on health care spending and physicians’ time and energy. We believe that the current PSA-based screening paradigm does not compare favorably with competing health care priorities.

Some people have argued that PSA screening should at least be available for black men, because the incidence and aggressiveness of prostate cancer are greater in black than in white Americans. This proposal, however well intentioned, is misguided. In 2007, the proportion of deaths among U.S. men that were attributed to prostate cancer was 3.3% among blacks and 2.3% among whites; these rates are close enough that race-specific distinctions for screening are unwarranted. Furthermore, there is no evidence that the balance of benefits and harms from PSA screening differs for blacks and whites. If PSA screening is worthwhile, it should be applied universally; if it is not, selective screening would be a disservice to black men. Eliminating the unconscionable racial gap in overall access to essential health care services would be a far better way to address disparities than promoting a questionably effective cancer-screening program: the percentage of blacks without medical insurance is nearly twice that of whites.5

For two decades, primary care physicians have been expected to present a flawed screening test to patients, cloaking the flaws in an elaborate ritual of informed decision making. In turn, men have been expected to make sense of a confusing mix of hypothetical outcomes. Although the USPSTF recommendation is unlikely to end the PSA controversy, a document finally exists that should provide guidance to clinicians and policy makers.

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One Man at a Time — Resolving the PSA Controversy
Mary F. McNaughton-Collins, M.D., M.P.H., and Michael J. Barry, M.D.

Who should decide about screening for prostate cancer: expert panels of clinicians and methodologists, primary care clinicians, specialists, or fully informed patients themselves? The U.S. Preventive Services Task Force recently released a draft recommendation on screening for prostate cancer, designed for primary care physicians and health systems, and has opened it for public comment until November 8, 2011.1 After completing a rigorous evidence review, the task force decided to recommend against screening for prostate-specific antigen (PSA), concluding that there is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. This grade D recommendation applies to healthy men of all ages, regardless of race or family history. The task force’s suggestion for practice for grade D interventions is to “discourage the use of this service.”

We applaud the task force’s careful evidence review and synthesis of results from five screening trials. At the time of the previous (2008) recommendation on PSA-based screening for prostate cancer, task force members had concluded that the evidence was insufficient to allow them to make a recommendation for younger men, but they recommended against screening for men 75 years of age or older. With the results of the screening trials now available, there is finally higher-quality evidence to bring to bear on the question of PSA screening. However, as noted in the task force’s review of the evidence, the results of the two largest, highest-quality trials conflict, and we have described the question of screening for prostate cancer as “the controversy that refuses to die.” Will this grade D recommendation finally sound the death knell for the PSA controversy?

Although we agree with the task force’s synthesis of evidence...
and conclusions regarding the substantial harms that can be associated with PSA-based screening and treatment of screening-detected prostate cancer, we have a different perspective on the key question of benefit. The task force points out that no trial showed a decrease in overall mortality with the use of PSA-based screening through 11 years of follow-up and that all trials showed either a small or no benefit in prostate-cancer–specific mortality. But who is to decide what constitutes a “small” benefit and whether it outweighs the potential harms?

We would argue that the European screening trial had fewer methodologic limitations than the U.S. trial (less contamination in the control group and less prescreening in the trial population). In addition, among men 55 to 69 years of age in the European trial, there was a significant absolute reduction in mortality related to prostate cancer of about 7 deaths per 10,000 men over a median of 9 years of follow-up. Such a reduction might be small in the eyes of some men, but larger in the eyes of others. It is also possible that a larger benefit might accrue with longer follow-up, as suggested by the Göteborg subgroup analysis in the European trial. However, only time can provide substantiation for that argument, and like all subgroup analyses, these data must be interpreted cautiously.

Our perspective is that this evidence of a possible small but finite benefit from the largest trial would best support a grade C recommendation for men 55 to 69 years of age. With a grade C recommendation, the task force would be recommending “against routinely providing the service” while indicating that “there may be considerations that support providing the service in an individual patient” and stipulating that “there would need to be at least moderate certainty that the net benefit is small.” The task force’s suggestions for practice in the case of a grade C recommendation include the suggestion that they “offer/provide this service only if other considerations support offering or providing the service in an individual patient.”

A grade C recommendation would allow the patient to be involved in the decision to skip or choose a PSA screening test, after a discussion with a primary care provider about the magnitude of the known harms and the potential for some benefit. The patient could then provide his perspective on how he views the trade-off. Weighing the pros and cons to make a decision about PSA screening is an individual process, and different well-informed men will make different decisions. A grade D recommendation removes the patient from the equation and puts the physician in the central position of discouraging use of the test. Uncertainty in medicine is more common than we usually let on, and the way to address uncertainty is to allow patients the central position in decision making. A grade C recommendation would acknowledge that whereas the evidence shows that the harms may outweigh the benefits on a population level, some individual patients will still elect PSA screening. We do not believe that anyone but the patient should decide whether the small and uncertain benefits of PSA screening are worth it.

A grade C recommendation would come with considerable responsibility for primary care clinicians. We cannot simply pay lip service to shared decision making. The PSA test could no longer be ordered routinely, without discussion, as if the benefits clearly outweighed the harms. Perhaps in making a grade D recommendation, the task force took into consideration the dubious record of decision making for PSA testing.

There is abundant evidence that we have not engaged in shared decision making for prostate-cancer screening in the United States. We have been ordering PSA tests without discussion, and we have been discussing PSA tests and frequently the pros of PSA tests and infrequently the cons, and we do not routinely ask our patients for their preferences regarding PSA screening. That has to change for a grade C recommendation to be reasonable.

The American Cancer Society (ACS) recently updated its guideline for the early detection of prostate cancer, recommending that asymptomatic men who have at least a 10-year life expectancy be given an opportunity to make an informed decision with their health care provider about screening for prostate cancer after they receive information about the uncertainties, risks, and potential benefits associated with screening. The ACS asserts that prostate-cancer screening should not occur without an informed decision-making process. We support that recommendation and the ACS’s accompanying analysis of what men need to know before making an informed decision about PSA testing and ways to make sure they know these key facts.

In addition to helping our patients make informed decisions about PSA testing, we should ensure that appropriate patients are offered the options of watchful waiting (observation and physical...
examination with palliative treatment of symptoms) and active surveillance (periodic monitoring with PSA tests, physical examinations, and repeated prostate biopsy with attempted curative treatment for signs of disease progression or worsening prognosis) if prostate cancer is diagnosed through PSA screening. Watchful waiting and active surveillance may help prevent the conversion of overdiagnosis to overtreatment, mitigating the harms of screening that are so accurately portrayed by the task force.

To make a grade C recommendation appropriate, we primary care clinicians must ensure there is no more routine, indiscriminate PSA screening — and no washing our hands of responsibility once the patient is referred to a specialist for prostate-cancer treatment. We owe it to our patients to provide them with the kind of guidance about this screening test that they need and deserve.

That’s the way to help put the controversy to rest . . . one man at a time.

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Stratifying Risk — The U.S. Preventive Services Task Force and Prostate-Cancer Screening

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On October 11, 2011, the U.S. Preventive Services Task Force (USPSTF) issued a draft report on prostate specific antigen (PSA)-based screening for prostate cancer, giving it a grade D recommendation. Grade D means that “the USPSTF recommends against the service” because it has concluded that “there is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.”

This recommendation contradicts the view that PSA-based screening saves lives by reducing the risk of death from prostate cancer. The task force acknowledges that “clinical decisions involve more considerations than evidence alone” and that “clinicians should understand the evidence but individualize decision making to the specific patient or situation.” The latter recommendation, which I support, is in line with several guidelines recommending individualized decisions after the provision of balanced information on the risks and benefits of screening. Such information is unfortunately not currently available in the form of an internationally accepted document, though a proposal for such a document is part of the Prostate Cancer Risk Calculator, which is based on data from the European Randomized Study of Screening for Prostate Cancer (ERSPC, for which I am the international coordinator), and is available online (www.prostatecancer-riskcalculator.com).

The current draft USPSTF recommendation is meant to apply to the general population of men who might be at risk for clinically relevant prostate cancer. The review and recommendations presented by the task force attempt to balance the risks and benefits of screening against those of treatment. The document presents a high-level review of current knowledge. The recommendations are in line with several sets of U.S. guidelines, as well as with the recommendations made in 2009 by the ERSPC group, which state that any deliberation over introducing population-based screening must take into account unresolved questions about potential harms — mainly, the problems of overdiagnosis and overtreatment.

But the USPSTF report has a number of key weaknesses. First, it relied heavily on a meta-analysis that combined higher- and lower-quality evidence. The Cochrane recommendations for establishing scientific truth state that “a systematic review of all relevant randomized controlled trials is the highest level of evidence.” Yet clearly the randomized, controlled trials included in the PSA-screening