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Informed Consent for PSA Screening: Does It Happen?

CONTEXT. Screening for prostate cancer with serum prostate-specific antigen (PSA) is controversial. Ideally, patients should be aware of the potential benefits and risks related to testing.

PURPOSE. To assess whether patients remembered having PSA screening and to determine whether they recalled having a discussion with their primary care provider about the pros and cons of such testing.

METHODS. A questionnaire was sent to patients who had PSA screening ordered by a primary care practitioner during a 2-month period at a university-affiliated Veterans Affairs medical center. Approximately 3 months after the PSA test was done, patients were asked about their baseline health as well as their knowledge of and attitudes toward screening with PSA and treatment for prostate cancer.

RESULTS. The overall response rate was 197 out of 421 (46%) patients. Among 173 eligible respondents without prostate cancer, 53 (31%) were unaware that their physician had ordered a PSA test. Among the 120 patients who were aware of receiving the test, only 56 (47%) recalled having a discussion with their primary care provider about the risks and benefits of screening. Support for the test was more common among patients who recalled having PSA screening than those who did not recall having the test (91% vs. 70%, respectively; $P = 0.003$).

CONCLUSIONS. Patients who have PSA screening often are unable to recall relevant facts about the test and may have no knowledge of its associated risks and benefits. The role and effectiveness of obtaining verbal informed consent for PSA screening should be re-evaluated.

In 1998, an estimated 184,500 American men received a diagnosis of prostate cancer, and 39,200 were projected to die from the disease.¹ For an individual man, the estimated lifetime risk for developing clinical prostate cancer is approximately 10% and the risk for death is almost 3%.² In an attempt to address this public health problem, screening for prostate cancer with prostate-specific antigen (PSA) and digital rectal examination has been advocated by the American Cancer Society,³ the American Urological Association,⁴ and the American College of Radiology.⁵ These organizations advocate screening partly on the basis of observational evidence that patients with prostate cancer diagnosed in the early stages survive significantly longer than patients with disease diagnosed in more advanced stages. Screening of asymptomatic patients or those with symptoms of benign prostatic hypertrophy has also led to a "stage shift" in the spectrum of newly diagnosed prostate cancer⁶—a higher percentage of cases are now being detected early (i.e., confined to the prostate).

Other organizations, including the U.S. Preventive Services Task Force⁷ and the Canadian Task Force,⁸ do not recommend screening for prostate cancer and emphasize that the (apparent) improved survival can be an artifact of lead-time or length bias.⁹ In addition, no published study to date has documented a survival benefit associated with prostate cancer screening. Moreover, some patients identi-

The abstract of this paper is available at ecp.acponline.org.

fied by screening have clinically indolent tumors and are destined to die with—not of—prostate cancer, and many of these patients will have complications of treatment, including pain, psychological trauma, impotence, incontinence, and sometimes death.

Whether to screen for prostate cancer has engendered considerable debate. In a recent position paper, the American College of Physicians¹⁰ recommended that patients who are screened for prostate cancer understand both the potential risks and benefits. The College states that “routine PSA measurement without a frank discussion of the issues involved is inappropriate.” To examine this issue, we determined whether patients who received screening PSA tests in our primary care clinics recalled having a discussion with their health care provider; such discussions have been described as verbal informed consent¹¹ or “truth in advertising.”¹²

Methods

Potential participants were identified by reviewing the records of the chemistry laboratory at the West Haven campus of the Department of Veterans Affairs Connecticut Health Care System. All patients who had a PSA test ordered by a primary care practitioner in June or July of 1996 were eligible for the study; responses from men with prostate cancer were excluded as nonscreening tests. For the purpose of this research, primary care practitioners included attending physicians and other providers who are supervised by physicians and care for patients in primary care clinics, such as internal medicine housestaff, nurse practitioners, and physicians’ assistants. These clinics are staffed by more than 75 full- and part-time practitioners (including residents) who provide primary care for approximately 8000 patients. Each eligible patient was sent a questionnaire asking about themselves and their knowledge of and attitudes toward PSA screening and treatment for prostate cancer (Appendix 1). Patients were also given a “fact sheet” (Appendix 2) about prostate cancer and PSA screening to read after completing the questionnaire and were asked whether they thought men should be screened with PSA.

The study protocol was approved by the local institutional review board with a requirement that information that could identify respondents not be collected. Because of this stipulation, nonrespondents could not be contacted with repeated mailings or telephone calls. An additional requirement was to mail questionnaires 3 months after PSA measurements were obtained, thereby allowing time for providers to discuss the results of testing with patients.

Data analysis was conducted using SAS software (Cary, North Carolina); all data were key-entered twice and checked for accuracy. Frequency counts and summary statistics were used to report the results of the questionnaire. Differences between groups of patients identified by responses to selected questions were assessed by using the Fisher exact test; “yes” responses were compared with combined “no” and “don’t know” responses.

Results

Of the 425 patients identified as having had PSA measured, 4 had either died or moved without leaving a forwarding address. Of the remaining 421 patients, 197 returned a usable questionnaire, for an overall response rate of 46%. Of these, 24 were excluded because the patients reported having prostate cancer, leaving 173 analyzable surveys. The median age of respondents was 69 years (range, 39 to 84).

Table 1 shows the self-reported health characteristics of the 173 analyzable patients who responded to the survey. Fifty-three percent indicated that their overall quality of life was fair or poor, and 68% stated that their health was fair or poor. Thirteen percent of patients reported having a family history of prostate cancer in a first-degree relative, and 51% stated that they had told their physicians that they were having frequent nocturia or difficulty passing urine. Regardless of whether patients were aware of having PSA screening, 92% of respondents recalled having had a digital rectal examination within the previous year.

Figure 1 shows that 31% of respondents were unaware that their physician had ordered PSA testing. Thirty-seven percent were aware of the test but

TABLE 1
Questionnaire Responses among All Respondents

RESPONSE	RESPONDENTS, % (n/n)
Quality of life fair or poor	53% (91/171)
Health status fair or poor	68% (116/170)
History of prostate cancer in father or brothers	13% (23/173)
Frequent nocturia or difficulty urinating	51% (86/169)
Reported having digital rectal examination within the past year	92% (159/173)
Aware that PSA screening was done	69% (120/173)

did not recall having a discussion with their physician, and 32% were aware of receiving the test and recalled a discussion with their physician about the test.

Table 2 shows the responses of the 120 patients who were aware of receiving a PSA test. Sixty-eight percent stated that the test was recommended by their health care provider, 22% reported that they (the patient) suggested having the test performed, 7% claimed that both the health care provider and the patient were involved in the decision, and 4% of patients did not respond or did not recall whose idea it was. Among this subset of patients who recalled being screened, 16% reported that their wife or girlfriend influenced their decision to receive screening, 9% were influenced by other family members, 13% were influenced by other persons, and 62% reported that no one else influenced their decision.

We also determined whether patients recalled being counseled about potential problems of PSA testing. Among the 120 respondents who were aware of PSA testing (**Table 2**), only 47% recalled having a discussion with their health care provider about the potential risks and benefits of PSA testing, including subsequent events related to treatment for prostate cancer. Among this group, 57% said they were told that not all elevated PSA levels are caused by prostate cancer, 29% knew that treatment of prostate cancer confined to the prostate has not been shown to improve survival, 50% recalled being told that treatment of prostate cancer could lead to impotence, and 48% were aware of potential urinary incontinence.

The questionnaire also included a fact sheet about PSA screening and treatment of prostate cancer. In this context, patients were asked whether they thought men should be screened. Of the 157 patients who responded to this question, 85% agreed that

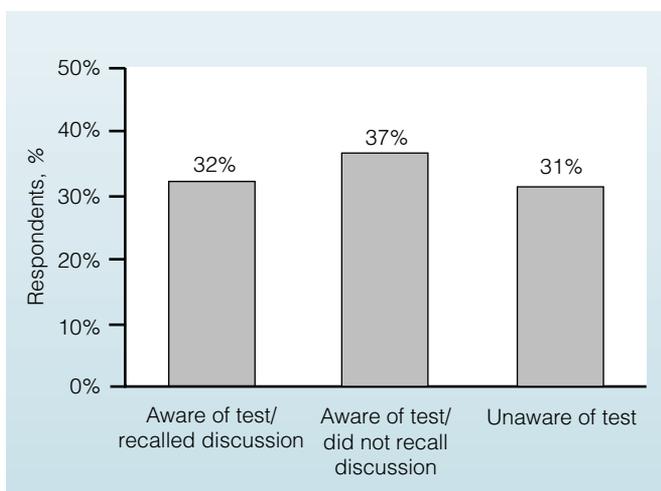


FIGURE 1. Questionnaire response in analyzable patients ($n = 173$).

TABLE 2

Questionnaire Responses among Respondents Aware of Testing

QUESTION AND RESPONSE	RESPONDENTS, %
Who recommended the PSA test? (n = 120)	
Provider	68%
Patient	22%
Patient/provider	7%
Did not recall/no response	4%
Who else influenced the decision? (n = 120)	
Wife/girlfriend	16%
Family member	9%
Other persons	13%
No one else	62%
If your physician discussed risks and benefits of PSA testing (n = 56), did he or she mention that:	
Abnormal PSA levels could result from another condition?	57%
Treatment may not prolong life?	29%
Treatment may cause impotence?	50%
Treatment may cause incontinence?	48%

physicians should screen with the PSA test. We did not find clinically or statistically significant associations between patients' attitudes toward PSA testing and their self-assessment of overall quality of life, health status, or presence of urinary symptoms (**Table 3**). Patients were more likely to agree with PSA testing if they recalled having had a PSA test done compared with those who did not know that they had received the test (91% vs. 70%, $P = 0.003$).

Discussion

Almost one third of patients at a primary care clinic were unaware that they had received a screening PSA test, and among patients who were aware of having the test done, fewer than half recalled having a discussion about the associated benefits and risks. Because a positive screening test result, which is usually followed by a prostate biopsy, inevitably leads to a diagnosis of cancer and subsequent treatment in a subset of men, we also asked about knowledge of events that may accompany

treatment. We found that most men did not know that treatment of localized prostate cancer has not been shown to increase survival and can lead to impotence and incontinence. The results indicate that, in most cases, the process of verbal informed consent between patients and health care providers was either ineffective or not done.

For this study, we selected men who received PSA screening tests as the focus of investigation because these men represent the group most likely to be aware of screening and its benefits and risks. In a similar study,¹³ more than half of 369 patients who received PSA testing at either of two Veterans Affairs medical facilities in California had not heard of the PSA test and were unaware of having the test done. Our study protocol allowed at least 3 months to elapse between PSA measurement and when the patients received their questionnaires, thereby giving providers an opportunity to explain the results to each patient and to obtain a “stable” measurement of the patient’s knowledge. The question of what was actually discussed during a patient encounter—that is, what the doctor said versus what the patient remembers, is a topic for future investigation. Our results indicate, however, that the educational efforts, if conducted, were ineffective in achieving lasting knowledge.

After reading a fact sheet that described potential problems associated with screening and treatment for prostate cancer, most of our patients (85%) thought that physicians should perform PSA screening. A significant difference about patients’ attitudes toward PSA testing was found between patients who knew that they had had PSA testing (more likely to agree with screening) and those who did not (less likely to agree with screening). This finding may reflect patients’ tendency to support their or the provider’s decision about PSA screening.

Our results are not directly comparable to those of another investigation¹⁴ of university-affiliated primary care practices in which patients who received a simulated informed consent presentation were significantly less interested in PSA screening than those who did not receive the intervention. Another investigation¹⁵ randomly assigned men who were 50 years of age or older to view a patient education videotape on PSA testing, another videotape, or no videotape. Men who viewed the educational videotape were better informed about PSA testing, prostate cancer, and its treatment and were less likely to prefer screening. We do not know how many of our patients would have declined PSA testing if given a fact sheet or videotape before screening.

Limitations of our study include a modest overall response rate (46%). Even if all nonrespondents were well informed, however, a substantial proportion of men would still not recall having had PSA testing (53/421 = 13%). In

TABLE 3		
Association of Patient-Related Factors and Support for PSA Screening (n = 157)		
FACTOR	RESPONDENTS SUPPORTING PSA SCREENING	P VALUE
Health status		
Good or excellent	92%	P = 0.10
Fair or poor	81%	
Quality of life		
Good or excellent	89%	P = 0.19
Fair or poor	81%	
Urinary symptoms		
Yes	85%	P > 0.2
No	85%	
Aware of receiving test		
Yes	91%	P = 0.003
No	70%	

addition, our institutional review board did not allow us to obtain information that would identify individual patients. Accordingly, our study does not include data with which to compare characteristics of respondents and non-respondents to the questionnaire and the knowledge and attitudes of men who did not respond are unknown. It is also likely that some men in the same clinics had (and would have recalled) a discussion with their provider that led to a decision to forgo screening, but such men were not identified by our study. Finally, findings from surveys conducted at a single institution may or may not be generalizable to other practice environments. Our patients and providers were potentially more aware of relevant facts than others in different settings, however, because the issue of screening for prostate cancer has received prominent attention in faculty discussions and housestaff clinic conferences and is a focus of patient education materials.

In the future, we expect newer approaches of shared decision making using patient education videotapes^{16, 17} to be evaluated in the context of screening for prostate cancer. Another topic of interest is whether some patients would rather *not* be given educational information that introduces uncertainty and may be confusing. In our clinical experience, some patients’ preferences are reflected by the statement, “You’re the doctor, tell me what to do.” Finally, an unanswered clinical question is whether patients with substantial comor-

bid conditions—such as most of our population with self-reported fair or poor quality of life and health status—are unlikely to benefit from PSA screening even if it is potentially effective for younger, healthier men.

Conclusions

Patients often have PSA screening without being able to recall relevant facts about the associated benefits and risks. Although the goal of obtaining verbal informed consent is attractive in theory, we found its use to be limited in practice. Primary care practitioners may understandably find it difficult to conduct a time-consuming discussion with patients about PSA screening while addressing the patient's chief complaint and pre-existing conditions in an era of 15- to 30-minute patient encounters and a lengthy checklist of health maintenance items. In addition, the impact of educational efforts, even when done, may be modest and short-lived. The current study suggests that the practice of conducting verbal informed consent should be evaluated further in terms of its role and effectiveness in the primary care setting.

Take-Home Points

- Among men in a general medicine clinic who received screening for prostate cancer with PSA, almost one third were unaware that their provider had ordered the test.
- Among patients who knew that PSA testing was done, fewer than half recalled having a discussion with their provider about the benefits and risks of testing.
- In our clinical setting, discussions about PSA screening were either ineffective or did not occur.
- The role and effectiveness of obtaining verbal informed consent for PSA testing should be re-evaluated.

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Appendix 1: Patient Questionnaire

Questions Regarding Patients' Knowledge of and Attitude toward Prostate-Specific Antigen Testing

1. How do you rate your overall quality of life at this time? Consider anything that is important to you, such as your health, your family, and your job. (excellent, very good, good, fair, poor)
2. How do you rate your physical health at this time? Consider your baseline health; do not consider a recent cold, sprained ankle, or similar problems. (excellent, very good, good, fair, poor)
3. Have you ever been told by a doctor or nurse practitioner that you have prostate cancer? (yes, no, don't know)
4. Do your father or brother(s) have (or did they have) prostate cancer? (yes, no, don't know)
5. Have you ever told your doctor that you've experienced difficulty passing your urine, or that you wake up frequently at night to urinate? (yes, no, don't know)
6. In the past year, has a doctor (or nurse practitioner) performed a rectal exam during a clinic visit? (yes, no, don't know)
7. To your knowledge, have you ever had a blood test called PSA (prostate-specific antigen) to screen for prostate cancer? (yes, no, don't know)
8. Whose idea was it to send the PSA test to screen for prostate cancer? (doctor's, mine [patient's], don't know)
9. Did anyone else influence your decision either to be screened or not to be screened for prostate cancer? (wife, girlfriend, other family member, other person, no one, don't know)
10. Prior to ordering the PSA test, did your doctor (or nurse practitioner) discuss the benefits and risks of the test with you? (yes, no, don't know)

If "Yes" to question 10, did he/she mention that:

11. A - Not all elevated PSA blood tests are caused by prostate cancer? (yes, no, don't know)
B - For prostate cancer that has not spread outside of the prostate, treatment has not been shown to make you live longer? (yes, no, don't know)
C - Treatment of prostate cancer can lead to impotence (inability to have an erection)? (yes, no, don't know)
D - Treatment of prostate cancer can lead to urinary incontinence (inability to control your urine)? (yes, no, don't know)

If "Yes" to question 7:

Appendix 2: Patient Fact Sheet

Facts about Screening for Prostate Cancer

- The American Cancer Society and the American Urologic Association recommend that men over 50 years of age receive screening each year for prostate cancer with a blood test called prostate-specific antigen (PSA).
- Another "official" organization, the U.S. Preventive Services Task Force, does not recommend screening for prostate cancer with the PSA test.

Facts about Prostate Cancer

- Prostate cancer is the second most common cause of cancer-related death in U.S. men; this year, about 35,000 deaths were linked to prostate cancer.
- At least 3 of 10 men over 50 years of age are thought to have at least "microscopic" evidence of prostate cancer (that is, a small number of cancerous cells that may or may not cause harm).
- To date, no evidence exists to show that treating prostate cancer confined to the prostate, with either surgery or radiation therapy, leads to improved survival.
- For every 100 men treated with surgery for prostate cancer confined to the prostate, about 1 to 2 will die related to the surgery, 6 will lose the ability to control their urine, and 25 will become impotent (that is, will become unable to have erections).
- For every 100 men treated with radiation therapy for prostate cancer confined to the prostate, about 0 to 1 will die related to the radiation, 3 will lose the ability to control their urine, and 25 will become impotent (that is, will become unable to have erections).

We hope this information helps you understand the possible benefits and risks associated with screening for prostate cancer. Based on this information, do you agree that doctors should screen for prostate cancer with the PSA blood test? (strongly agree, agree, not sure, disagree, strongly disagree)