The Evaluation and Treatment of Men with Asymptomatic Prostate Nodules in Primary Care: A Decision Analysis

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Background. Whether to perform periodic rectal examinations in asymptomatic men as a screening test for prostatic cancer remains controversial. A randomized clinical trial that tests the efficacy of further evaluation and treatment of men who have been found to have asymptomatic prostate nodules may never be carried out. Decision analysis was therefore used to further investigate this clinical issue.

Methods. A decision tree was developed to model the decision of whether to biopsy an asymptomatic prostate nodule found by digital rectal examination in a 65-year-old man by his primary care physician. Test operating characteristics, probabilities of disease at different stages, probabilities of side effects from various treatments, and average life expectancies were obtained from the medical literature. Utilities for the various possible health outcome states were obtained from ratings by two experienced primary care physicians using the Kaplan-Anderson Quality of Well-Being Scale. These were used to adjust the quality-of-life expectancies for each outcome state. Multiple sensitivity analyses were performed to assess the robustness of the conclusions.

Results. Disregarding patient utilities, the average survival benefit of evaluation and treatment is 1.1 months. When quality-of-life adjustments are included in the analysis, evaluation and treatment results in an average loss of 3.5 quality-adjusted months of life. Factors that shift the decision toward evaluation and treatment include a positive predictive value of a prostate nodule for cancer of 49% or greater, specificity of prostate biopsy of 98.3% or greater, and the availability of much more effective treatment for stage D cancers. Factors that do not substantially affect the decision are cancer-free life expectancy, the percentage of cancers that are stage B at time of discovery, the sensitivity of prostate biopsy, and more effective treatment for stage C cancer, assuming the same rate of adverse consequences from treatment.

Conclusions. The evaluation and treatment of prostatic nodules found by digital rectal examination in asymptomatic men in the primary care setting does not lead to significant improvement in life expectancy and adversely affects quality of life. Digital rectal examination should not be performed by primary care physicians as a screening test for prostate cancer.

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Screening for prostate cancer by currently available methods has not been recommended by the US Preventive Services Task Force,[1] the Canadian Task Force,[2] or Frame.[3] An annual digital rectal examination beginning at age 40 years for the early detection of both rectal and prostate cancer is, however, recommended by both the American Cancer Society[4] and the National Cancer Institute.[5] Many primary care physicians do a digital rectal examination as part of a complete physical examination.

Much of the data on which the estimated predictive value of the digital examination of the prostate is based come from selected populations (eg, urology clinics,[6] urology inpatients,[7] or specific prostate cancer screening programs[8,9]) in which the prevalence of clinical disease appears to be 2 to 10 times higher than in populations undergoing multiphasic screening.[10] Estimates of the

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sensitivity and specificity of the test are flawed by an absence of biopsy results from persons with normal prostate examinations.

No randomized prospective trials examining the value of prostate cancer screening (eg, using survival or quality-adjusted survival as outcome measures) have been reported. Such a study would require that half of those enrolled either not have a prostate examination at all or not be told the result of their examination. There might be concerns that such a study would be unethical.

Love and Fryback[11] have reported the results of a cost-effectiveness analysis of prostate cancer screening by digital rectal examination. Based on the assumptions that (1) 50% of prostate nodules are cancerous, (2) 50% of stage B cancers would be detected by rectal examination, and (3) all stage B cancers would be cured with treatment, they estimated a maximum average gain in life expectancy of 45 days per patient screened. Patient utilities were not included in the analysis.

We attempted to model, using decision-analysis techniques, the potential consequences of the evaluation and treatment of an otherwise healthy, asymptomatic 65-year-old patient found by his primary care physician on routine physical examination to have a prostate nodule. Quality-of-life adjustments were included in the analysis.

Methods

A standard decision analysis was performed. This analytic method is useful for evaluating clinical options under conditions of uncertainty.

Computer software. The decision tree was constructed and all analyses were performed using SMLTREE software (a commercially available software package).

Decision tree structure. The major branches of the decision tree are shown in Figures 1 to 4. The entire tree with all of its minor branches can be obtained in printed form or on a computer disk on request from the authors.

Clinical assumptions. Table 1 lists the assumptions used in the analysis, including probabilities, life expectancies, and quality-adjusted life expectancies. In the case of treatment complications where a range of values was reported, we chose values in the lower mid-range based on the assumption that treatment techniques are improving but that the very best values can only be achieved under ideal conditions. A number of these estimates were systematically varied in one-way sensitivity analyses (Table 2). Sensitivity analysis involves changing the value of one variable estimate at a time in order to see if the decision changes. If the decision analysis yields approximately the same result over a wide range of variable

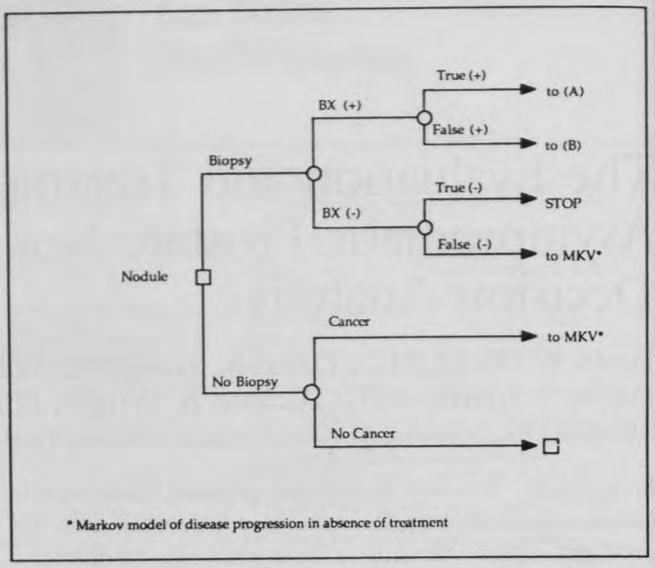

Figure 1. Decision tree modeling the choice between biopsying or not biopsying a suspect prostate nodule. BX denotes biopsy.

values, we can say that the decision is robust to the uncertainty in the variable estimates.

The prevalence of clinically significant prostate cancer detectable by rectal examination in asymptomatic 65-year-old men seen by primary care physicians was estimated to be 0.3%. This figure was based primarily on the results of a large multiphasic screening program reported by Gilbertsen.[10] Higher prevalence figures, 1% to 2%, quoted in some studies probably reflect selection bias.[6,8,9] In these studies, the predictive value of a posi-

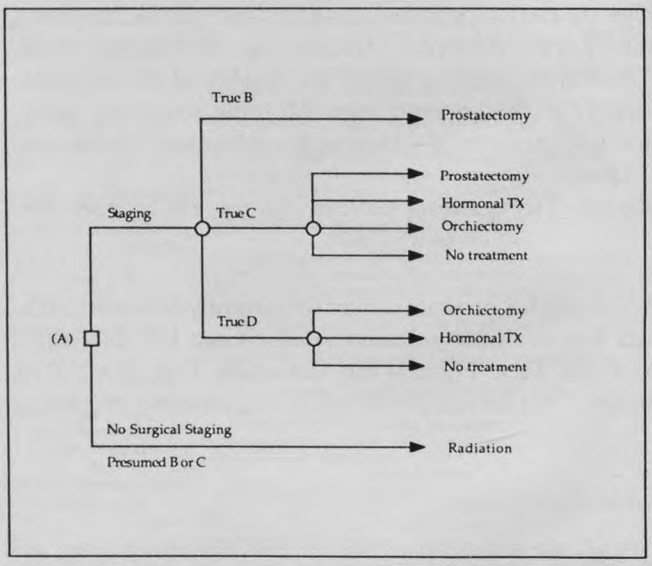

Figure 2. Decision tree branches modeling the choice between clinical and surgical staging and treatment versus clinical staging and radiation therapy for patients with true-positive biopsies. TX denotes treatment.

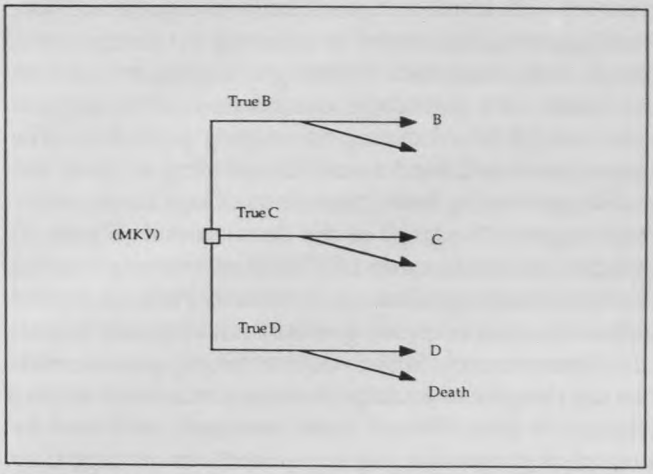

Figure 3. Decision branches modeling the outcomes of patients with undetected and untreated cancers using a Markov (MKV) process.

tive digital prostate examination was 26% to 34%. Sufficient information was not available in Gilbertsen's report to calculate positive predictive value. We estimated it to be 10% for patients screened by family physicians (approximately one third of the number reported for urology clinic populations).

The presence or absence of cancer in a prostate nodule is ordinarily determined by the results of a transrectal needle aspiration biopsy. This test has a sensitivity of 82% and a specificity of 85% when compared with the transperineal punch biopsy.[19] The sensitivity can be improved by about 10% by repeating the test. The specificity of the test is limited by difficulties in distinguishing benign, atypical prostatic cells from well-differentiated carcinoma cells, and by the high prevalence of latent

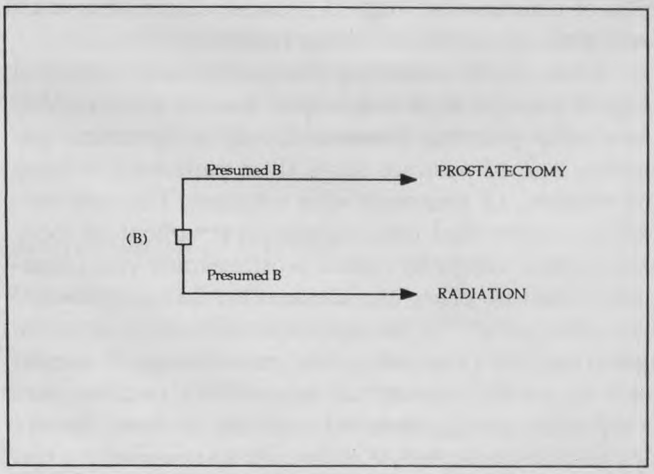

Figure 4. Decision branches modeling the choice between prostatectomy and radiation therapy for patients with false-positive biopsies (presumed stage B cancers).

Table 1. Assumptions Used for the Base-Case Analysis Based on the Medical Literature

Prostate Cancer Stage, Treatment, and Consequences	Patients (%)	Life Expectancy (y)	Quality-Adjusted Life Expectancy (y)
Stage B[12,13]	30		
Prostatectomy			
Death[14,15]	2	0	0
Thromboembolism, survive[15]	10	14.2	13.2
Impotence[16]	20	14.2	8.5
Incontinence[13]	5	14.2	7.9
Rectal injury[15]	3	14.2	9.6
Urethral stricture[14,15]	10	14.2	9.2
No adverse effects	50	14.2	13.2
Radiation			
Impotence[13,15,16]	40	14.2	8.5
Incontinence[15]	8	14.2	7.9
Gastrointestinal complications[13,15]	12	14.2	7.9
Urethral stricture[13,15]	6	14.2	9.2
Lymphedema[13,15]	10	14.2	7.6
No adverse effects	24	14.2	13.2
Stage C[12,13]	20		
Prostatectomy			
Death[14,15]	2	0	0
Thromboembolism, survive[15]	10	8.2	7.6
Impotence[16]	20	8.2	4.6
Incontinence[13]	5	8.2	4.6
Rectal injury[15]	3	8.2	5.6
Urethral stricture[14,15]	10	8.2	5.3
No adverse effects	50	8.2	7.6
Orchiectomy			
Impotence[17]	100	8.2	4.6
Hormones			
Impotence[18]	50	8.2	4.6
No adverse effects	50	8.2	6.3
No treatment		7.7	6.0
Radiation†			
Impotence[13,15,16]	40	8.2	6
Incontinence[15]	8	8.2	4.6
Gastrointestinal complications[13,15]	12	8.2	4.6
Urethral stricture[13,15]	6	8.2	5.3
Lymphedema[13,15]	10	8.2	4.4
No adverse effects	24		7.6
Stage D[12,13]	50		
Orchiectomy			
Impotence[17]	100	2.6	1.4
Hormones			
Impotence[18]	50	2.6	1.4
No adverse effects	50	2.6	1.9
No treatment		2.6	2.0
Radiation†			
Impotence[13,15,16]	40	2.6	1.5
Incontinence[15]	8	2.6	1.4
Gastrointestinal complications[13,15]	12	2.6	1.4
Urethral stricture[13,15]	6	2.6	1.7
Lymphedema[13,15]	10	2.6	1.4
No adverse effects	24	2.6	.3

**Superscript citations refer to studies found in the References section at the end of the paper.*
†Radiation done without surgical staging.

Table 2. Sensitivity Analyses for Selected Assumptions

Variables	Model Assumptions (%)	Range of Values Tested (%)	Threshold (%)
Predictive value of a positive rectal examination	10.0	0–50	49
Specificity of biopsy	85.0	0–100	98.3
Sensitivity of biopsy	82.0	0–100	Not found
Probability of stage B	30	0–100	Not found
Probability of stage C	20	0–100	Not found
Probability of stage D	50	0–100	Not found
Probability of impotence after resection	20.0	0–60	Not found
Probability of impotence after radiation	40.0	0–60	Not found
Life expectancy	14.2	10–25	Not found

(stage A) carcinomas in elderly men.[20–23] No well-designed study was found that compared needle aspiration with operative or postmortem histologic findings. Those studies attempting to do so suffer from a lack of explicit criteria for classification of true positives.[24–27] Transrectal needle aspiration is associated with a 4.4% incidence of prostatitis, epididymitis, or hematuria.[19]

The modified Whitmore-Jewett staging criteria for adenocarcinoma of the prostate gland are shown in Table 3. More recent staging criteria incorporating pathologic grading could not be used for this analysis because of lack of sufficient published outcome data. Clinical staging is based on information obtained from physical examination, blood tests, chest radiographs, and pelvic computed tomography scans. Surgical staging is done when the cancer is thought clinically to be stage B (surgically resectable). It involves exploration of the gland and surrounding structures as well as unilateral or bilateral pelvic lymph node dissection. Pathologic staging is based on the results of a pathologic examination of the surgical specimens obtained during the staging procedure. The stages shown in Table 1 assume that clinical, surgical, and pathologic staging have been done. They are therefore "true stages." "Staging" in the decision tree (Figure 2) includes the combination of clinical and surgical staging or clinical staging alone as indicated. Patients treated with radiation therapy are generally not surgically staged.

Table 3. Modified Whitmore-Jewett Criteria for Staging Adenocarcinoma of the Prostate

Cancer Stage	Criterion
Stage A	Microscopic areas of cancer confined to the gland found in pathologic specimens
Stage B	Macroscopic areas of cancer (associated with a nodule) confined to the gland with no penetration through the capsule of the gland or elsewhere
Stage C	Cancer that has spread through the capsule of the gland and may involve other local structures such as the seminal vesicles but has not yet metastasized to other sites
Stage D	Cancer that has metastasized to the pelvic lymph nodes, bones, or other distant sites

Approximately 50% to 60% of biopsy-positive nodules are thought to be stage B cancers by clinical staging criteria. At least 30% of these, however, are found by surgical or pathologic staging, or both, to be stage C or D.[12,28–30] Retrospectively, 7% to 10% of pathologic stage B cancers were probably in fact stage C or D, based on the rate of recurrence after radical prostatectomy.[28,29] Thus, 10% of prostate nodules found by a family physician are caused by prostate cancer, and only about one third of those that are cancerous are stage B cancers. Conversely, 97% of asymptomatic primary care patients with prostate nodules do not have stage B prostate cancer ($100\% - [10\% \times 33\%]$).

Only stages A and B cancers are known to be curable using either radical prostatectomy or radiation therapy. Since stage A cancers cannot be detected by rectal examination, and most require no treatment, they were ignored for the purposes of this analysis. For stage B cancers, actual cure rates are difficult to ascertain since repeat surgical explorations are not routinely done on prostatectomized patients, and since patients treated with radiation therapy rarely have surgical or pathologic staging before treatment. The determination of treatment benefit is made even more difficult because as many as 50% of patients with stage B prostate cancer do not die from their cancer even without treatment.[30–32]

Most studies reporting the outcomes of untreated stage B patients were not helpful for our purposes because of population bias (eg, mostly symptomatic patients), lack of accurate surgical or pathologic staging information, or treatment with estrogen. The only randomized controlled trial comparing treatment of localized prostate cancer by radical prostatectomy vs no treatment found no effect of treatment on 5-year survival.[33] Uncontrolled studies of radical prostatectomy or radiation treatment of histologically proven stage B tumors have shown 15-year survival rates of 50% to 60%, rates comparable to age-matched controls without known prostate cancer.[28–30,34] We assumed that successful surgical or radiation therapy for true stage B cancer is associated with a normal life expectancy.

A Markov process, a commonly used model of pro-

gression through multistate disease processes, was used to model the progression of untreated patients from stage B to stage C to stage D. The constant annual rate of progression from stage B to stage C used was assumed to be approximately 13% (transition probability), and the same from stage C to D. The constant annual mortality rate in stage D patients was estimated to be about 28%.

In the decision tree, choice of treatment was modeled as a decision node. This reflects the clinical reality that physicians can select from available treatment options. The use of a decision node for the treatment choice in this case meant that the software program evaluated all available treatment options and always selected the one resulting in the best outcomes. For example, all stage B patients in the model received surgical staging and prostatectomy, since radiation therapy was found to be an inferior option based on a higher rate of complications adversely affecting quality of life.

Average life expectancies for patients with stages C and D prostate cancer were estimated from 5-, 10-, and 15-year survival data in the literature using the DEALE formula.[35] Currently there is no conclusive evidence that treatment of patients with stage C or D prostate cancer during the asymptomatic phase of their disease prolongs survival.[1,15] While there is some evidence that modern hormonal therapy increases survival by a few months in patients with advanced symptomatic disease,[36] there may be no advantage conferred by treatment in the asymptomatic phase of the disease. We have therefore assumed no benefit from treatment of patients with asymptomatic stage D tumors. For stage C patients we arbitrarily assumed that treatment by either surgery or radiation yields an average survival benefit of 6 months. To allow for the possibility of additional treatment benefit, however, sensitivity analyses were done for both stages C and D cancers.

Assumptions regarding the incidence of complications associated with radical prostatectomy, radiation therapy, and hormonal treatment were based on the most recent information available regarding current treatment modalities.

Determination of Utilities

The various treatment modalities yield clinical results that vary in their effects on the quality of the patient's life. Patients have different preferences (ie, "utilities") for these various health states. Estimated utilities for the various terminal outcomes were determined using the Kaplan-Anderson Quality of Well-Being Scale (QWB).[37]

Two experienced primary care physicians used the QWB to rate the utilities of the various outcome states in the tree. Their ratings were then averaged, and these mean ratings were used in our base-case analyses. QWB scores for each terminal branch of the decision tree were multiplied by life expectancy for that branch to obtain the number of quality-adjusted life years (QALYs). This scale has been devised to yield quantitative values for the quality of life lived in various health states.

Table 4. Itemized Consequences of Full Evaluation and Treatment of 100 Men with Prostate Nodules

Evaluation/Treatment	No. of Patients
Prostate biopsies done	100
Clinical staging evaluations	23
Surgical staging evaluations	19
Radical prostatectomies	17
Stage B cancers correctly identified and cured	3
Average years of life gained	2.7
Stage C cancers correctly identified and treated	2
Average years of life gained	0.5
Stage D cancers correctly identified and treated	5
Average years of life gained	0
Stage B cancers incorrectly identified and treated	13

Results

Disregarding estimated utilities, the decision to fully pursue the evaluation and treatment of all prostate nodules using our base-case assumptions yielded an average gain in life expectancy of 1.1 months (13.48 years [biopsy] vs 13.39 years [no biopsy]). Inclusion of estimated utilities in the analysis resulted in an average *loss* of 3.5 months of quality-adjusted years of life (13.0 QALYs [biopsy] vs 13.29 QALYs [no biopsy]).

The results of sensitivity analysis of the positive predictive value of a prostate nodule for cancer are shown in Table 2. A threshold was found at 49%. That is, if more than 49% of prostate nodules are cancerous, then full evaluation and treatment is favored. The threshold for specificity of prostate biopsy is 98.3%; for values higher than this, evaluation and treatment is favored.

Thresholds for efficacy of treatment for stages C and D cancers were not found. No other thresholds were found by sensitivity analyses as shown in Table 2. This means that the base-case results of the decision analysis are quite robust to the uncertainty inherent in most of the variable estimates.

Some of the consequences of fully evaluating and treating 100 men with prostate nodules are listed in Table 4. Although evaluation and treatment increased length of life in five men, it led to unnecessary procedures and consequences in many others. No attempt was made

to estimate the psychologic impact of the early diagnosis of cancer on those for whom treatment during the asymptomatic period provided no substantial benefit.

Discussion

A frequent consequence of decision analysis is the discovery of missing data, information that should be taken into account in the decision but that is simply not available. For primary care decision making, information on prevalence of disease and predictive values of tests are vital, and yet too often they have never been determined. Prostate cancer screening by rectal examination is a good example. Most of the reported screening studies have used populations so different from those seen by family physicians that the results are simply not applicable. In this case, we are reasonably confident about our prevalence estimate, which was derived from the multiphasic screening project reported by Gilbertsen.[10] The positive predictive value of prostate examination for cancer, however, could only be estimated because of the lack of reliable information on the sensitivity and specificity of the rectal examination for prostate cancer. Fortunately, sensitivity analysis demonstrated that increasing the value that we chose to use, 10%, by a factor of up to 4.9 does not affect the decision.

It is important to point out that although a threshold of 49% was found for positive predictive value, the slopes of the lines describing the biopsy and no biopsy options were so similar that the decision is approximately neutral at all levels of predictive value. That is, very little quality-adjusted life is gained by evaluation and treatment even when the predictive value of the screening test is above 50%.

In a recent trial of prostate cancer screening reported by Catalona et al[38] in which serum prostate-specific antigen (PSA) levels above 4 μg/L were used as an initial screen before prostate examination and prostatic ultrasonography, the positive predictive value was 33%. Raising the PSA cutoff level to 10 μg/L increased the positive predictive value to 67%. However, no staging information was reported for these latter patients, who by virtue of their higher PSA levels would be more likely to have advanced disease. The prevalence of detectable cancer in the study population of well over 2%, almost seven times higher than that of the Gilbertsen study, once again suggests considerable selection bias. This is understandable since patients were recruited specifically to participate in a prostate cancer screening study. Therefore, the implications for this sort of screening protocol in a primary care setting is, at best, uncertain. Another approach might be to measure PSA only in those patients with nodules, and then biopsy those with both nodules and elevated PSA.

A threshold value of 98.3% was found for specificity of prostate biopsy. That is, if more than 98.3% of cancer-negative patients had negative biopsy results, the decision analysis would favor evaluation and treatment. Problems associated with increasing the specificity of prostate biopsy have been mentioned earlier. Our base-case estimate of specificity, 85%, though based on the best data that we could find, is bound to be controversial.

Maksem et al[39] have stated that "an outright positive cytologic diagnosis of carcinoma, in the presence of a simultaneously negative histologic result and in the absence of prostatitis, cannot be dismissed as a false positive if the aspirate was correctly obtained and processed and the pathologist is experienced in cytodiagnosis of the prostate." Based on autopsy studies, however, more than one third of 65-year-old men have focal areas of prostate cancer unassociated or only coincidentally associated with nodules, 60% to 70% of which are peripheral.[20,22] Thus, as pointed out by Ansell,[23] if one were to blindly biopsy the prostate gland of a 65-year-old man without a nodule, cancer could be expected to be found 5.4% of the time. We therefore acknowledge the possibility that the true specificity is greater than 85%, but doubt that it is greater than 98.3%.

A new biopsy procedure may soon replace aspiration biopsy as the method of choice. This sampling method employs an intermediate-caliber needle (larger than for aspiration but smaller than for core biopsies) in a spring-loaded biopsy gun.[40] Multiple samples, usually in a gridlike distribution, can be obtained with little pain or bleeding. The sensitivity and positive predictive value for this procedure are reportedly higher than for aspiration. It can be expected, however, to detect a greater number of latent cancers. Therefore, specificity will still be a significant concern.

It is worth reiterating that sensitivity analyses performed on several other variables (Table 2) found no other thresholds. We conclude that our base-case results are quite stable. That our findings are quite similar to those of Love and Fryback,[11] who used very different base-case assumptions, adds credence to the robustness of the decision.

Although the newer criteria for staging and pathologically grading prostate cancer give more accurate prognostic information, they generally do not affect treatment choices for the cancers addressed in our analysis. Both well-differentiated and poorly differentiated nodular cancers confined to the gland are still treated with radical prostatectomy. Controversy continues regarding the relative effectiveness of radiation therapy for stage B prostate cancer. In our analysis, prostatectomy

was the preferred treatment, even though we assumed the two forms of therapy to be equally efficacious, primarily because of the greater risk of impotence associated with radiation therapy.

There has been recent excitement regarding the potential for blocking the effects of androgen on the prostate almost completely by using a combination of leuprolide and flutamide.[36] In fact, in a small group of patients with symptomatic advanced metastatic disease, treatment led to a survival benefit of greater than 3 months. However, until a survival benefit has been demonstrated for asymptomatic patients that is greater than that which can be achieved once symptoms have begun, a compelling argument for screening to detect advanced disease cannot be made. In fact, treatment availability for stage D cancer, unless it was extremely effective, if just as toxic, would not change the decision in question (base-case assumption of 1.9 years' life expectancy vs sensitivity threshold of 12.58 years' life expectancy).

With regard to the analysis itself, determination of average utilities for each outcome is always the greatest challenge. Clearly, one would like to survey several hundred elderly men regarding their feelings about the various health outcomes considered in this analysis and develop the utilities from those data. This was not done in the present study. Sensitivity analyses were done for each utility separately, however; no important thresholds were found. This finding indicates that although our base-case utility values may not equal the true values held by the general populace, an expensive study to better assess those values is probably not warranted at this time.

As a final point, this study has also raised important ethical questions that have not been dealt with but deserve further study. One question is whether the use of "average" utilities has any moral bearing on the decisions of a specific individual. If, as we often claim, "everyone is unique," it would seem morally necessary to establish the appropriate utilities on a case-by-case basis. But that would also mean reassessing how both the physician's utilities and the patient's utilities should appropriately factor into the final decision, since the physician's utilities would also vary on a case-by-case basis. Because we are only just beginning to understand the ethical role of a values base in medical decision making,[41] further study is clearly necessary.

A second ethical question centers on patient autonomy and its related concern with informed consent in the following way: Our analysis has shown that an asymptomatic patient is potentially worse off if the examination reveals a prostate nodule and the patient is informed of that finding and decides to pursue evaluation and treatment, since pursuing it would result in a loss of quality-adjusted life. At the same time, physicians have a prima facie obligation to reveal to the patient the discovery of such a pathologic finding. The physician then faces a moral dilemma: either do the examination and withhold the information in order to protect the patient; or do not do the examination, thus protecting the patient from the knowledge of disease, but precluding medical management if there is actually a nodule present, and thereby preventing the patient from exercising his option to have it evaluated and treated.

On the one hand, the physician has an obligation to be as thorough as possible in a physical examination, since the purpose of the examination is discovery. The patient's right to make truly informed decisions also seems to obligate the physician to report any discovered disease. On the other hand, the physician has an obligation to "prevent harm," such that, given our findings, avoiding examination of the prostate, or not reporting a prostate nodule when discovered, might also be obligatory. These conflicting obligations form the basis for a significant moral dilemma. The appropriate ethical framework for resolving such a dilemma needs serious study, because there is no intuitively obvious "correct" answer. While each physician makes a moral decision in such matters, our findings show the necessity of carefully studying these moral decisions in an effort to understand their basis and validity.

Pending the ethics research called for, our findings suggest to us that the appropriate way to avoid this dilemma is to avoid examining the prostate gland of patients with no symptoms suggestive of prostate cancer. If such examination is unavoidable or specifically requested and a prostate nodule is found, we believe that the physician's obligation is to explain the risks and benefits as outlined in our study, and recommend against further evaluation and treatment, but leave the final decision to the patient.[41]

References

1. Fisher M, ed. Screening for prostate cancer. In: Guide to clinical preventive services. Report of the US Preventive Services Task Force. Baltimore, Md: Williams & Wilkins, 1989:63–6.
2. Canadian Task Force on the Periodic Health Examination. The periodic health examination. Can Med Assoc J 1979; 121:1194–1254.
3. Frame PS. A critical review of adult health maintenance. Part 3. Prevention of cancer. J Fam Pract 1986; 22:511–20.
4. American Cancer Society. Guidelines for the cancer-related checkup: recommendations and rationale. CA 1980; 30:194–240.
5. Working guidelines for early cancer detection. Rationale and supporting evidence to decrease mortality. Bethesda, Md: National Cancer Institute, 1987.
6. Mueller EJ, Crain TW, Thompson IM, Rodriguez FR. An evaluation of serial digital rectal examinations in screening for prostate cancer. J Urol 1988; 140:1445–7.
7. Guinan P, Bush I, Ray V, Veith R, Rama R, Bhatti R. The

accuracy of the rectal examination in the diagnosis of prostate carcinoma. N Engl J Med 1980; 303:499–503.
8. Chodak GW, Schoenberg HW. Early detection of prostate cancer by routine screening. JAMA 1984; 252:3261–4.
9. Lee F, Littrup PJ, Torp-Pedersen ST, Mettlin C, McHugh TA, Gray JM. Prostate cancer: comparison of transrectal ultrasound and digital rectal examination for screening. Radiology 1988; 168:389–94.
10. Gilbertsen VA. Cancer of the prostate gland: results of early diagnosis and therapy undertaken for cure of the disease. JAMA 1971; 215:81–4.
11. Love RR, Fryback DG. A cost-effectiveness analysis of screening for carcinoma of the prostate by digital examination. Med Decis Making 1985; 5:263–78.
12. Thompson IM, Rounder JB, Teague JL, Peek M, Spence CR. Impact of routine screening for adenocarcinoma of the prostate on stage distribution. J Urol 1987; 137:424–6.
13. Narayan P, Jajodia P. Prostatic oncology. Clin Geriatr Med 1990; 6:131–61.
14. Catalona WJ, Avioli LV. Diagnosis, staging, and surgical treatment of prostatic carcinoma. Arch Intern Med 1987; 147:361–3.
15. Ahmann FR. Dilemmas in managing prostate carcinoma (Pt 1): localized disease. Geriatrics 1985; 40:34–42.
16. Olsson CA, Babayan R, White RD. Surgical management of stage B or C prostatic carcinoma: radical surgery vs radiotherapy. Urology 1985; 25(2 suppl):30–5.
17. Zorgniotti AW. Prostate cancer and impotence. Prostate 1983; 4:487–92.
18. Millar JGB. Drug induced impotence. Practitioner 1979; 223: 634–9.
19. Maier U, Czerwenka K, Neuhold N. The accuracy of transrectal aspiration biopsy of the prostate: an analysis of 452 cases. Prostate 1984; 5:147–51.
20. Rich AR. On the frequency of occurrence of occult carcinoma of the prostate. J Urol 1935; 33:215–23.
21. McNeal JE, Kindrachuk RA, Freiha FS, Bostwick DG, Redwine EA, Stamey TA. Patterns of progression of prostate cancer. Lancet 1986; 1:60–3.
22. Breslow N, Chann CW, Dhom G, et al. Latent carcinoma of the prostate at autopsy in seven areas. Int J Cancer 1977; 20:680–8.
23. Ansell JS. Is ultrasound of the prostate indicated for screening purposes? An opposing view. J Fam Pract 1988; 27:525–8.
24. Epstein NA. Prostatic biopsy: a morphologic correlation of aspiration cytology with needle biopsy histology. Cancer 1976; 38: 2078–87.
25. Sunderland H, Chir M, Lederer H. Prostatic aspiration biopsy. Br J Urol 1971; 43:603–7.
26. Esposti P. Cytologic diagnosis of prostatic tumors with the aid of transrectal aspiration biopsy: a critical review of 1110 cases and a report of morphologic and cytochemical studies. Acta Cytologica 1966; 10:182–6.
27. Anandan N, MacKenzie E, Gingell JC, Rowell MJ, Johnson DH. Role of Frantzen needle aspiration biopsy in carcinoma of the prostate. J R Soc Med 1983; 76:828–30.
28. Gibbons RP, Correa RJ, Brannen GE, Mason JT. Total prostatectomy for localized prostate cancer. J Urol 1984; 131:73–6.
29. Walsh PC, Jewett HJ. Radical surgery for prostatic cancer. Cancer 1980; 45:1906–11.
30. Whitmore WF. Natural history and staging of prostate cancer. Urol Clin North Am 1984; 11:205–20.
31. Cook GB, Watson FR. Twenty single nodules of prostate cancer not treated by total prostatectomy. J Urol 1968; 100:672–4.
32. Larson A, Norlén BJ. Five-year follow-up of patients with localized prostate carcinoma initially referred for expectant treatment [abstract]. Scand J Urol Nephrol [Suppl] 1985; 93:30.
33. Byar DK, Corle DK. VACURG randomized trial of radical prostatectomy for stages I and II prostate cancer. VA Cooperative Urological Research Group. Urology 1981; 17(suppl):7–11.
34. Bagshaw MA. Management of localized prostate cancer. Hosp Pract 1986; Dec 15:73–88.
35. Sox HC, Blatt MA, Higgins MC, Marton KI. Medical Decision Making. Stoneham, Mass: Butterworth, 1988:186.
36. Crawford DE, Eisenberger MD, McLeod DG, Spaulding JT, Benson R. A controlled trial of leuprolide with and without flutamide in prostatic carcinoma. N Engl J Med 1989; 321:419–24.
37. Kaplan RM, Anderson JP. A general health policy model: update and applications. Health Serv Res 1988; 23:203–35.
38. Catalona WJ, Smith DS, Ratliff TL, Dodds KM, Coplen DE. Measurement of prostate-specific antigen in serum as a screening test for prostate cancer. N Engl J Med 1991; 324:1156–61.
39. Maksem JA, Park CH, Johenning PW, Galang CF, Tannenbaum M. Aspiration biopsy of the prostate gland. Urol Clin North Am 1988; 15:555–75.
40. Gittes RF. Carcinoma of the prostate. N Engl J Med 1991; 324:236–45.
41. Wright RA. Clinical judgment and bioethics: the decision making link. J Med Philos 1991; 16:71.