Screening for Prostate Cancer

How can patients give informed consent?

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SUMMARY

Many urologists in North America are increasingly enthusiastic about prostatic cancer screening. Annual digital rectal examination is almost universally endorsed, and prostate-specific antigen testing is favored by most. But doctors really should not screen by either method without patients' informed consent. However, the information required for informed consent is complex and contradictory, difficult for physicians to give and for patients to absorb.

RÉSUMÉ

De nombreux urologues en Amérique du Nord manifestent un enthousiasme croissant envers le dépistage du cancer de la prostate. Le toucher rectal annuel est reconnu presque universellement, et la plupart sont en faveur du dosage de l'antigène prostatique spécifique. Par contre, les médecins ne devraient pas utiliser l'une ou l'autre de ces méthodes de dépistage sans avoir obtenu du patient un consentement éclairé. On constate toutefois que les informations nécessaires pour en arriver à un consentement éclairé sont complexes et contradictoires, que les médecins ont de la difficulté à les communiquer et les patients à les retenir.

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No test is innocuous and, therefore, before one is ordered, patients should give informed consent.[1,2] We all agree with this statement. However, practising what we preach is far from easy.

As Lee has recently stated about informed consent for casefinding procedures, "...how realistic is it to expect busy office physicians to guide patients through the current maze of conflicting recommendations and statistics?"[1] A corollary to this, which Lee also addresses, is how can busy practising physicians keep up-to-date, understand, and evaluate the significance of all the data, let alone relay the information in a meaningful way to patients?

The screening, or really casefinding, issue that is overwhelming me as a family physician is the current enthusiasm of urologists for screening patients for prostate cancer.[3-5] The media have picked this up and, as a result, primary care physicians are being deluged with patients who want to be checked out for prostate cancer.

The urologists' concern is understandable. Cancer of the prostate is common and it kills.[6-8] Canadian cancer statistics for 1992 indicate that cancer of the prostate is both the second most common cancer among men and the second most common cause of cancer deaths among men. (Lung cancer still leads the field for both incidence and mortality for men, while colorectal cancer is third.) Researchers estimate that 8.75% of Canadian men will develop prostate cancer during their lifetime (lifetime arbitrarily set at 90 years), and that 3.33% of them will die of the disease. Canadian figures show the discouraging fact that during the last 20 years both the incidence and the mortality rate of prostate cancer have increased steadily.[6]

Figures from the United States are equally gloomy. As of 1991, prostate cancer was the most common cancer among men in the United States. On the basis of 1987 figures, it was the third leading cause of cancer death, closely following colon and rectum, but well behind lung cancer.[7]

However, the manner in which statistics on prostate cancer are presented, and their implications for patient care, depend on which author reports which figures.[9] A useful set of working figures for primary care physicians might be those of the European Community.[8] These figures are

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probably closer to clinical reality than the Canadian figures quoted above because 74 years is used as the life expectancy rather than 90. In Europe, the cumulative risk of developing a clinically detectable prostate cancer by age 74 is 3.9% and the cumulative risk of dying of prostate cancer by age 74 is 1.2%.[8]

At present, very few patients with prostate cancer present with localized disease that is truly amenable to cure. In fact, according to Scardino et al,[10,11] only 10% to 20% of prostate cancer patients fall into this group. Figures such as these are distressing and are the impetus behind screening or casefinding endeavors that aim to detect more "early" and, it is hoped, curable cancers.

Concern is one thing. To translate good intentions into actual screening or casefinding is not so easy. Even if casefinding could decrease prostate cancer mortality, and there is as yet no good evidence that it could,[9,11-17] the process might lead to significant morbidity related not only to the screening itself but also to ensuing therapeutic interventions. Adverse psychological effects include varying degrees of anxiety[9,12,13,15] as well as the consequences of the inevitable detection of incurable prostate cancers.[13] Physical morbidity (and mortality) includes all the complications of biopsy and radical surgery (or radiotherapy) and covers the spectrum of pain, infection, anastomotic leakage, incontinence, impotence, and death.[9,12,14,15,18,19]

It seems evident, therefore, that it would be unethical either to perform a digital rectal examination on or to order a prostate-specific antigen test for a patient as a casefinding or screening procedure unless the patient had the necessary information to give informed consent.

Is it feasible, within the context of an office setting, to present to a patient the data he requires to give informed consent for a digital rectal examination and a prostate-specific antigen evaluation? To answer that question, we must carefully evaluate the process that goes on between a physician and a patient when the physician tries to present in layman's language the information necessary for the patient to make a reasonable decision. The following scenario is typical of what has been going on in my office day after day for the last few months.

"Good morning, Mr Smith. I'm sorry I'm late, but I've had to spend a lot of time with my previous three patients explaining some complicated issues about cancer screening."

"That's all right, Doc, I won't be long. I just want this prostate test."

"I presume you are talking about the PSA or prostate-specific antigen blood test as well as my checking your prostate with my finger"

"I don't know about the finger test, but I guess that's the blood test all right. It's the one that prevents you from getting cancer of the prostate – the one I've been reading about in the *Gazette*, the *Globe and Mail*, the *New York Times*, and *Time*."

"Yes, Mr Smith, we're talking about the same test. But it doesn't prevent cancer. It's supposed to tell us whether you have a cancer of the prostate that we wouldn't know about otherwise. The idea is that the cancer would be small, you could be treated right away, and you could be cured."

"That's great. Since you're running late, why don't you just fill in the form and I'll go down to the test center and get my blood drawn."

"I'm afraid it isn't that simple. I'd better tell you a bit more about PSA.[20-25] First of all, you could have cancer of the prostate without elevation of your PSA. In other words, the test would be 'normal' but you would still have cancer."

"I guess no test is perfect. I can live with that, but thanks for telling me. Now if you'll just fill in the form, I'll be out of here."

"Hold on a minute. There's more to it than that. You see, many people who have an elevated PSA test don't have cancer of the prostate."

"They don't? What do they have?"

"Usually they just have a big prostate. It's very common and doctors have a fancy name for it, which is BPH, or benign prostatic hypertrophy."[20-25]

"So if I have this test, and the PSA is up, how do you know whether it's cancer or this blown up prostate thing you were talking about?"

"That can sometimes be difficult. First I'd have to examine your prostate with my

finger. If I felt a lump that could be a cancer, I'd send you to a urologist."

"What would he do?"

"He would feel your prostate as well to see if he agreed that there was a suspect lump, and then he would probably arrange to insert an ultrasound probe in your rear end to see whether there were other suspect spots in your prostate he wasn't able to feel.[14,26-30] Assuming there weren't any others, he would then biopsy the lump."

"How would he do that?"

"He'd stick a needle through your rectum into the lump in the prostate."

"Ugh! Does it hurt?"

"I don't really know. I've heard urologists talk about it and they say no, or not very much."

"But what would happen if my PSA were up and you didn't feel a lump on my prostate?"

"A good question. I'd send you to a urologist. He would go through the same routine of examining you and getting a rectal ultrasound scan. If any suspect spots were found by ultrasound, he would biopsy them. He has to do this because a lot of spots that look like they might be cancer on the ultrasound turn out not to be cancer. The real problem is what happens if no worrisome spots are found. A common current practice is to do six blind biopsies in various parts of your prostate with the idea that one of them might detect a cancer if you had one. We do this because we know that ultrasound not only overcalls cancers of the prostate, but also misses a fair number of them."

"That doesn't sound too pleasant. Are there any complications to having six needles stuck in your prostate?"

"I understand there aren't too many. You might well have blood in your semen for a while. But if it ever came to that, you'd have to discuss the issue of complications with the urologist."

"I'm beginning to see that there is more to it than I thought. I guess the good news about this procedure would be that if no cancer were found in those six needle sticks, I certainly wouldn't have cancer."

"That's not for sure, either. You probably wouldn't have cancer, but you couldn't be sure of that. The urologist would most likely recommend that you check your PSA every year. If at any point it started to go up, he would reevaluate you and probably re-biopsy you."

"So it could be years before I knew whether or not I had cancer. That would be hard to live with. There seems to be a lot of uncertainty about this, eh?"

"Yes, indeed. As you can see, tests have their disadvantages."

"But surely you are being too pessimistic about all this. There must be something good about the test. Can't you detect cancer early with it and so cure it? I mean, if I have the test, the PSA is up, and you find a cancer, you can cure it, can't you? That's the idea, isn't it?"

"That's certainly the idea. Sometimes you do find an early cancer and, at least in theory, it can be cured.[31-34] However, even at this early stage, recurrences, which might not happen for many years, are common,[10,11,34] and 20% or more of these patients eventually die of their cancer.[10,11] You have to realize that there are a lot of things we doctors do on the basis of hope rather than evidence. Maybe in 10 or 20 years we will have found out that screening for prostate cancer has saved lives, but then again, maybe not. You know, it seems to make sense to say that small or early cancers are always curable, but this is not necessarily so.[17,35] Unfortunately, there is as yet no study to prove that screening for prostate cancer saves lives."[9,11-17]

"I can tell from your tone of voice that the subject gets even murkier."

"We've already spent quite a bit of time together and you're getting to know me well. Complexities abound. To start with, when we do these tests and find prostate cancers, only about half to two thirds of them are even potentially curable.[11,13,31,32] The remainder have already spread and are incurable. In cases like this, where we find cancer that has already spread, we have probably done a lot more harm than good by doing the tests. If that happened to you, I'd have to say, 'I'm sorry Mr Smith, but you have prostate cancer and there is no cure for it. If we hadn't done the tests, we probably wouldn't have known about your cancer for months or even years, because some of these tumours grow slowly.[35] If at some point in the future you get symptoms, we can certainly treat them. In the meantime, I'd be glad to see

you a few times to help you get used to the idea that you have inoperable cancer.'"

"But what about the operable ones? I'm beginning to see there aren't many, but you did say there were some."

"There are, indeed. I suspect that a number of people are cured, but even here there are uncertainties. You see, some prostate cancers either don't grow, or grow so slowly that they would never affect you.[35-39] These cases don't need any treatment, but we have no way of telling which small or 'early' cancers will grow, and which won't. As a result, with the exception of a few British[36-38] and Swedish[39] urologists, we usually treat them all, and the treatment is not all that innocuous."

"I was going to ask you about that. How do you treat cancer of the prostate, anyway?"

"There are two ways of treating an 'early' prostate cancer with the goal of cure. One is radiotherapy and the other is radical prostate surgery. Let's start by talking about the surgery. A number of complications can occur, but I'll just mention the main ones. Some people die of the operation. How many varies from centre to centre, but the average is about 1%. About 5% to 6% will be permanently incontinent of urine, and, in the best of circumstances, 30% will become impotent."[18,19,40]

"Boy, that doesn't sound too encouraging. Doc, this whole thing is getting to be impossible. What do you think I should do?"

"I know we've been at this for quite a while now, but if you are going to make a rational decision about these issues, you need information, and you don't have it all yet."

"I don't? I've already got too much."

"I realize it's a lot, but we haven't yet talked about whether you want me to check your prostate with my finger as part of the screening test for cancer of the prostate."

"That's not true. I'm pretty confused about all you've told me, but I distinctly remember you talking about sticking your finger in there."

"I did, but in the context of what would happen if your PSA were elevated. This is different. All sorts of medical organizations, such as the American Cancer Society and the Canadian Urological Association, recommend that men of your age have an annual rectal examination to check their prostates for cancer."

"OK. I know what you're going to say. It's recommended but it's not that simple."

"I'm getting transparent. You're right. Examining the prostate with a finger leads to the same types of problems as doing the PSA test.[11-13,31,32] While some early cancers are detected in this way, and so treated, no one knows whether this ends up saving lives. On the other hand, some more advanced cancers are also detected, which is too bad because there is no curative treatment for them. Something else you should know is that most lumps that are felt turn out not to be cancer, but you still have to go through the routine of rectal ultrasonography and biopsies. Finally, many cancers are missed by this examination, so even if I do a rectal examination and find nothing, this does not mean you don't have prostate cancer."

"So what should I decide?"

"I'm not really sure. Such a decision might be more philosophical than medical. One might say that those who choose the tests tend to believe in the Holy Grail, whereas those who don't are fatalists or nihilists. If you look for expert opinions, you won't get very far because you will receive authoritative contradictory views. One interesting aspect of all this is that where you live makes a big difference on the advice you will receive. While a few urologists in the United States clearly state that there is as yet no evidence that screening for prostate cancer does any good,[11,13,15-17] nearly all American urologists actively push screening.[3] Many European urologists, on the other hand, argue that screening for prostate cancer is of no proven value.[9] However, there are articles in the medical literature that try to answer this dilemma. Let me tell you about two of them.

"The first study was headed by Dr Mold from the University of Oklahoma.[2] Since no one has ever done a conclusive study on real patients to see whether screening for prostate cancer does any good, his group decided to develop a computerized decision analysis program to estimate the probable effects of screening on life expectancy and quality of life. The conclusions were that, on average, screen-

ing for prostate cancer would extend life by 1 month and would decrease good quality life by 3.5 months.

"The second study is by a group of Canadian experts who performed a careful and exhaustive review of the medical literature on the detection and results of treating early prostate cancer.[41] Their conclusions are provisional because conclusive data are just not available. They found that the weight of evidence was against doing PSA tests and that the evidence for doing rectal examinations was equivocal."

"So now I'm supposed to make up my mind? I can't do that. I can't even remember half of what you told me. You're the doctor. You tell me what to do."

"No, Mr Smith. You have to decide, but to help you, I will tell you what I would do. I'll give you my personal, subjective, philosophical, and inevitably biased choice. But before I do that, we have one other matter to talk about. Are you still smoking two packs of cigarettes a day?" ■

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