FIT testing: a reality check for family physicians

An open letter from Sections on General Surgery and Gastroenterology on colorectal cancer screening

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Ontarians will develop colorectal cancer, making it the leading cause of cancer death in non-smokers in the province. Treatment costs in Ontario alone are almost \$1 billion per year. But colorectal cancer is a highly preventable disease – if the screening target is the polyp.

Ontario's general surgeons and gastroenterologists have significant, evidence-based reservations about the Colon Cancer Check Program, and in particular the move to FIT – Fecal Immunochemical Test. (To access information on how colorectal cancer screening has changed in Ontario, see p. 28).

Polyps - Not Cancers - Should Be The Target

The primary patient-centred objective of colon screening is to find polyps, not cancers. Polypectomy prevents colorectal cancer; this is far preferable to finding early cancers and then hoping that patients do well. If we can reduce the incidence of colon cancer by prevention, mortality reduction follows automatically.

The difference between prevention and early detection is huge. Early detection of cancer still entails major surgery with its risks and complications and then years of anxiety about cancer recurrence. Even early stage cancers have significant mortality. A five-year survival of 90% might sound pretty good, however, that's equivalent to the average survival of a 73-year-old Canadian, and close to the overall five-year survival for breast cancer (87%).

FIT Misses Most Polyps

FIT has very poor sensitivity in detecting polyps: zero for small polyps, about 7% for medium-sized polyps, and only about 25% for advanced polyps. For serrated polyps, responsible for about one-third of cancers, the sensitivity is essentially zero. For early cancers where intervention can still make a difference, FIT is still only in the 40%-50% range. The sensitivity of FIT for advanced cancers is approximately 80%, but that's absolutely irrelevant to a screening program. Finding an advanced cancer a few months before it would become clinically apparent is not going to change the outcome, or the treatment course.

FIT aficionados state that the "Programmatic Sensitivity" of FIT is in the 80% range. This is the dubious concept of

"sensitivity with repeated testing": you may miss it the first, second, third or fourth time, but hopefully you'll catch it before it becomes clinically apparent – and then declare it a success for the screening program. No other test presents its accuracy in such a distorted fashion. For many patients the potential benefits of early detection will have been squandered.

FIT Is Actually Riskier Than Screening Colonoscopy

If missing a cancer is considered a harm, then the risk of FIT testing is far higher than the risk of harm from a screening colonoscopy. For a 65-year-old Canadian male, the probability of harbouring a polyp destined to become a cancer is about 1 in 50. The risk of having a latent undiagnosed cancer is about 1 in 100, about 25 times higher than the risk of serious complications with outpatient colonoscopy. The probability that a single FIT test will miss either a cancer, or a polyp destined to become a cancer, is about 70%. Delaying detection by two years results in up-staging of most latent cancers. Clinically significant missed polyps will also grow larger – and in many cases will be riskier to remove. Some polyps will reach the point where surgery is required. This results in potential harm to about 1 in 80 screenees in this age group, far higher than the risk of colonoscopy.

Colonoscopy Costs Less Than FIT When Treatment Costs Are Included

The cost of screening tests always needs to be interpreted against the cost of treating the disease. Treating colorectal cancer costs in excess of \$100,000 per case in direct medical costs, or almost a billion dollars per year in Ontario.² If the patient's own costs are included, the total is far higher. This is a disease which is far cheaper to prevent than to treat. A recent analysis done in Sweden shows that average risk screening by colonoscopy is more cost-effective than FIT testing and saves more lives.³

The total cost of a colonoscopy, including lab, hospital,

anesthesia and physician's costs, is only about \$600 – far cheaper than in most other countries. If done every 10 years, that is only \$60 per year. This is not much more than the cost of FIT testing (\$32)¹ and barely more than the aggregate prescribing fee for a prescription filled four times a year. It is a fraction of the cost of most long-term drugs, even generic ones. If we compare it to other preventive interventions such as mammography, cervical cancer screening, poly pharmacy for hypertension, and long-term management of GERD, they all cost more per QALY (quality adjusted life year) than screening colonoscopy.⁴

International Comparisons Prove The Point

The U.S. has had widespread average risk colonoscopy-based screening since the 1990s and it was formally approved by Medicare in 2001. The U.S. used to have a higher incidence of colon cancer than Canada, but it is now 21% lower, and they've effectively reduced the incidence by 40% in 30 years.

The poster child is Massachusetts, where 76% of the population has been screened and the incidence of colorectal cancer dropped a massive 53% between 2001 and 2016.⁵ Germany, with modest participation rates, estimates that its colonoscopy screening program has averted 180,000 cases and they have had incidence reductions of 25%.⁶

Canadian rates have dropped by 19% in the last 15 years, almost certainly due to fairly high rates of colonoscopy-based screening. Ontario, with the highest rate of colonoscopy, has had the most success with a substantial drop in incidence of 25% in 15 years. It is the polypectomies done 10 or 15 years ago that are driving Ontario's cancer incidence lower today. Attributing that to FOBT would be a fallacy as even the RCT's of gFOBT showed no reduction in incidence.

A study looking at Ontario data found that patients of family doctors who were "colonoscopy enthusiasts" had an 80% reduction in colorectal cancer mortality compared with the patients of "colonoscopy skeptical" family doctors. Another Ontario study showed that regions with higher rates of colonoscopy have lower rates of colon cancer.

European countries such as the United Kingdom and the Netherlands that just rely on stool tests have seen flat or rising incidence whereas countries such as Austria and Switzerland with higher levels of endoscopy-based screening have seen significant reductions.

Perhaps most tellingly, only 12% of Ontario doctors do fecal screening for themselves; most have a colonoscopy.

Screening By Colonoscopy Is Feasible In Ontario

The screening age population of Ontario is 4.3 million. If we had 80% compliance it would require about 500,000 colonoscopies per year. We already do 280,000 in patients of screening age. But since every diagnostic colonoscopy is already a screening colonoscopy, the increment required would be around 200,000 per year. We achieved that rate of growth in just six years in the early 2000s without any formal program. The incremental cost of such a screening program

would thus be about \$120 million per year – a fraction of the \$1 billion in treatment costs, which would be more than recouped within a decade.

Manpower is also not an issue. In a city of 100,000, with reasonable assumptions about compliance, current volume and workload, the incremental volume would be about 1,500 scopes per year – or just 2.5 endoscopy days per week. With typical manpower levels, that is about an extra half-day per week per endoscopist. This is easily achievable if the government committed to funding it.

What Gastroenterologists And General Surgeons Want

We look after the carnage that colorectal cancer brings to patients and their families, but it doesn't have to happen. We know how to prevent it: simple average risk colonoscopy. On the patient side, it doesn't even require willpower or lifestyle modification. All it requires is political will and a modest expansion of resources that will be easily recouped.

Most Ontario gastroenterologists and surgeons follow the U.S. Multi-Society Guidelines for colon screening. They are simple: any screening is better than no screening, and patients should be offered screening tests which fit their risk tolerance and value systems. A screening strategy that prevents colon cancer is highly preferable to one that just detects latent cancers. In short, all patients should be encouraged to have a screening colonoscopy, but if unwilling should be offered FIT testing. The only thing to quibble over is what age to start and stop.

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