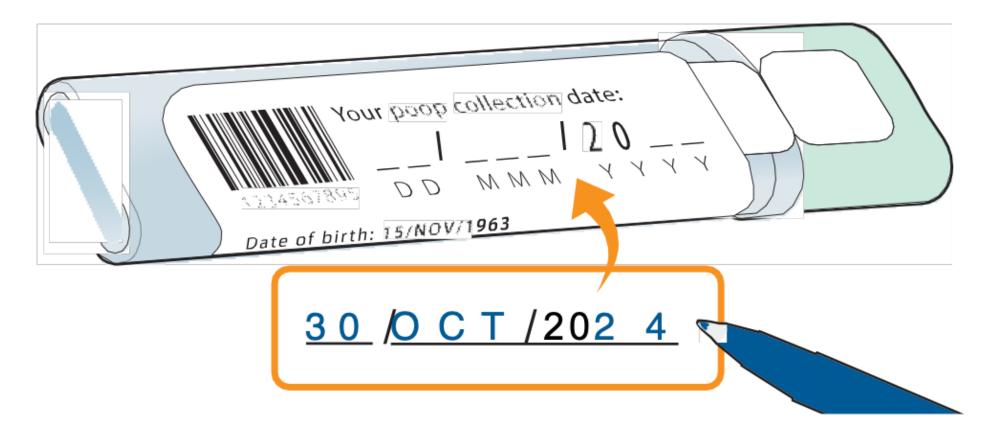




Supporting Patients- Lab Label









FIT Return

Completed FIT kit should be returned as soon as possible to LifeLabs ideally within 2 days of collecting the specimen



- Mail
 - Regular mail
 - Expedited mail included for some areas
- Drop off at LifeLabs Patient Service Centres

Results received 15-30 days after collection that are below the positivity threshold will be reported as "invalid"

 If your patient lives on a First Nations reserve, contact the health centre or nursing station for return options



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

Results

LifeLabs will send FIT result to PCP

Cancer Care Ontario will send FIT result letter to patient

Invalid result or rejected device

Normal result

Abnormal result

Repeat FIT in the next few weeks – new requisition required

Repeat FIT in 2 years*

PCP is responsible for arranging follow-up colonoscopy to be performed within 8 weeks



Do NOT repeat FIT- test will be rejected

The Patient Perspective

An abnormal FIT result can be stressful for your patient and their family

- At the time of ordering FIT, explain that an abnormal FIT:
 - Is NOT a cancer diagnosis
 - Needs timely follow-up with colonoscopy within eight weeks
 - Can identify a polyp before it becomes cancerous
- For patient materials explaining an abnormal FIT result, visit: cancercareontario.ca/FITresult



Anna is a 64 year old woman who has recently completed a FIT. When her FIT result comes back as abnormal, Anna calls you and mentions that she completed her FIT just one day after having a tooth removed by her dentist. Anna would like to repeat the FIT. What should you do and why?

- a) Complete another FIT requisition for Anna
- b) Refer Anna for flexible sigmoidoscopy
- c) Have Anna come for an in-office gFOBT
- d) Counsel Anna on the importance of a follow-up colonoscopy and refer her
- promptly for colonoscopy
- e) None of the above



Receiving and Interpreting Lab Reports

- Lab reports for providers will include the FIT result and recommended next steps, including follow-up
- FIT results will be reported as normal, abnormal, invalid or rejected

Sample draft lab reports: Normal and abnormal FIT results			
Test	Result	Canned comments	
FIT	Normal	Action required for you: Re-screen your patient with FIT in 2 years if they continue to meet the ColonCancerCheck eligibility criteria for average risk colorectal cancer screening.	
	Abnormal	Action required for you: REFER TO COLONOSCOPY as soon as possible. The colonoscopy should be completed within 8 weeks of the abnormal FIT result.	

Receiving and Interpreting Lab Reports

• Lab reports for *invalid* results or *rejected* devices will include the reason for the invalid result and rejected device

Sample lab reports: Invalid FIT result and Rejected FIT Collection Device			
Test	Result	Canned comments	
FIT	Invalid	Comment: The specimen collection date was not recorded on the FIT collection device or was illegible. Action required for you: Complete a new FIT requisition for your patient. Action required for your patient: Please advise your patient to complete a new FIT and remind them to clearly record the date they collect their stool on the FIT collection device.	
	FIT collection device rejected	Comment: No stool was in the FIT collection device for testing. Action required for you: Complete a new FIT requisition for your patient. Action required for your patient: Please advise your patient to complete a new FIT and remind them to use the stick to collect their stool, put it in the FIT tube and close the cap tightly.	

Receiving and Interpreting Lab Reports

 If the FIT requisition was rejected or if there was a problem with FIT kit mailing, the lab report will clearly identify the issue under the *result* column of the lab report

Sample lab report: Requisition rejected			
Test	Result	Canned comments	
FIT	Requisition rejected	Comment: Your patient is not eligible for screening with FIT because our records indicate that they had a normal or abnormal FIT result in the last 2 years. Action required for you: Please contact your patient to let them know they will not receive a FIT kit. If your patient had an abnormal FIT and has not yet had a follow-up colonoscopy, please refer them as soon as possible. The colonoscopy should be completed within 8 weeks of the abnormal FIT result.	



Discontinuation of CCC gFOBT in Ontario

- Do not delay! Continue to screen your patients with gFOBT until FIT is available through the CCC program
- Laboratories will continue to test gFOBT kits 6 months after FIT is introduced

Prior to FIT Launch

Order less gFOBT inventory for office

FIT Launch

- Remove remaining gFOBT inventory from office
- Do not distribute gFOBT

>1 Month

 FIT data available in screening activity report (SAR)

>6 Months

 Patients who complete gFOBT no longer considered up-to-date for CRC screening

Key FIT launch milestones



Disposing of CCC gFOBT Kits in Ontario

- Once FIT is available in Ontario, 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.





Understand the Burden of Colorectal Cancer (CRC) in Ontario



Order the Fecal Immunochemical Test (FIT) and Counsel your Patients

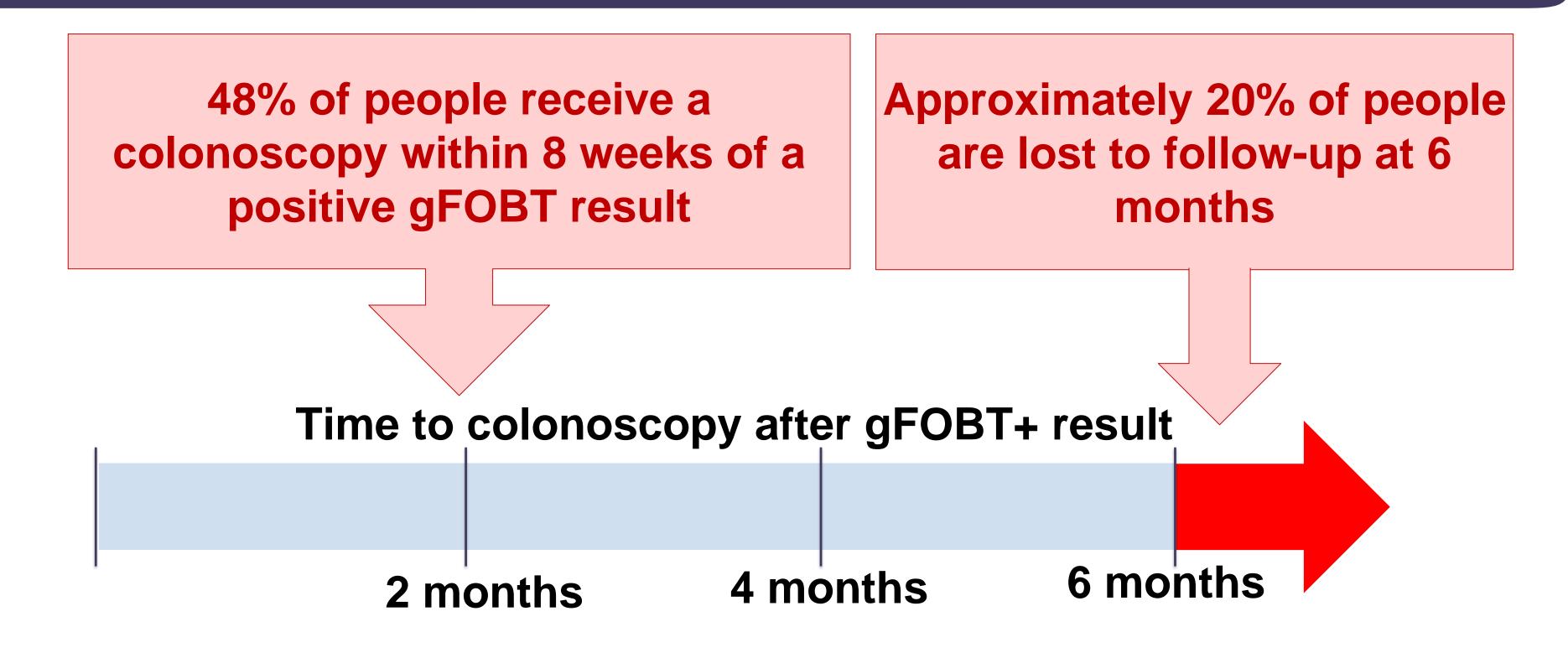


Compare CRC Screening
Tests for Average Risk
Patients



Select Appropriate Follow-Up: Screening Interval and Surveillance

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





Benchmark: follow-up within 8 weeks

Ensure Timely Follow-Up

- Colonoscopy should be completed within 8 weeks of an abnormal fecal immunochemical test (FIT) result
- Abnormal FIT results are associated with a higher chance of colorectal cancer (CRC)
- Diagnostic delays can lead to disease progression
- Timely follow-up is critical to minimize patient anxiety



Importance of Timely Follow-Up

Time to colonoscopy after FIT+	% cases receiving colonoscopy after FIT+		
	Any CRC	Advanced-stage CRC	
8-30 days	2.97%	0.81%	
2 months	2.78%	0.70%	
3 months	3.06%	0.69%	
4–6 months	3.14%	0.88%	
7–12 months	4.56%	1.49%	
>12 months	7.55%	3.13%	

Impact of diagnostic delay is seen within months

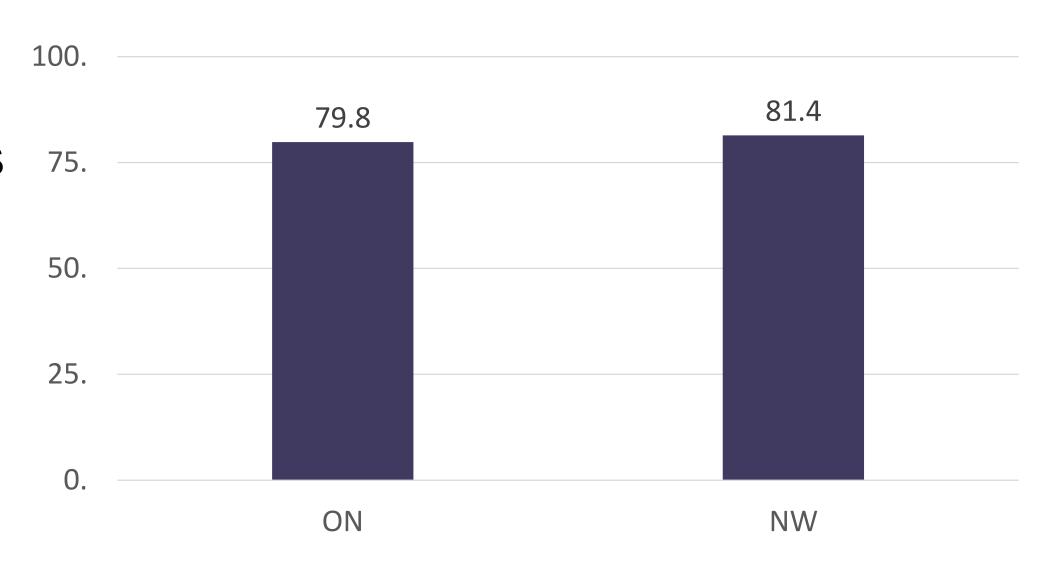
- significantly higher risk of CRC outcomes after 6 months



Follow-up of gFOBT is currently a problem

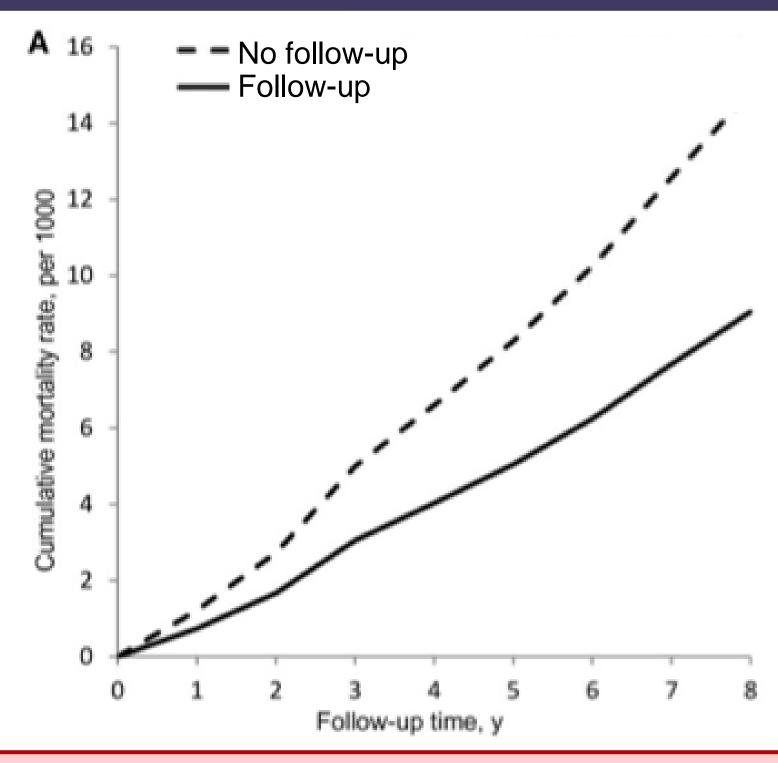
- People are being lost to follow-up
- In 2016, 79.8% of Ontarians who had an abnormal gFOBT result had a colonoscopy within 6 months, which is similar to the 6-month follow-up in 2015 (78.3%)

Percentage of screen-eligible Ontarians with an abnormal fecal occult blood test, ages 50–74 who underwent colonoscopy within 6 months of the abnormal screen date, by LHIN, 2016





Importance of Follow-Up



Patients with an abnormal FIT who do not undergo colonoscopy are more likely to die from CRC (1.63 fold increase)



You receive a lab report indicating that your 54 year old patient, Katya, has an abnormal FIT result. Following this report, what would the appropriate test and timing be for Katya's follow-up?

- a) Follow-up colonoscopy within eight weeks
- b) Follow-up with colonoscopy or computed tomography colonography within eight weeks
- c) Follow-up with colonoscopy within 12 weeks
- d) Follow-up with colonoscopy within six months
- e) None of the above





Strategies to Reduce Lost to Follow-Up Rates

Proactively follow-up with your patients:

- Preemptively counsel your patient on what to expect before, during and after the procedure
 - Explain that an abnormal result is not a cancer diagnosis
- Set electronic medical record reminders and alerts for FIT results
- Review your Screening Activity Report (SAR) monthly report (for help accessing and using your SAR, visit cancercareontario.on.ca/SAR)
- Verify that patient has been scheduled for a FIT-positive colonoscopy appointment within eight weeks
- Find out where FIT-positive colonoscopies are performed in your region and save central FIT colonoscopy referral fax number

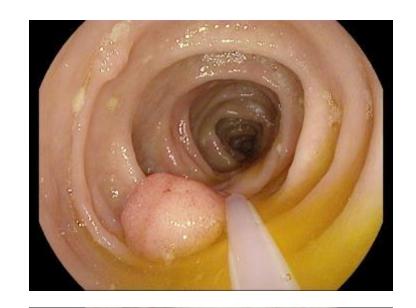


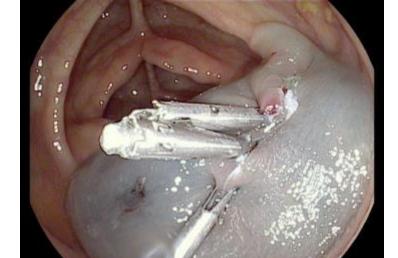
Carefully Consider Where Follow-Up Occurs

- FIT+ colonoscopies are more complex require more expertise, time and resources
- Patients with an abnormal FIT result should be referred to a facility that offers FIT+ colonoscopy
 - Ask your Regional Cancer Program who to contact for FIT+ colonoscopy











FIT+ Guidance

- Designed to ensure safe, complete and timely FIT procedures
- Provides guidance for facilities and endoscopists
- Informed by best practices from other jurisdictions and experts in GI endoscopy
- FIT+ Guidance includes:
 - Booking management: Access to FIT+ colonoscopy should be provided within eight weeks, adequate time and expertise should be available for procedures
 - Endoscopist expertise: Should be comfortable in removing most polyps (e.g., threshold up to 2 cm polyps)
 - Facilities: Should provide access to all the necessary tools and equipment, access to appropriate referral channels for complex cases

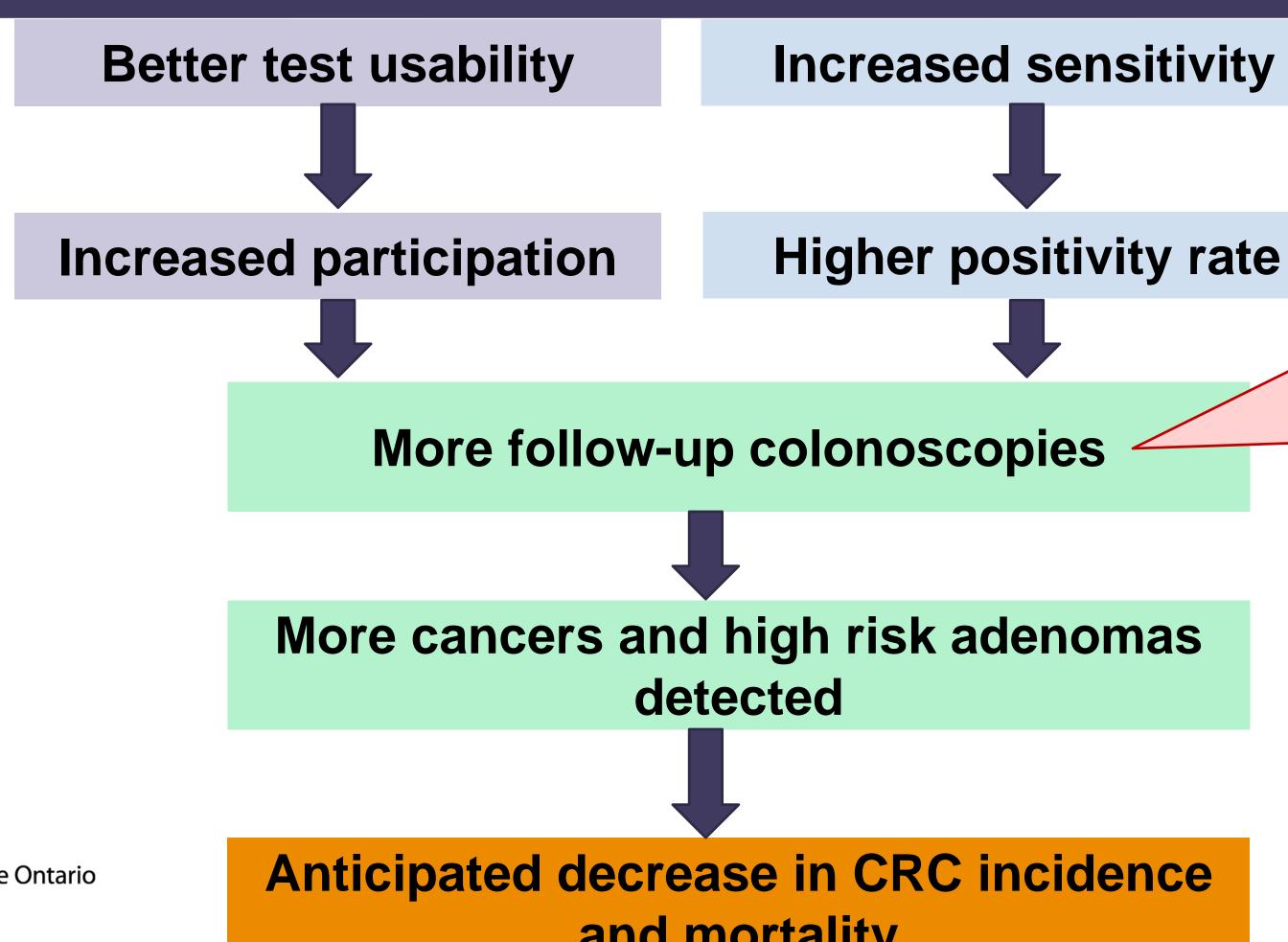


Referral for Colonoscopy

Endoscopy Services COLONOSCOPY REFERRAL Centre Suidelines: 1. Physician to complete referral. 2. Fax to Disgnostic Assessment Program at 807-684-5810. Patient will be 3. Completed referral forms will be filed on the patient's health record				Place Patient Label with Barcode Here professional to organize the Colonoscopy booking.	
	FOR COLONOSCOPY				
Screening	PF - Patient (50-74yrs) referred after a positive Fecal Occult Blood Test Date:		FD – Patient (74yrs old or younger) referred first-degree relative had colorectal cancer Specify relative:		
Symptomatic	SA- Patient is symptomatic (other than Fecal Occult Blood	Patient is symptomatic or has had an abnormal lab nan Fecal Occult Blood Test)		Persistent Change in Bowel Habits Anemia New Onset Abdominal Pain Other	
Surveillance	CN- Surveillance for Colore	CN- Surveillance for Colorectal Neoplasm or Disease		☐ Please attach most recent colonoscopy report and pathology report (if applicable). Comments:	
* Urgent F	Referrals (palpable rectal mass	or abdominal imaging suspic	ious for colorectal can-	cer) should go directly to a colonoscopist *	
COLONOSC	OPY REQUESTED				
	ilable Screening Appointment Dr. P. Zezos FORMATION	☐ Dr. S. Cassie ☐ Dr. E.	Davenport 🔲 Dr. K. (Gehman Dr. W. Harris Dr. H. Telang Mapeso Dr. M. Cooper Dr. K. Raman	
			Date of Birth (day/n	nonth/year)	
Last Name, First Name:			Version Code:		
Address	remaie 🗆 Male	Postal Code:	Telephone:	Home	
Primary	Contact (Last Name, First N		_ WOIK		
Relationship t				Number:	
☐ Patient in	capable of giving his/her own accompanied by an interpret	Informed Consent			
	EDICAL HISTORY	er at the time of appointment	ii triey do not read/sp	eak English.	
Is patient on anticoagulants, ASA, NSAIDS or natural blood thinners? No Yes If yes, list: Allergies: No known drug allergies Latex Penicillin Other:		Cardiac Disorders Ischemic Heart Disea Hypertension Valvular Heart Diseas Pacemaker/Internal D Respiratory Disorders Asthma Chronic Obstructive P Kidney Disease Renal Insufficiency	e efibrillator	Gynecological Surgery History of Gastrointestinal Bleeding History Colorectal Cancer Coagulation Disorders Hemophilia Diabetes Communicable Diseases HIV Hepatitis C Tuberculosis	
Abdominal Surgery Acute medical condition requiring hospitalization in past year: List current medications		supplements and ot	her relevant history:		
(ie MRSA, V					
	INFORMATION				
After discuss	sion with you, the patient is	willing to go for direct referra	al colonoscopy. Date	9:	
Name: Phone:	Fax:	s	ignature:		
ENDOSCOP	Y USE ONLY Date Receive	ed:			



Impact of FIT



FIT leads to better use of follow-up colonoscopy



and mortality



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

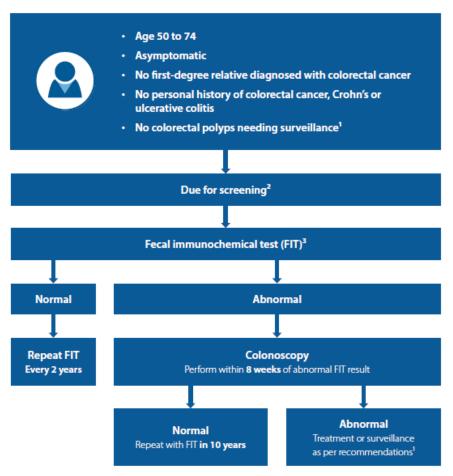
Tools that Support Colorectal Cancer (CRC) Screening: ColonCancerCheck Screening Recommendation Summary



ColonCancerCheck (CCC)

Average Risk Screening with FIT—in Ontario as of [date TBC]

Average risk



- Recommendations for post-polypectomy surveillance: <u>cancercare.on.ca/cccquidelines</u>
 No flexible sigmoidoscopy or colonoscopy (without polyps) in past 10 years, and no FIT in past 2 years
- 3. Flexible sigmoidoscopy every 10 years is an acceptable screening test

Not at average risk

Is your patient at increased risk?

- · One or more first-degree relatives with colorectal cancer
- · Colonoscopy—start at age 50, or 10 years earlier than the age their relative was diagnosed, whichever occurs first
- Take a complete history of cancers in the family—if hereditary cancer syndrome is suspected, refer for genetic assessment

Is your patient symptomatic?

- · Important symptoms include iron deficiency anemia and rectal bleeding, among others:
- Refer to specialist for evaluation
- · Do not use FIT for symptomatic patients
- · See [URL] for more information, including screening intervals

Tests not recommended for colorectal cancer screening

For patients at average risk:

Colonoscopy

For all patients:

- · Metabolomic (blood or urine) tests
- · DNA (blood or stool) tests
- · Computed tomography colonography
- Capsule colonoscopy
- Double contrast barium enema
- Guaiac fecal occult blood test (now replaced by FIT)

More clinical information and resources

Visit: cancercareontario.ca/en/pcscreeningprograms

Email: screenforlife@cancercare.on.ca

Call: 1-866-662-9233



About FIT

FIT is an at-home stool-based screening test for people at average risk of colorectal cancer

• Safe • Sensitive • No dietary or medication restrictions • One sample • Easy to use • Pre-labelled

How to screen with FIT



- 3 steps for primary care providers:
- 1. Confirm mailing address for FIT kit, patient address
- 2. Explain to patient how to complete FIT
- 3. Submit completed FIT requisition to central lab (fax x-xxx-xxxx-xxxx)



Lab: Mail pre-labelled FIT kit to patient

3 steps for patients:

- 1. Check label accuracy and clearly record specimen collection date
- 3. Mail or drop off completed FIT to the lab as soon as possible, ideally within 2 days, to ensure it arrives at the lab within 14 days of specimen collection



Lab: Send FIT result to primary care provider

Cancer Care Ontario: Mail FIT result letter to patient



- Follow-up by primary care providers:
- Normal FIT result: Repeat FIT in 2 years
- Abnormal FIT result: Refer for follow-up colonoscopy to be perform

*Make sure patients get their FIT

- To prevent mailing errors and delays, double check patient address information, such as unit number and postal code
- Providers can use the FIT requisition to indicate that the FIT kit should be mailed to an alternate address, which may differ from the patient's primary mailing address (e.g., health centre or nursing station for patients who live on a First Nation reserve; community health centre for home insecure patients).

Placeholder for FIT drop-off messaging

- Des esto endions ectent eiciis eos ulloribusam ra debis delent est dero dolores ciduntia solorae provide nisimossit optione mporeperunt
- · Quibusapit labori toribus apiditas deliquia voluptiant.

FIT resources

- · Designated FIT lab, including optional FIT drop-off locations and hours: [add phone & URL]
- FIT requisition: [add URL]
- OHIP billing for FIT: [add URL]
- FIT specimen collection instructions for patients: [add URL]
- More information and resources: <u>cancercare.on.ca/FITHub</u>

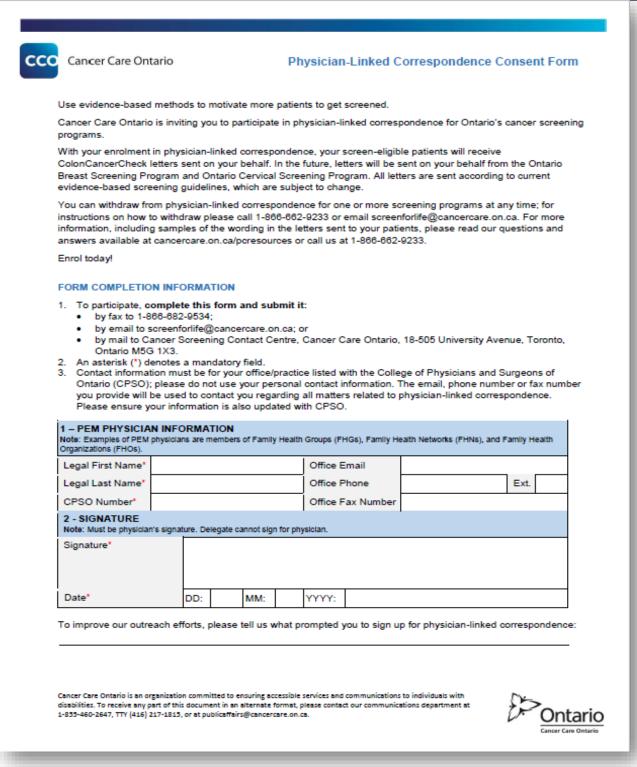
Need this information in an accessible format? 1-855-460-2647, TTY 416-217-1815, publicaffairs@cancercare.on.ca



Copies can be found at: cancercareontario.ca/pcresources

Tools that Support CRC Screening: Physician Linked Correspondence

- Sign up for physician-linked correspondence to improve screening participation!
 - 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.



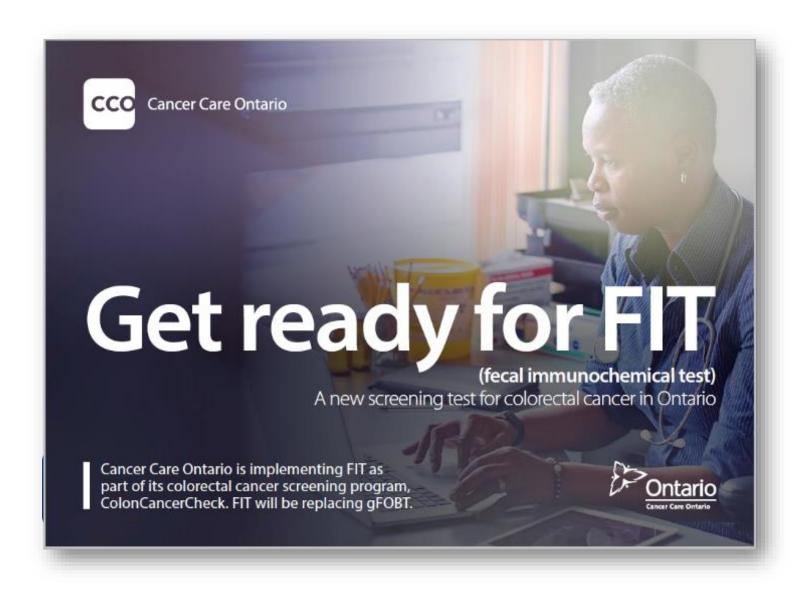
Sign up here! cancercareontario.ca/en/physician-linked-correspondence

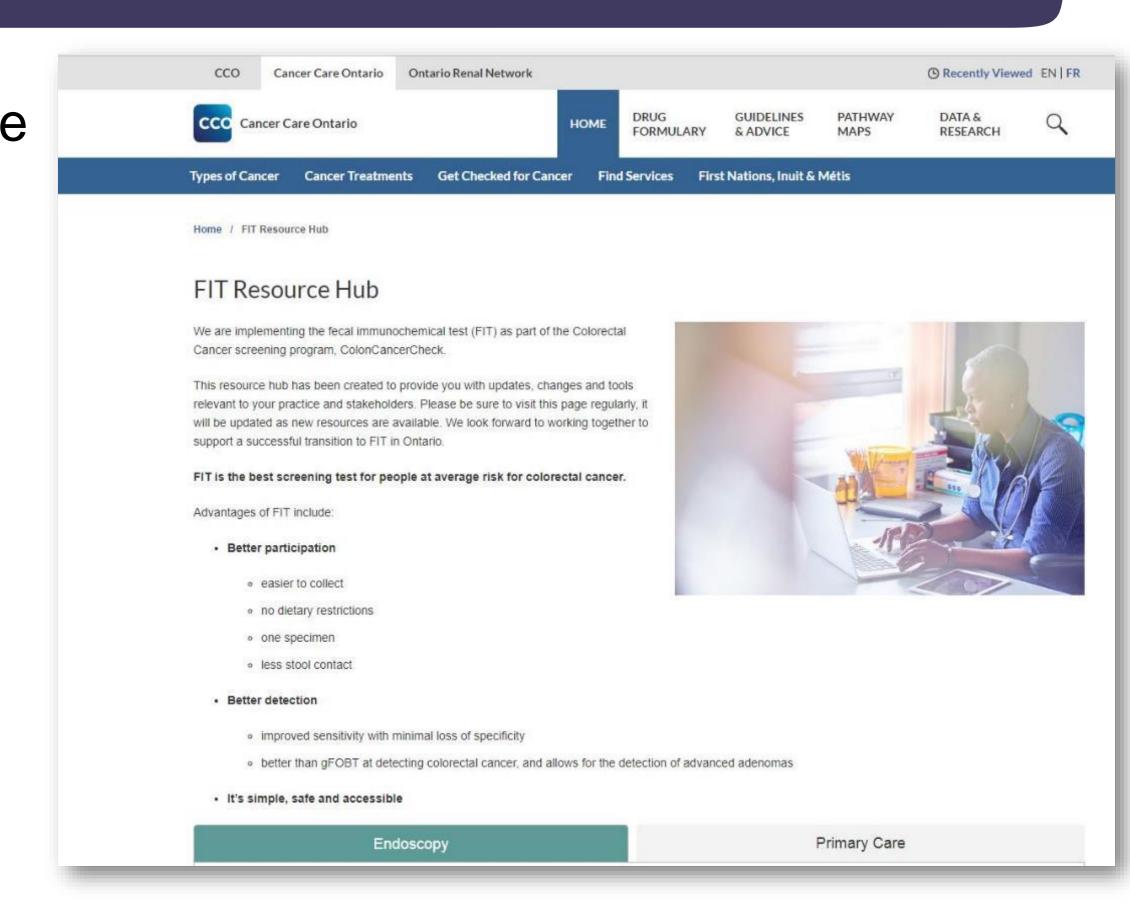


Source: Tinmouth J, Baxter NN, Paszat L, Sutradhar R, Rabeneck L, Yun L. Using physicianlinked mailed invitations in an organised colorectal cancer screening programme: effectiveness and factors associated with response. BMJ. 2014 Mar 12;4(3):e004494. doi: 10.1136/bmjopen- 79 2013-004494

Tools that Support CRC Screening: FIT Resource Hub

- Information and tools to help prepare for the fecal immunochemical test (FIT): cancercareontario.ca/FIThub
- Frequently asked questions are available on the FIT hub

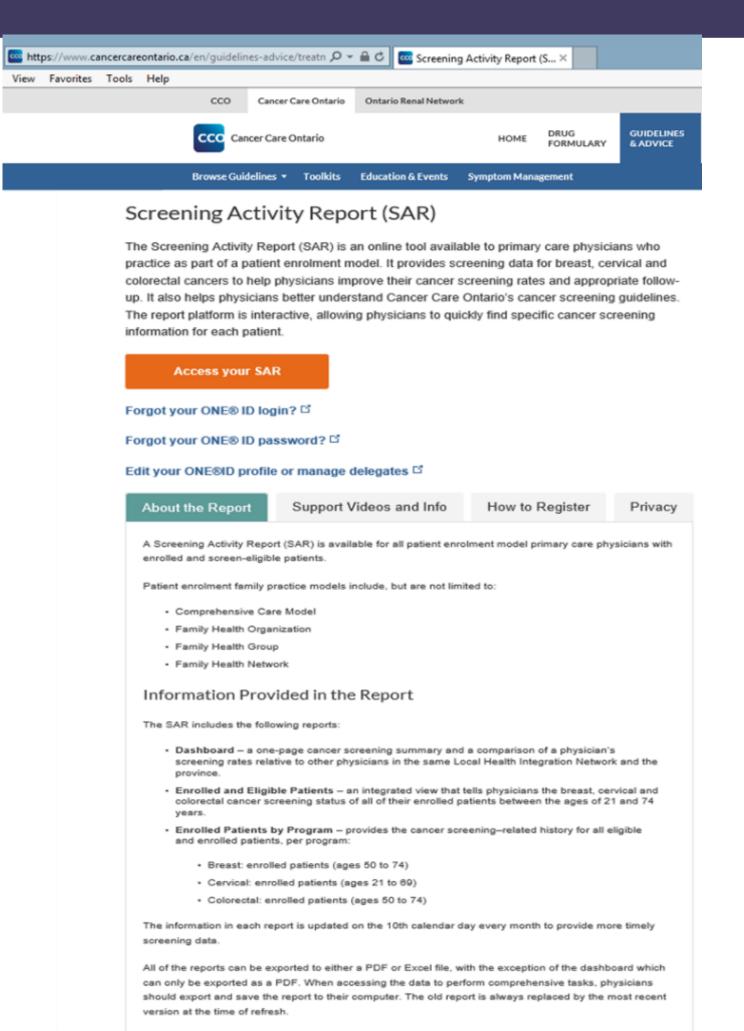




Tools that Support CRC Screening: Screening Activity Report (SAR)

 Sign up for Cancer Care Ontario's SAR to identify screen-eligible patients and to monitor FIT results that may require follow-up: cancercareontario.ca/SAR





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

After an abnormal FIT result, what is the recommended follow-up intervention and timing?

- a) Follow-up colonoscopy within 12 weeks
- b) Follow-up colonoscopy within eight weeks
- c) Follow up flexible sigmoidoscopy within eight weeks
- d) Repeat FIT or gFOBT within four weeks
- e) b or c





With the shift from the gFOBT to the FIT, the recommended screening interval for people at average risk of developing CRC will be:

- a) Screen every two years between ages 50 74
- b) Screen every year beginning at age 50
- c) Screen every year beginning at age 40
- d) Screen every year beginning at age 40; and every two years after age 50
- e) Screen every year between ages 50 74





Which of the following is/are appropriate indications for FIT?

- a) Confirmation of rectal blood loss
- b) Anemia
- c) CRC screening
- d) Abdominal pain
- e) a and c





Your patient Jenny is a 60 year old woman who completed CRC screening with flexible sigmoidoscopy two months ago. At a recent book club meeting, Jenny's friend mentions to her that she has recently completed a FIT. Jenny calls your office to find out if she is eligible to complete a FIT. How should you respond to Jenny?





Flexible Sigmoidoscopy (FS)

FS vs. No Screening

- Strong evidence to support the use of FS to screen those at average risk for CRC
 - 28% reduction in CRC-mortality
 - o 22% reduction in CRC-incidence



How Patients Get Their FIT Across Canada



- Five programs mail FIT kits directly to patients
 - Initiative is led by organized colorectal cancer screening programs
 - No PCP referral required

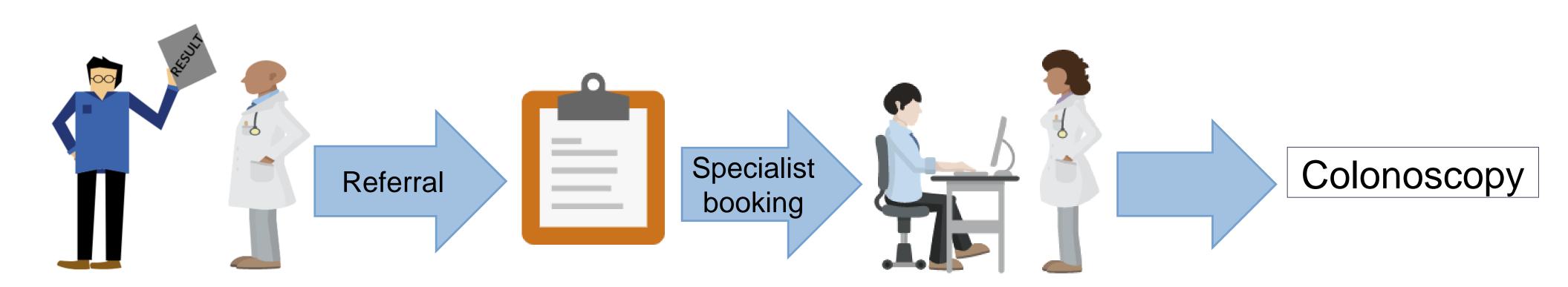


- Four programs use PCP referral:
 - Pick-up location can be a PCP office or a secondary location (e.g., lab, community health centre)
 - Some of these programs offer the option of patient selfreferral, in which case patients must pick-up their kit

Unique features of programs across Canada include: sending pre-notification letters to participants; sending risk assessment questionnaires prior to kit mailing; and some programs offer self-referral via online forms, telephone, fax or email

How Patients Follow Up after an Abnormal FIT Across Canada

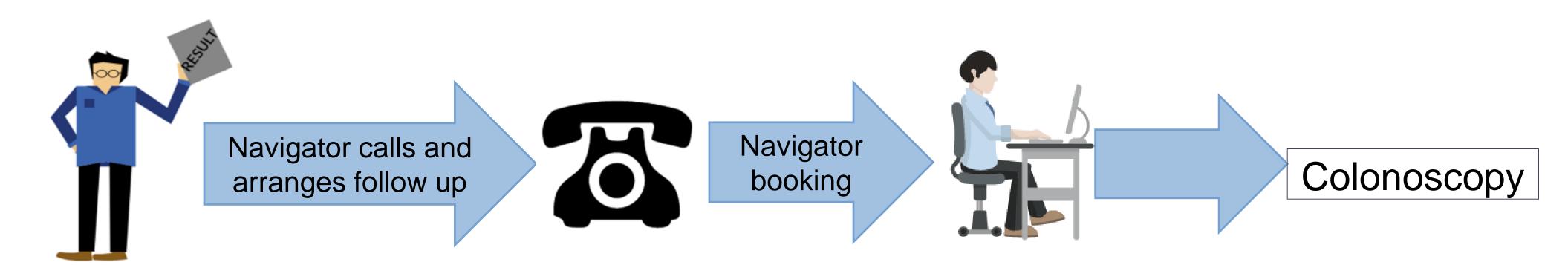
Four programs require a primary care provider to refer patients for follow-up colonoscopy





How Patients Follow Up After an Abnormal FIT Across Canada

Five programs offer centralized navigation services to assist with follow-up colonoscopy





Supporting Patients

- Patients will continue to receive CCC program correspondence
 - Invitations/recalls
 - Reminders
 - Results
- Physician-linked correspondence helps increase screening rates
- cancercareontario.ca/en/physician-linked-correspondence



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

- Physician-Linked Correspondence (PLC) Pilot (2009, 2012)
 - PLC helps increase screening rates vs no mailed invite, and vs non-PLC invites
- Focus testing & consultation with health behaviorists (2013)
 - Informed revisions to CCC correspondence messaging and approach
- Male-specific correspondence RCT (2014)
 - Male-specific invitation: 21% greater odds of screening with gFOBT among men, compared to standard letter
 - Among men & women, receiving any letter significantly increased screening uptake

