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Colorectal screening in the U.S.: What is the best FIT?

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In the United States (U.S.) colorectal cancer (CRC) incidence and mortality have declined by roughly 3%/year since 2001.[1] Screening probably explains much of this public health success; however, the optimal method remains unclear. Colonoscopy accounts for at least 60% of all CRC screening in the U.S., despite its greater expense and risk of complications compared with other options.[2] Surprisingly little published evidence supports the predominance of colonoscopy. Unlike fecal occult blood testing or flexible sigmoidoscopy, no controlled studies have shown that colonoscopy reduces CRC incidence or mortality. Most studies have reported that the cost-effectiveness of other CRC screening methods equals or exceeds that of colonoscopy.[3] Recently, the clinical effectiveness of screening colonoscopy itself has come under fire with multiple studies showing excellent protection against left sided CRC, but far less against right-sided disease.[4] Long awaited trials comparing colonoscopy with stool blood-based screening methods are underway, but informative results will take years.

Review of this evidence has prompted national CRC screening programs in Europe, Asia and elsewhere to emphasize guaiac fecal-occult screening test (gFOBT) and, more recently, fecal immunochemical testing (FIT) as the primary screening modality. For example, the Canadian Task Force on Preventive Health Care recently published statements supporting FIT while specifically recommending against colonoscopy.[5]

In light of these controversial aspects of CRC screening, the U.S. Multi-Society Task Force, which is comprised of the major U.S. gastroenterological professional associations, has just released an extensive and timely examination of evidence regarding use of FIT for CRC screening in average risk populations.[6] This consensus statement summarizes well the advantages of FIT over gFOBT. First, in pooled analyses, the sensitivity of 79% (95% CI 69%−86%) for FIT comfortably exceeds that of gFOBT (approximately 35%), while maintaining similar specificity 94% (95% CI 92%−95%). Second, FIT detects advanced adenomas (intermediate precursors to CRC) more consistently than gFOBT. In a recent meta-analysis of RCTs, FIT detected twice as many CRCs and advanced adenomas as

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gFOBT (RR 2.28, 95% CI 1.68–3.10). Third, patients prefer FIT to gFOBT; this is a distinct advantage because continued adherence is one of the greatest challenges for CRC screening. These data provide tremendous clinical support for a switch from gFOBT to FIT in US primary care settings.

This Multi-Society consensus statement also offers useful recommendations about implementation of FIT screening such as: How many FIT tests per screening round? (one); What is the interval between screening rounds? (annual); Is a qualitative or quantitative immunochemical assay for blood better? (quantitative); and what cut-off should define a positive test result? (≤20 μg blood/g stool). Although, the authors acknowledge that the supporting evidence is “weak” due to “low quality”, their recommendations are similar to those of other expert panels in Europe.

Given the preference for colonoscopy screening in the U.S., strong evidence would be required to shift this norm. Advocates of colonoscopy point to its unrivalled ability to identify and remove adenomas, thereby preventing cancer. gFOBT (or FIT) is seen as useful for detection rather than prevention of CRC. However, recent modelling studies have shown that when adherence to serial completion is high, FIT-based screening yields similar reductions in CRC incidence to colonoscopy.[7] In addition, preliminary results from controlled head-to-head trials found participants more likely to accept FIT than colonoscopy when offered.[8] As a result, more cancers (but fewer advanced adenomas) were detected in populations screened with FIT than colonoscopy. These early results underline that the absolute number of detected CRCs in any screening initiative reflects the balance between test adherence (better for FIT than colonoscopy) and test sensitivity (better for colonoscopy than FIT).

At present, colonoscopy and stool testing for blood are the only readily available CRC screening tests in the U.S.. Primary care clinicians will undoubtedly be concerned about practical aspects of implementing more broad based, annual FIT screening. Nationally, there is no infrastructure to support CRC screening program with any method. Despite the proliferation of electronic health records (EHRs), large scale FIT screening efforts will require efficient tracking mechanisms to ensure that the test is offered, returned, and positive results followed up by colonoscopy, while negative tests spur repeat FIT in one year. Additional logistical barriers loom. The FDA has approved only qualitative FIT reporting in the U.S., effectively pre-determining the cut-off level that defines a positive test. More sensitive tests (lower cut points) will trigger a larger number of follow up colonoscopies. The cutpoint for FIT recommended by the Multi-Society task force balances sensitivity and specificity. However, that cutpoint may not equal the manufacturer’s choice for some FIT products available in the U.S. In contrast, quantitative FIT testing provides flexibility in selecting a positive cut-off. Varying cut points allows some FIT programs to take into account access to follow-up colonoscopy.

The Affordable Care Act (ACA) mandates that preventive services endorsed by the U.S. Preventive Services Task Force (USPSTF), including CRC screening, be offered at no cost to the patient, thereby reducing a major barrier to screening uptake. All persons with a positive FIT (about 5% of tests in average risk settings) need a follow-up colonoscopy but,

unfortunately, this subsequent “diagnostic” test is no longer defined as “screening” so patients can be responsible for deductible and other costs. This paradox could push patients and physicians to opt for screening colonoscopy despite it being more expensive, risky, and for some patients, unappealing.

The USPSTF advocates a variety of options to complete CRC screening, acknowledging that no one screening method clearly outperforms the others, plus the best test is the one the patient completes.[4] Research has shown that, when patients are offered a choice of gFOBT or colonoscopy, they are more than twice as likely to complete screening than if they had been only offered colonoscopy.[9] Furthermore, in a randomized trial, compared with usual care, a CRC screening program featuring centralized provision of CRC screening tests linked to the EHR led to lower costs and greater screening rates over a two year period.[10]

For primary care and other clinicians who provide CRC screening services, this authoritative consensus statement offers strong evidence for FIT as an excellent alternative for CRC prevention. To continue to increase CRC prevention and early detection, patients need to have access to multiple, effective, low or no cost screening options. For a variety of reasons including access, cost and patient preference, FIT is a worthy component of any average risk screening program. Utilization of this test should be promoted with the same enthusiasm as colonoscopy.

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