Informed consent decreased patient interest in prostate-specific antigen screening


Objective
To determine the effect of informed consent on patient interest in having prostate-specific antigen (PSA) screening.

Design
Randomized controlled trial.

Setting
4 university-affiliated primary care practices in the United States.

Patients
205 English-speaking men (mean age 65 y) visiting their primary care physicians for outpatient appointments. Exclusion criteria were previous PSA screening or history of prostate cancer.

Intervention
103 patients were allocated to a 3-minute scripted overview of PSA screening read aloud by a trained research assistant (intervention group), and 102 patients were allocated to a brief statement (2 sentences), which said that a blood test known as PSA is available and can sometimes detect early prostate cancer (control group). The information intervention included data on the lifetime probability of developing and dying from prostate cancer, known risk factors for prostate cancer, and the ability of the PSA test to detect early asymptomatic cancer.

Main outcome measure
Interest in PSA screening measured on a 5-point Likert scale (from definitely not interested to definitely interested).

Main results
On the 5-point scale, mean interest in PSA screening was 3.0 in the intervention group compared with 3.8 in the control group ($P < 0.001$). Compared with patients in the control group, patients who received the intervention were much more likely to indicate that they had no interest in PSA screening (odds ratio [OR] 2.11, 95% CI 1.06 to 4.18, $P = 0.04$) and were much less likely to indicate that they had high interest in PSA screening (OR 0.34, CI 0.19 to 0.60, $P < 0.001$). In a multivariate model, the intervention was the strongest predictor of interest in PSA screening and was associated with decreased interest in PSA screening (OR 0.32, CI 0.19 to 0.54, $P < 0.001$). Family history of prostate cancer was associated with increased interest in PSA screening (OR 3.95, CI 1.52 to 10.3, $P = 0.005$), and advanced age was associated with decreased interest in PSA screening (OR 0.97 per y of age, CI 0.94 to 1.00, $P = 0.04$).

Conclusion
Informed consent decreased patient interest in prostate-specific antigen screening.

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Much controversy exists about the use of PSA for routine screening of prostate cancer. At the heart of the controversy is the fact that no randomized trial has ever shown that routine PSA screening improves life expectancy or quality of life (1). The question that has yet to be answered by a randomized trial is: Does routine PSA screening do more harm than good (2, 3)?

Trials are currently examining the benefit of routine PSA screening. Until we have conclusive evidence from these trials, clinicians will have to make recommendations to their patients. This well-designed trial by Wolf and colleagues outlines a method to assist clinicians and patients in dealing with these uncertainties. The method involves patients in the decision-making process and investigates the effect of formal informed consent. The authors found that patients who received the information intervention were less likely to ask for the test than were those who did not receive information. Interestingly, 2 other variables were also independent predictors of interest in PSA screening: A family history of prostate cancer was linked to increased interest, and increased age predicted decreased interest. Before applying the results of this study, the reader must be aware of the exact content of the script offered to both groups because slight changes in either script could have significantly affected the study results. For example, the 2-sentence script given to the control group emphasized the benefit of PSA screening, perhaps encouraging more of the control patients to choose PSA screening. A slight change in wording may have caused fewer patients to select PSA screening and reduced the difference between the 2 groups. In fact, the sentences offered to the control group did not constitute a true control. A true control group would not have been given any information about PSA.

Until conclusive evidence is available about the benefits of PSA screening, this study highlights the importance of removing "the routine" from PSA screening and allowing patients to make informed decisions.

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References