

ONLINE FIRST | LESS IS MORE

Can We Stop Ordering Prostate-Specific Antigen Screening Tests?

IRUN THE SECOND LARGEST SAFETY-NET SYSTEM IN the United States. As is true of all safety-net systems in the United States, we have a finite budget; overwhelmingly, our patients are uninsured or publicly insured, so we cannot raise our rates to pay for emerging populations and treatments. Instead, I see our mission as trying to provide the best health care we can for the available funding (highest value).

Few would disagree with the mission of providing the highest-value health care possible. Unfortunately, the consensus dissipates when a particular practice is targeted for elimination because it provides little or no value. Such is the state of the prostate-specific antigen (PSA) test for prostate cancer screening. Although the US Preventive Services Task Force (USPSTF) recommended against its use for men 75 years or older in 2008¹ and in 2012 concluded that there is insufficient evidence to recommend routine screening for anyone,² the test is still being ordered every day in every health care system including mine, reimbursed not only by private insurance but by public insurance (Medicare and Medicaid) and scarce county health dollars for the uninsured. Why is this? If the test is so unhelpful, why are we not able to devote the money to higher-value care?

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Indeed, operationally eliminating screening PSA tests would be much easier than adopting other practices for achieving higher-value care. For example, there is widespread agreement on the importance of helping patients develop advanced directives to clarify their goals for end-of-life care. Any physician will tell you that such conversations are rewarding but time consuming, and they are often initially difficult because they raise complicated issues of mortality, trust, and religious beliefs. In addition, advanced directives need to consider a wide range of circumstances and need to be reconsidered as circumstances change. Compare this with how easy it would be, after appropriate notification of physicians, for a health care system to refuse to run any PSA test ordered for a patient without prostate cancer or previously elevated levels or at least for anyone older than 75 years. That is all it would take, yet I do not foresee it happening, at least not yet. Why not?

CHALLENGES IN ELIMINATING PSA TESTING

First, for better or worse, most physicians wish to make their own decision on the basis of available evidence, even in fields in which they are not necessarily expert. In the case of PSA screening, many physicians and others simply do not agree with the USPSTF. And, when physicians disagree, they do not follow the recommendations. Is this a particularly noble aspect of our profession

(doing what we believe even if the experts disagree) or a kind of arrogance (yes, the USPSTF of experts recommended against this test, but I know better)? Or is it both?

Because medical practice is generally viewed as an autonomous activity, almost any test that a physician orders from a standard laboratory is considered to fall within the hard-to-pin-down “community standard” of practice. Compared with laboratory test ordering, medication ordering seems to be a tightly regulated activity. Even though we know that US Food and Drug Administration (FDA)-approved drugs are often used for unapproved indications (eg, proton pump inhibitors for dyspepsia), at least there is a regulating body charged with determining whether medications are safe and effective for specific indications. No such regulatory body exists for determining the appropriate indications for most laboratory tests. One might argue that we require FDA labeling for medications for specific indications because we know that a drug given for other untested indications can cause more harm than good. We have been slow to realize that the same types of concerns occur with use of laboratory tests, but no regulatory body evaluates their safety and effectiveness.

CASCADE OF HARM

Two articles in this issue of *JAMA Internal Medicine* illustrate that PSA screening tests cause a cascade of events that cause real harm to patients. Walter et al³ followed 25 208 male veterans 65 years or older who had a PSA level of greater than 4 ng/mL (nanograms per milliliter and micrograms per liter are interchangeable units). Effort was made to ensure that these levels were all results from screening PSA tests. Of the men with PSA levels greater than 4 ng/mL, 8313 (33%) underwent a biopsy; 468 (6%) had a complication of the biopsy. Of the men who had at least 1 biopsy, 5220 (63%) received a prostate cancer diagnosis during the study period. Of 4284 men treated with radical prostatectomy, radiation, or hormone therapy, 584 (14%) developed incontinence and 588 (14%) developed erectile dysfunction.

That is a lot of adverse effects to have from a screening test that is not recommended because there is no clear benefit. The authors' use of the term *cascade* is instructive. Once a test result is abnormal, it is hard for us (and our patients) to ignore.

It turns out that a PSA test result may not even have to be abnormal to cause a cascade of potentially harmful events. This is illustrated by a clever experiment reported in this issue by Sah et al.⁴ The investigators gave 727 men aged between 40 and 75 years information about prostate cancer and the risks and benefits of prostate biopsy. The men were then randomized into 4 groups. Group 1 received no additional information. Groups 2, 3, and 4 were instructed to imagine that they had undergone a PSA test. Group 2 was

to imagine that the result was normal; group 3, that the result was inconclusive; and group 4, that their PSA test result was abnormal. The survey respondents were then asked whether they would have a prostate biopsy. Even though the men receiving the inconclusive result were told that the result “provides no information about whether or not you have cancer,” men randomized to the inconclusive result were significantly more likely to favor a biopsy than were the men in group 1, who were not given any information at all about their PSA levels (40% vs 25%).

We have seen other occasions when test ordering by itself, without abnormal results, propels more interventions. In a recent *JAMA Internal Medicine* article, Mannis et al⁹ surveyed women who underwent genetic counseling and BRCA testing. Among 690 women for whom BRCA testing was uninformative, 85 (12.3%) nonetheless underwent a risk-reducing salpingo-oophorectomy. Uninformative laboratory results can lead to unproven invasive interventions.

IS INFORMED CONSENT THE ANSWER?

A common and seemingly sensible proposal to eliminate PSA screening testing involves a more rigorous informed consent of the patient. After all, a strong ethical principle of health care is patient autonomy. If patients understand that PSA screening does not seem to increase life expectancy and is associated with adverse effects, most will decline and those who choose the test are making decisions on the basis of their preferences—something we want to encourage. In favor of this strategy, it does not inflame individual physicians, their professional organizations, patients, or their advocacy groups. And documenting a patient's decision not to have the test ameliorates physician concerns about malpractice were they not to order a test and the patient were later to develop the disease.

However reasonable this proposal sounds, it does not work well for several reasons. First, when as a profession did we decide that we had an ethical obligation to offer interventions that cause more harm than good (the current state for men older than 75 years)? When we offer an intervention that is on the whole detrimental, are we not sending our patients a mixed message? Presumably there are any number of interventions that cause more harm than good. Should we be offering our patients a menu of ineffective interventions on the idea that they are better able than we are to determine effectiveness? Second, high-value care for a population means eliminating low-value care. Because the value accrues to the entire population, it makes much more sense to make a broad decision not to offer PSA screening tests and instead to pump our money into interventions of proven benefit (eg, smoking cessation and Papanicolaou tests at appropriate intervals). Third, we already lack enough time to do all the useful preventive counseling that our patients need. Do we want to carve out from that precious time enough time to review with each of our patients the data on risks and benefits of prostate cancer screening? And how many of us are capable of correctly quoting the likelihood of erectile dysfunction and incontinence (age adjusted) to our patients? And are we prepared to do the same for all low-value tests and treatments? Finally, the best way of minimizing the risk of malpractice is to make a systemwide decision not to order a

test; that way, it is no longer the physician's discretion that determines whether a test is ordered.

CONCLUDING THOUGHTS

I spoke recently with a leader of a major academic medical institution. I admire him very much and posed to him the idea of eliminating the PSA screening test in my county safety-net system. As with many men of prostate screening age, he immediately had a gut reaction: he would not be comfortable with that. Why not? He thought that many people disagreed with the USPSTF recommendations, and he knew that many of his male colleagues continued to have PSA tests. I posed to him a different question: If I cannot eliminate PSA testing, for which there is a USPSTF conclusion that the test cannot be recommended for men of any age, what is the likelihood that I could eliminate any low-value test, given that most things are not so well studied with such clear expert advice? That, he thought, was a good question. Much of why the US health care system is so expensive for the benefits we gain is because we do not treat it like a system. If a new test or treatment is approved, we increase premiums to pay for it. Although we are slowly incorporating cost-effectiveness data into medical choices, especially when choosing among drugs used for the same indication or among diagnostic algorithms for evaluating a particular symptom, there is little dialogue about how to divert money from low-value care to higher-value care. Yet that is exactly what must occur if we are to become a high-value health care system. Otherwise, the United States will continue to lag behind other Western countries in the value of our health care.

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