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Clinical Practice Guidelines for Colorectal Cancer Screening New Recommendations and New Challenges

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For 32 years, the United States Preventive Services Task Force (USPSTF) has served the nation with analyses that are scientific, transparent, and untainted by conflict of interest and political influence. While the task force has been the acknowledged leader in developing preventive services

guidelines, its work environment is evolving under intense scrutiny from many powerful interests, including patients, clinicians, insurers, and politicians. The Affordable Care Act of 2010 added to the challenges by mandating private insurance coverage for preventive services that the USPSTF strongly recommends (that is, preventive services that receive a grade of A or B).^{1,2}

This issue of *JAMA* contains the USPSTF Recommendation Statement for colorectal cancer screening,³ along with an updated systematic Evidence Review⁴ and report of the microsimulation modeling study⁵ that were used to inform the screening recommendations. This editorial summarizes the clinical implications of the colorectal cancer screening recommendations, provides historical background information, and shows how the adoption of a shared decision-making paradigm could herald a new era in cancer screening guidelines.

The 2016 guideline strongly recommends screening for colorectal cancer (A recommendation). It lists 7 different screening strategies, stating that “the screening tests are not presented in any preferred or ranked order,” implying that the task force considers them to be equivalent. However, the task force presents evidence that some strategies are better than others when tested in representative populations. Four strategies result in essentially the same life expectancy gains and consumption of health care resources: colonoscopy, fecal immunochemical testing (FIT) for occult blood, sigmoidos-

copy plus FIT, and computed tomography (CT) colonography. The task force lists the FIT-DNA test (multitargeted stool DNA test) but states that it is less efficient. Finally, the task force lists 2 strategies (guaiac-based fecal occult blood testing [gFOBT] and sigmoidoscopy alone) but cites evidence suggesting that they, although effective, are inferior to the other listed strategies.

The USPSTF appears to be saying that some tests are better than others, but then does not specify a preference. How can tests differ and yet be the same in the eyes of the task force? In the Recommendation Statement, the task force states a principle that may explain this paradox: “the best screening test is the one that gets performed.” A test can rank low when tested on a representative population but still be better aligned with an individual patient’s preferences and, therefore, be most likely to get done. Thus, to choose among the screening strategies, the USPSTF recommends shared decision making, a process in which physician and patient share information and reach a consensus about what screening test is best for the patient. In shared decision making, the choices do not necessarily have similar outcomes or equivalent efficiency. For the physician, sharing information means providing access to a description of the benefits and harms of the alternatives. For patients, this means describing how they value the strategies and their potential outcomes or declaring their willingness to complete the screening process. To be an equal partner in this conversation, patients must learn about the strategies and their consequences. The physician could describe them or send the patient home with a decision aid to review in advance of a subsequent conversation about screening. This embrace of shared decision making for choosing a screening test is a pivotal step forward for the task force.

It is possible to reconstruct some of the steps along the pathway to shared decision making for colorectal cancer screening. In 2008, the task force issued a screening guideline that stated “The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy in adults, beginning at age 50 years and continuing until age 75 years.”⁶ In October 2015, as required in the development of updated USPSTF reports, the task force posted the draft version of the new colorectal cancer screening recommendations for public comment.⁷ The 2015 draft recommendation statement gave an A grade to colorectal cancer screening, indicating that “The USPSTF recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years. The risks and benefits of different screening methods vary.”⁷ The draft recommendation statement also listed 3 options for screening, including colonoscopy, sigmoidoscopy plus an annual FIT for occult blood, and annual FIT alone.⁷ The decision modeling analysis⁸ requested by the USPSTF estimated that these 3 tests provided roughly the same number of life-years gained vs no screening and equivalent resource consumption (measured as the lifetime number of colonoscopies needed, including for screening and diagnosis).

The draft recommendation also included a new category, termed “alternative tests,” in which 2 other tests, CT colonography and FIT-DNA, were listed but not explicitly recommended,⁷ even though the estimated life-years gained and resources used with these tests were only modestly different than the 3 recommended strategies.⁸ As with other USPSTF reports, the draft version of the recommendation statement generated public comment, including, as the task force clearly acknowledges,³ many comments expressing concern that the terms “recommended” and “alternative” lacked clarity.

In the final Recommendation Statement³ published in this issue of *JAMA*, the main conclusion is as follows: “The USPSTF recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years. (A recommendation).” The Recommendation Statement also includes a section on Clinical Considerations that lists 7 strategies: the original 3 strategies, the 2 previously termed “alternative,” and 2 others (gFOBT and sigmoidoscopy without a stool-based test).

Clinicians and patients will understand the importance of screening and making an informed choice among the 7 strategies. For private insurers, the A recommendation mandates coverage for colorectal cancer screening, but the lack of a statement indicating that the task force recommends specific tests or strategies leaves some ambiguity about whether private insurance must cover each of the specific tests.

Ideally, the USPSTF would have based its recommendations for specific colorectal cancer screening tests on randomized trials, the strongest kind of evidence about the effect of screening on the length and quality of life. However, the only strategies based on randomized trial findings are sigmoidoscopy plus annual FIT, sigmoidoscopy alone, and gFOBT. In contrast, the source of the main evidence for CT colonography, FIT alone, and FIT-DNA is cross-sectional: studies that measure test sensitivity and specificity at a point in time but cannot mea-

sure the effects on life expectancy or resource utilization. Decision modeling can project screening test results forward to their estimated effects on life expectancy and colonoscopies needed. The USPSTF has been a leader in using decision modeling to translate evidence of screening test accuracy into health effects.

In both 2008 and the draft recommendations in 2015, the short list of acceptable screening strategies was derived by using a modeling concept called “the efficient frontier.”^{8,9} The frontier is a line connecting the strategies with the highest expected gain in life-years per colonoscopy performed; these are called efficient strategies. Strategies that were below the frontier but with life-years gained at least 98% of that of the efficient frontier were near efficient and all others were inefficient. In the final recommendation, the USPSTF list of 7 acceptable strategies included 4 that were efficient and 1 near efficient (FIT-DNA), as well as 2 that were inefficient.

The process the task force used to decide which screening strategies are acceptable deserves scrutiny because the recommendation affects everyone: patients, clinicians, payers, policy makers, and test manufacturers. The accompanying article on decision modeling⁵ describes the USPSTF process in detail. The openness of that description invites questions. For example, how did the task force decide on the minimum effect of screening (measured in life-years gained) to qualify as an acceptable screening strategy? Based on the exclusion of 2 near-efficient strategies, an acceptable strategy had to be on—or very close to—the efficient frontier in 2008⁹ and at the time of the 2015 draft recommendations.⁸ In the final recommendations, FIT-DNA, a near-efficient strategy, was included in the list of acceptable strategies despite performing below the efficient frontier, as were gFOBT and sigmoidoscopy alone.⁵ In its current Recommendation Statement, the USPSTF now acknowledges, appropriately, the many other “moving parts” that affect the clinical outcomes of screening programs in practice. For example, colonoscopy quality may vary widely^{10,11} as may the performance and accuracy of imaging procedures and stool-based screening tests. The task force appears to believe that the most important of these moving parts is the likelihood that the patient will actually undergo screening with a test that has been deemed “acceptable.” The predictors of submitting to different colorectal cancer screening procedures are not known, so the task force could not expect the modeling teams to list the predictors of success for each screening procedure. Instead, they provide population-based information about the consequences of the strategies that, together with the patient’s preferences, can inform a shared decision.

The USPSTF should be applauded for taking a global approach to a screening recommendation. The unique feature of the 2016 recommendations is that a goal—to increase screening rates—is driving the implementation strategy, which is to use shared decision making about an unusually broad range of screening options. Stakeholders—patients, physicians, health plans, and insurers—will want to know if the task force plans to take this approach for future screening topics. When the task force does recommend shared decision making, it would be

helpful to develop a patient-friendly table that displays all of the evidence about all of the acceptable strategies.

Guidelines creation—going from evidence to policy—is one of the most important and demanding duties of our profession. Preventive services recommendations are especially challenging for reasons involving clinical, scientific, and political considerations. Fortunately, the federal government has invested in its preventive services program since 1984, and the

program has steadily increased in stature and in scientific leadership. The colorectal cancer screening guideline is a prime example of strong leadership. However, as the USPSTF has evolved and as the ramifications of its recommendations have become increasingly important, some difficult challenges have arisen. Ensuring that the USPSTF receives the support to meet these challenges and to continue to fulfill its critical mission is more important now than ever before.

ARTICLE INFORMATION

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advisory board of the Epigenomics Corporation from 2011 to 2014. He reports receiving no fees, equity, salary support, or any other income for this service. No other disclosures are reported.

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