

Quality of the screening process

An overlooked critical factor and an essential component of shared decision making about screening

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Mrs Murphy was anxious about cancer, but also about having a colonoscopy, in particular about any potential complications. She had asked her gastroenterologist whether he had ever had any serious complications with the procedure, and he had assured her that he had not. She told my (J.A.D.) colleague about this reassurance from the gastroenterologist. He was aware that only a short time before, a patient had been admitted with a perforation following a colonoscopy done by that same gastroenterologist. Was the gastroenterologist lying? Or maybe he did not know, as the patient with the perforation was admitted to a surgical service. Many doctors do not know the outcomes of the work they do, at times simply because these outcomes are not measured.

This event highlights that screening is a probability game—balancing the probability of a person gaining from the test against any harms or costs he or she might sustain to obtain those benefits. Suboptimal performance, leading to lower potential benefits or higher potential harms, can tilt the balance to ineffective or even detrimental screening. This article describes performance quality for common screening tests to help family physicians understand the issues they need to consider to ensure that patients get the benefits while reducing the harms of screening. We will discuss blood pressure measurements, laboratory testing for diabetes and lipid levels, and cancer screening.

The vast majority of people will not get the diseases that they are screened for, while only a proportion of those destined to get the disease will be helped by reducing their probability of getting the disease (eg,

cervical and colorectal cancer screening, stroke during treatment of hypertension) or finding the disease early enough to reduce serious outcomes arising from the disease (eg, diabetes screening, mammography). Therefore, benefits from screening are rare.

Those benefits usually occur at a time considerably in the future—at least a few years, but sometimes more. For example, the mortality benefit of treating hypertension for those with systolic blood pressure between 140 and 159 mm Hg is estimated as 0.86 per 1000 after 4.5 years; for preventing major cardiovascular events (myocardial infarction, stroke) it might be 11 per 1000.¹ However, harms are more common and often immediate.² **Figure 1** depicts the balance between the large benefits for a few

Figure 1. Effects of a screening test: Balance of large benefits for a few compared with smaller harms for many.



Key points

- There is usually a delicate balance between the benefits and harms of screening tests. Even a small decrease in benefits or a small increase in frequency of harms tips the balance against the value of screening processes previously proven to be efficacious.
- Many harms occur during screening and the follow-up process. To reduce these, family physicians should ensure the quality of their own screening and advocate for transparent information from specialists and laboratories that they refer to.
- Quality monitoring occurs currently in most Canadian certified clinical laboratories but is limited in other components of the health care system.
- Because there is vast variation in the quality of care provided in usual practice, family physicians should prefer screening services that use quality assessment and improvement processes.

and the small harms to many that occur after screening and subsequent management. Assessment of that balance of possible benefits and harms will differ for every person, depending on the weight assigned to these outcomes by the person making the choice. To keep the probability of benefits higher than the possibilities of harms consequent upon the screening decision, those harms must be minimized and benefits maximized. Although the most frequent harms will be graded by many as minor compared with the potential benefits, serious harms are possible. As physicians, we find it difficult to talk about the harms caused by what we do, but patients should be helped to understand the probabilities and size of benefits and harms to make their choice *before* they enter the screening cascade.^{3,4}

In order not to miss true cases, most screening tests are designed to produce positive results at a higher rate than the prevalence of disease. Follow-up procedures are inevitably necessary to diagnose true positives; therefore, most “screen positives” turn out to be false positives. Thereafter, some of these people suffer unnecessarily from the consequences of the tests. In most of the trials that inform our practice—whether for drug treatment or screening—the quality was carefully controlled to ensure clear-cut conclusions. To replicate the benefits demonstrated by research studies requires the same level of tight quality control through all stages of the screening and diagnostic process. As Muir Gray

notes, “Screening programmes that are shown to be efficacious in a research setting require an obsession with quality to be effective in a service setting.”⁵ We cannot be confident that this applies in daily practice so must inquire in our local setting.

Pathway of screening

The pathway of screening (Table 1) applies to any screening program. In this article, we will focus on the role of family physicians during stages 1 to 4 of the screening pathway—what we do and which screening services we refer patients directly to.

Selecting the right patients. Most guidelines for screening limit their positive recommendations to a specific group of patients, mostly by age but sometimes by demographic characteristics or by specific risk factors, such as risk scores for diabetes. Sometimes there is inadequate evidence outside that group. More often, there is a specific recommendation against testing outside that group, largely because the disease is so rare that there is little chance of benefit, while harms are still likely; examples include cervical cancer screening for those younger than age 25⁶ or colon cancer screening for those younger than age 50 (among those with no specific risk factors).⁷ In addition, most recommendations are focused on “normal risk” individuals without elevated probabilities of the disease, for example,

Table 1. Pathway of screening and associated problems

STAGE	SCREENING PATHWAY	FACTORS TO CONSIDER	PROBLEMS
1	Selecting the right patients	<ul style="list-style-type: none"> • Correct age group • Patients with high enough risk 	<ul style="list-style-type: none"> • Patients are too young or too frail • Exposing a low-risk patient to CT screening for lung cancer
2	Doing the primary test properly	<ul style="list-style-type: none"> • BP measurement • Lung screening with low-dose CT scan • Using FIT if available rather than guaiac-based testing 	<ul style="list-style-type: none"> • Not using an automated BP device • CT interpreted by non-specialized radiologist
3	Rescreening at the right interval	<ul style="list-style-type: none"> • Right frequency • Stop screening when harms outweigh benefits 	<ul style="list-style-type: none"> • “Annual” laboratory tests being recommended for simplicity • Annual mammography findings identify more false positives than every second or third year
4	Ensuring high-quality secondary tests	<ul style="list-style-type: none"> • Proper follow-up of positive screening test results • Biopsy quality 	<ul style="list-style-type: none"> • Not ordering colonoscopy after positive FIT results • Pathologist not reviewing marginal or difficult cases with others
5	Determining route to starting treatment	<ul style="list-style-type: none"> • Overcrowded waiting list 	<ul style="list-style-type: none"> • Overdiagnosed patients whose “cancer” needs no treatment
6	Providing definitive treatment	<ul style="list-style-type: none"> • Quality of treatment and complication rates • Long-term management 	<ul style="list-style-type: none"> • Overtreatment of diabetes causing episodes of hypoglycemia
7	Following up treated patients	<ul style="list-style-type: none"> • Repeat colonoscopy after polyp removal 	<ul style="list-style-type: none"> • Repeating too soon, or too late, after high-grade polyp

BP—blood pressure, CT—computed tomography, FIT—fecal immunochemical testing.

because of family history. For such patients at higher risk, we must carefully select appropriate guidance. Those who have some other disease that limits their probable life span should be considered for exclusion, as they will be subject to risk of harms in the short term but might not live long enough to gain any benefits.

Doing the primary test properly. Blood pressure must be measured carefully, following recommendations for taking valid measurements⁸; failure to do so will overdiagnose hypertension, resulting in labeling and overtreatment.^{9,10} When measuring the blood pressure of someone with suspected hypertension, repeat measurements using an automated device¹¹ or ambulatory pressure over 24 hours must be performed before deciding to treat¹²—a life-altering decision as treatment can transfer the person from the land of the healthy to the world of “the patient.”

High-quality cervical cancer screening starts with taking a good specimen. Currently in Canada, this is still a cellular sample from the cervix. We should try to sample the whole of the transition zone, which means carefully applying the spatula and rotating it fully, including any irregular shapes of the cervix, so as to sample localized areas of abnormal cells. It must then be preserved properly. In most provinces, liquid-based technology is used, but some still require application to a slide, in which case the process of spreading and fixation is critical to give the cytotechnologists their best chance to detect abnormal cells. The laboratory should give you feedback if your samples are consistently inadequate.

Rescreening at the right interval. Most screening test results are negative and patients are then asked to return at an interval for repeat testing. The interval matters; it must be long enough that disease progresses sufficiently to make screening worthwhile. If the interval is too short, there will be minimal new disease, so nearly all findings will be false positives; if it is too long, some disease will have “escaped.” Cautious recommendations consider the interval period carefully and adapt it for people with varying risk profiles, not just recommend annual frequency of testing for simplicity.¹³

Ensuring high-quality tests. Most diagnostic laboratories across Canada run sophisticated systems for quality assurance. Provinces license laboratories and review them every few years. Quality assurance processes include performing control samples on each run of tests, double testing of some abnormal results, testing against external standards, and identifying the normal range and extent of variability in test results. These apply to lipid and hemoglobin A_{1c} levels, and therefore we can be confident of the results we obtain.

Because screening tests usually focus on the earliest deviation from normal, they are more challenging than

diagnostic tests. For judgment-based pathology, such as cytology screening or reading biopsy samples, there is a substantial amount of double reading to check quality. The Canadian Partnership Against Cancer has assisted laboratories across the country to agree upon standards for handling biopsies and reporting terminology. Pathologists should also correlate their reports with radiologic or clinical findings. As advocates for their patients, referring physicians can ask about their local laboratory quality assurance programs and how they perform.

Where work is done by individual clinicians outside a formal system that monitors quality, there is potential for much more variation and, therefore, referring family physicians need to be much more aware of quality issues. We might need to question our colleagues and change our referral patterns, if we can, to send patients to services that will provide better-quality tests.

Issues in cancer screening

Here we will identify what we perceive to be the most important issues associated with cervical, breast, colorectal, lung, and prostate cancer screening.

Cervical cancer screening. If Papanicolaou test results are positive and the woman requires a colposcopy, that process also requires quality control. This is based on following protocols, taking appropriate biopsies, and undertaking the minimal size of LEEP (loop electrosurgical excision procedure). Although there are no systematic processes in place across Canada to ensure that colposcopy and LEEP procedures are done well, some provinces have developed quality control processes; for example, Alberta uses an electronic system to systematically record each colposcopy outcome and, with discussion at provincial colposcopy meetings, there is increasing standardization. In the United States, evidence-based guidelines include recommendations to improve colposcopy quality.¹⁴

Breast cancer screening. Mammography must be performed by a radiology practice. Quality control of the machinery and technologists is specified. Radiographers perform the imaging and the Canadian Association of Radiologists has a set of standards that focus on the quality of images¹⁵; however, when it comes to reading those images, standards for radiologist quality control are not openly available. British centres require that mammography readers have formal extra training and perform at least 5000 readings per year in order to estimate their diagnosis and miss rates.¹⁶ It is difficult to assess accuracy for those who perform few readings. The Canadian standards regarding the qualifications of interpreting physicians (radiologists) require only 40 hours of training and reading a minimum of 480 mammograms per year.¹⁷ This might not be a sufficient number of reads to maintain the skill set and to measure important quality indicators.

In addition, radiologists in North America tend to focus on maximum sensitivity, rather than a balance between sensitivity and specificity. The rate of positive mammogram findings in European mammography screening programs and in Australia¹⁸ is around 4%, whereas in the United States it is 8% to 9%.^{16,19} Across Canada, in 2011 and 2012, the positive rates for second and subsequent screening tests in large provinces ranged from 4.0% to 9.2% (**Figure 2**).²⁰ Sadly, there is no recent comparison. The incidence of cancer detected in those provinces does not vary accordingly, so extra “sensitivity” comes at the cost of many false positives. In British Columbia, different screening centres report false-positive rates ranging from 3% to 9%. Subsequent biopsy rates range from less than 2 to more than 8 per 1000 women. On average, a woman who is screened biennially between the ages of 50 and 69 has a 41% chance of a false-positive result and a 5% to 6% chance of a false-positive biopsy.²¹ Screening at a “high rate” centre, over a wider range of years and more often, might lead to an even higher risk of harm.²² Given the delicate balance of small benefit against potential for harm,²³ it is likely better not to screen than to have a poor-quality mammogram reading.

Those provinces with a formal systematic screening program and specific centres with quality control are likely to produce a better balance between benefits and harms

than those with more laissez-faire approaches. It would seem advisable for family physicians to inquire and refer to screening centres that do not produce excessive false-positive results. This process might be daunting, but perhaps local family medicine leaders could lead an initiative to ask their local radiologists and discuss the response with their colleagues. You will find a list of questions that might be used in that conversation at **CFPlus**.*

We should avoid referring to centres that recommend routine annual mammograms or encourage the use of new screening approaches, such as tomosynthesis or magnetic resonance imaging and additional breast ultrasound. Such more costly approaches produce extra diagnoses, mostly of either noncancer disease or overdiagnosed disease, with no high-quality evidence of concomitant benefit.^{24,25}

Colorectal cancer screening. Screening is accomplished by several methods. Guaiac-based occult blood tests have been, or are being, phased out in most provinces, superseded by fecal immunochemical testing (FIT). Different provinces set the sensitivity

*A list of questions about quality to ask practitioners performing screening tests is available at www.cfp.ca. Go to the full text of the article online and click on the **CFPlus** tab.

Figure 2. Abnormal call rate* for second and subsequent mammograms for women aged 50 to 69, by provincial program: 2011 and 2012 screen years.

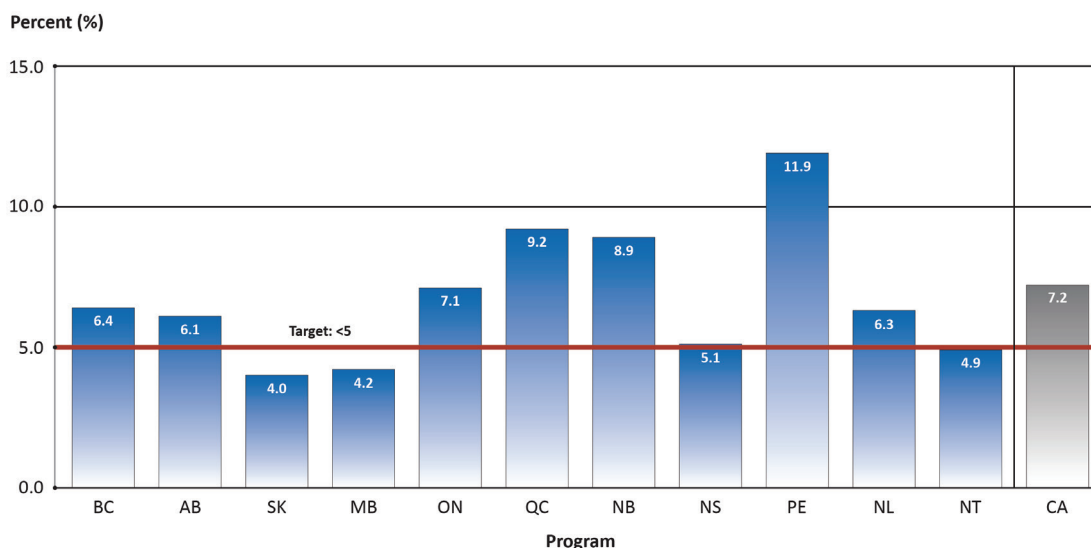


Photo credit: Canadian Partnership Against Cancer.

AB—Alberta, BC—British Columbia, CA—Canada, MB—Manitoba, NB—New Brunswick, NL—Newfoundland and Labrador, NS—Nova Scotia, NT—Northwest Territories, ON—Ontario, PE—Prince Edward Island, QC—Quebec, SK—Saskatchewan.

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*Abnormal call rate is the percentage of screening mammogram findings that are identified as abnormal.²⁰

of FIT at different levels, so the false-positive rates vary. Individual clinicians must use the test supplied and the cutoff used in their jurisdiction. If there is an option, it is important to use FIT, which has many advantages over the guaiac-based occult blood tests.

Colonoscopy is the key variable in colon cancer screening, as it is the follow-up for any positive initial test results and the first test for higher-risk people. The rate of cecal intubation (ie, complete colonoscopy rate) has been reported to vary widely among different endoscopy providers. Adequate bowel preparation is essential for good examination and should be recorded in the reports. A key parameter is detection and removal of adenomatous polyps, (ie, adenoma detection rate [ADR]).²⁶ A higher ADR is predictive of lower risk of subsequent occurrence of and deaths due to colon cancer, but the ADR varies widely among endoscopy physicians. Colonic perforation is one of the more serious potential complications of colonoscopy. The perforation rate should be low (1 per 1000 for screening colonoscopies), but could be more when large polyps are removed. Endoscopists should know about their perforations, other complications, and outcomes, such as polyp detection rates. When events are rare, rates are difficult to generate for individual providers, but this information should be available for endoscopy centres.

All physicians aim for the best outcomes for their patients; therefore, individual colonoscopists need to participate in measurements of their quality. The quality of colonoscopies cannot be measured by whether the provider is a surgeon, gastroenterologist, family physician, or nurse, rather by his or her colonoscopy training, number of colonoscopies performed, and, most important, how meticulous he or she is in performing this procedure. Many centres limit screening colonoscopies to those performing more than 200 to 300 per year, as there is a large volume effect on outcomes with colonoscopy. Although audit and feedback is an effective approach to improvement,²⁷ not all centres have established such systems. Family physician colonoscopists in Alberta have published their quality indices.²⁸ If family physicians regularly ask for this information from the screening services they refer to, likely more endoscopists will obtain it.

Lung cancer screening. Low-dose computed tomography (CT) is a screening test for lung cancer among those at high risk.²⁹ However, the benefits are uncommon—3 per 1000 persons screened will live longer—while the potential harms of false positives and from subsequent investigations, including lung biopsy, are much more common. Without very expert radiologists and pathologists, as well as highly skilled thoracic physicians and surgeons, the harms are likely greater than any benefit. The Canadian Task Force on Preventive Health Care was careful to specify that screening should only be offered to people who have sufficient risk that the potential for

benefit outweighs the harms, and that lung screening by low-dose CT be performed only in centres with a dedicated service.²⁹ This recommendation was prescient; recent reports from the United States demonstrate rates of harms are twice as high as in the trials.³⁰ This requirement might seem problematic for Canadians outside large centres, but if low-dose CT equipment is available in smaller cities, the reading can be performed remotely by an expert radiologist. Any patients with positive results must be referred to an expert centre, as further investigation and management requires judgment and skill, as it can lead to considerable damage. Do not refer patients for lung screening by standard CT, nor refer to any centre without a quality assurance program.

Prostate cancer screening. The Canadian Task Force gives a weak or conditional recommendation against prostate-specific antigen screening³¹; but if, after shared decision making, your patient chooses to be tested and has a high result, what do you do? There are varied thresholds for referral. Thereafter, it is difficult to obtain evidence on the quality of decision support for men, how biopsies are performed, and the risk of consequent infection.³² The higher the tumour grade is, the lower the accuracy of pathology diagnoses from biopsies is.³³ Much effort is currently devoted to improving standardization. There is a high rate of overdiagnosis, so men in many centres are encouraged to consider active surveillance, which regularly assesses whether the disease is progressing. However, figures are not readily available on how many eventually go on to radical prostatectomy, an operation with substantial morbidity and a small mortality rate. These uncertainties must be discussed with men before they enter the screening cascade.³¹

Conclusion

Family physicians cannot assume that screening will benefit patients to the extent reported in the screening trials or implied by guideline recommendations. In practice, each step in the screening pathway is subject to various threats to quality. We must ensure quality for the components that we are responsible for. Reporting and giving feedback leads to improvement, which is essential to enhance net benefits to our patients and tilt the balance toward achieving effective and efficient services. Ideally, patients should be aware of the outcomes in the setting where screening is offered, so they can choose not to participate if their personal judgment of the balance is negative. Having accurate information is an essential prerequisite for the process of shared decision making that is recommended before entry to the screening cascade. Knowing that quality provides some reassurance that screening is more likely to help our patients than harm them.

While it is difficult to question the quality of care provided by our specialist colleagues, it is clearly crucial to ask,

as there is vast variation in the quality of care provided. The good referral resources that do participate in quality assurance will mostly be very happy that you asked and to show their results. The list at **CFPlus*** provides examples of the types of questions that might be incorporated in that discussion. Where such information is unavailable or quality processes are not in place, family physicians must advocate through their organizations to demand that such analyses be performed and made available and quality improvement processes be instituted. If not, we should stop supporting screening through such services. After all, our first goal is to do “no harm” and, hence, we need reasonable assurance that the balance of benefits and harms is beneficial in our setting before we send people down the screening cascade.

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Competing interests

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