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Does Information and Agreement Equal Informed Consent?

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Does INFORMATION & AGREEMENT equal informed consent?

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The human understanding is not a dry light, but is infused by desire and emotion, which give rise to 'wishful science.' For man prefers to believe what he wants to be true. He therefore rejects difficulties, being impatient of inquiry; sober things, because they restrict his hope; deeper parts of nature, because of his superstition; the light of experience, because of his arrogance and pride, lest his mind should seem to concern itself with things mean and transitory; things that are strange and contrary to all expectation, because of common opinion.

— Francis Bacon
Novum Organum

The following essay is based on a talk delivered last summer in England and on the chapter "Information, Decisions, and the Limits of Informed Consent," in (Michael Freeman and Andrew D. E. Lewis, eds.) Law and Medicine: Current Legal Issues 2000, *Volume 3 (Oxford University Press, 2000). This version appears with permission of the publisher.*

For many years, a principal labor of bioethics has been to find a way of confiding medical decisions to patients and not to doctors. The foremost mechanism for doing so has been the doctrine of informed consent. The theory of and hopes for that doctrine are well captured in the influential case of *Canterbury v. Spence* (464 F2d772, 780 [DC Cir 1972]): "True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each."

Anxious as bioethicists and courts have been to promulgate this doctrine, they have been less anxious to discover how well it works. The bioethical tradition has been far more interested in articulating principle than testing practice. But as Law School Professor Don Herzog drolly warns, "theory had better not be what you get when you leave out the facts." So in this chapter we will reflect on the empirical literature on informed consent and present some findings of a study on the way men decide whether to use PSA (prostate specific antigen) screening to detect prostate cancer. This will lead us to reflect on the limits of informed consent.

The success of informed consent depends on two things. First, patients must be able to understand and remember the information doctors give them. Second, patients must be able to analyze that information and use it to make a decision. The first of these requirements has been studied extensively. Despite prolonged struggle to improve informed consent, success remains elusive. As Cassileth *et al.* wrote some years ago, "It is well known that many patients, despite all efforts to the contrary, remember or understand little of what they agree to during the consent process." And as Cassileth *et* a different *al.* said, studies of informed consent "have shown that patients remain inadequately informed, even when extraordinary efforts are made to provide complete information and to ensure their understanding. This appears to be true regardless of the amount of information delivered, the manner in which it is presented, or the type of medical procedure involved." What is worse, the sicker patients become, the less they understand and retain.

The second requirement for the success of informed consent — that patients be able to analyze the information they are given — has, in contrast, been virtually

unstudied. We have been interested in what patients hear, but not in how they consider what they hear. Yet what evidence we have is deeply unsettling. As Irving Janis says, "[T]he stresses of making major decisions and the various ways people deal with those stresses . . . frequently result in defective forms of problem solving that fail to meet the standards of rational decision making."

In *The Practice of Autonomy: Patients, Doctors, and Medical Decisions* (Oxford University Press, 1998), Schneider suggests that most people regard making decisions of all kinds as forbidding work and that medical decisions are exceptionally challenging. Doctors themselves must often try to draw sound conclusions from dynamic and unreliable data and problematic theories. Thus, the information patients receive is often frustratingly uncertain. Worse, doctors most comfortably speak to patients in the language of medicine, a tongue that dismays even the brightest and best-educated patients. And while information cannot be put in completely objective terms, often neither doctor nor patient recognizes the assumptions and preferences recommendations silently embody.

The Practice of Autonomy further suggests that medical decisions are made yet harder because of their social and moral context. Medicine is becoming bureaucratized. This means that an astonishing number of people may have information and opinions to contribute to a medical decision, that the players change rapidly, and that responsibility is diffused. In addition, while some medical decisions present a single issue at a single moment, more often patients face a series of decisions over days or even months whose individual importance is often not apparent at the time. Even the non-medical aspects of medical decisions may boggle patients. For instance, people's "values" are often more obscure than the theory of informed consent assumes, and (reasonably enough) they change over time and with experience. Nor will it always be clear what conclusions are to be drawn even from well-established and stable preferences.

Furthermore, most medical decisions are made by sick people, and sickness impairs thought. When you are ill you are weary. When you are ill you are diverted by a regiment of unfamiliar problems, not least reconciling yourself to your disease, reconstructing your future, and coping with the quotidian. You may want to avoid facing the dismal facts of your illness. You may even want to "deny" your condition (which may be quite a wise deception). You may not find your medical condition absorbingly interesting. (We even have a pejorative term — valetudinarian — for people too fascinated by their illness.) And you may be so frightened that you cannot think lucidly and dispassionately.

All this may help us understand why Janis speaks so discouragingly about how patients address decisions. It also helps explain the emerging evidence about how patients go about making decisions.

One of the plainest elements of that evidence suggests that patients often make decisions with a rapidity that forecloses the systematic deliberation many students of decisions prescribe and the doctrine of informed consent presupposes. This has been most extensively studied among people asked to donate a kidney, who tend to decide instantly whether to donate or to decline. As one study put it, "Not one of the donors weighed alternatives and rationally decided. Fourteen of the donors and 9 of the 10 donors waiting for surgery stated that they had made their decision immediately when the subject of the kidney transplant was first mentioned over the telephone, 'in a split-second,' 'instantaneously,' and 'right away.'" In short, "all the donors and potential donors interviewed . . . reported a decision-making process that was immediate and 'irrational' and could not meet the requirements adopted by the American Medical Association to be accepted as an 'informed consent.'"

The most detailed, circumstantial, and vivid descriptions of how patients make medical choices appear in the memoirs so many of them have written about the experience of illness. Many of these memoirs, like the studies of kidney donors, report truncated decisions. For one lymphoma patient, for example, "[n]ot even a split second was needed to opt for chemotherapy despite all I had heard about it."

Such instantaneous decisions are possible partly because many patients seem to fix on one factor, make it the basis of decision, and then close their minds to new data. (This psychological conservatism is often called the "anchoring heuristic.") Penny Pierce, one of the closest students of how patients make medical decisions, reports such thinking among many of the breast cancer patients she studied. Schneider frequently observed it among people asked to choose a dialysis modality. Such patients

> **"Often seem to listen until they hear some arresting fact and then make it the basis of their decision. For instance, as soon as some patients hear that hemodialysis requires someone to insert two large needles into their arm three times a week, they opt for whatever the alternative is. When some other patients hear peritoneal dialysis means having a tube protruding from their abdomen, they choose "the other kind of dialysis."**

Not only do many patients decide quickly and consult only a few criteria — or even a single criterion — but even patients well educated and reflective enough to write memoirs regularly describe no decisional process at all. Instead, they invoke intuition, instinct, and impulse. An AIDS patient, for example, wrote, "I've learned to listen to my inner voice for guidance when choosing treatments. If I get what Louise refers to as a 'ding' (a strong instinct) about a vitamin, herb, drug, or other treatment, I try it." A multiple sclerosis patient "got a flash," found that a "little light flashed inside my head," came to "trust my instincts and intuition," and asked why she should not "play my hunches." Even the patients most committed to making their own decisions on rational bases often cannot, even in retrospect, explain their choices. For instance, a Rice sociologist with prostate cancer who was virtually a poster-boy for patient autonomy, wrote, "Without knowing precisely why or being able to provide a clear rationale, I decided I would ask Peter Scardino to perform my surgery."

A case study: screening for Prostate Specific Antigen (PSA)

Our survey of the evidence about the two requirements for successful informed consent suggests two things. First, we have a great deal of evidence about how much patients understand and retain of what they are told by their doctors about their medical choices: In brief, troublingly little. Second, we have little evidence about how patients analyze what they hear and remember. But that evidence gives us good reason to doubt that their analyses meet the expectations of the bioethicists who advocate informed consent or the judges who demand it.

To gain further insight into the way patients think about their medical choices, let us examine a case study. The most common cancer among men attacks the

prostate. Traditionally, physicians tried to detect prostate cancer before its symptoms became acute by "digital rectal examination," that is by trying to feel the cancer in the prostate. However, this method is roughly as effective as it is pleasant, at least where the cancer is in its early stages. This made it seem desirable to find another way of identifying men with this common and potentially fatal disease. The best current way to do so arises from the fact that distressed prostates emit abnormally high levels of prostate-specific antigen (PSA). A number of physicians thus favor screening men by testing their blood for elevated PSA levels and then, where the PSA is elevated, performing ultrasound examinations and, usually, biopsies.

Other physicians, however, disagree. These PSA skeptics make several points. First, they observe that many things besides prostate cancer can distress a prostate and that therefore the PSA test provokes numerous biopsies that reveal no cancer. Indeed, at least 70 percent of the men with elevated PSA levels do not have cancer. The 30 percent who do from the 70 percent who don't are generally distinguished through a biopsy of the prostate. While the PSA test is relatively inexpensive and only trivially burdensome (it is a blood test often performed on men who are already having blood drawn for some other purpose), few men find the biopsy agreeable. Furthermore, it is both expensive and fallible.

Second, opponents of PSA screening say that most prostate cancer grows so slowly that most men who have the disease do not die from it. Autopsies of men who did not die of prostate cancer found evidence of the disease in a quarter of the 65-year-olds and 40 percent of the 85-year-olds. One estimate is that 10 percent of all men contract prostate cancer but only two to three percent of these actually die or suffer seriously from it. This suggests that for most men, inaction may be the best reaction to a diagnosis of prostate cancer.

Third, opponents of PSA screening note that the treatments for prostate cancer — surgery and radiation — can be painful and that they are likely to cause quite trying complications. Seventy percent of the men treated suffer temporary impotence or incontinence, and 30 percent of those treated suffer from one of these conditions permanently. Others have persistent infections. Since the treatment will be unnecessary for many men, this means that these complications would — for those men — have been pointless. For a number of other men, treatment will not work. For these men, the unpleasantness and complications of treatment may well outweigh its benefits.

The studies necessary to determine whether PSA screening is on balance worthwhile are under way but are years from completion. Meanwhile, opponents of screening say there are hints that screening — on the average — increases life expectancy by only a few days and that screening even *reduces* one's "quality adjusted" life expectancy lead by a few days. In short, the PSA skeptics fear that, on average, screening does not improve health and longevity and thus is not worth the cost.

A number of attempts have been made to resolve this controversy among physicians by bringing them together to issue guidelines. These attempts, however, have failed. Instead, these groups have recommended that each patient be given the evidence and decide for himself. In short, the medical dispute among doctors has been deferred to their patients under the aegis of informed consent.

How well will this work? How will men confronted with these conflicting arguments analyze them? To find out, we interviewed 40 men who were 40 to 65 years old. They varied widely in income and occupation. The men were on average better educated than the American population. Only nine of them had no college experience, and three of these did not finish high school.

The interviews were generally held in the interviewee's home and lasted from one to two hours. A central feature of the interview was an attempt to give the men the kind of information about whether to be screened for PSA that an exceptionally conscientious physician who was struggling to be as neutral as possible would offer. In other parts of the interview, the men were also asked about their health, their experience with prostate problems and tests, their relationships with physicians, their views about participating in medical decisions, and their skill in handling simple arithmetic.

Strikingly, the interviewees generally seemed committed to making the kind of formally correct cost-benefit decision that has traditionally characterized the medical literature on medical decisions. A number of men not only aspired to make sound decisions, but felt obliged to do so. They disparaged friends or even spouses who had avoided the responsibility of making medical decisions. They often spoke contemptuously of such people and their dangerous course.

The interviews were structured to promote the kind of rational decisions to which the participants seemed to aspire. The interviewer presented the relevant medical data in much the way a careful physician might (although at much greater length than most physicians would have time for) and tried to come as close as possible to the idea envisioned by the medical groups that have called for doctors to give patients the information they need to decide for themselves whether to be screened.

The thinking of 40 men over a prolonged discussion is not easily summarized. When humans speak, their ideas are fluid, incomplete, and even contradictory. These men were no different. Nevertheless, two central and significant generalizations are inescapable: First, only two of the 40 seemed to change their minds about PSA screening despite all the information they were given. This may be partly because three-quarters of them had already had a PSA test and because prostate cancer and screening for it have by now entered into public discourse.

Second, despite the professed desire of a number of these men to make their own rational decisions, and despite the exceptionally favorable circumstances for doing so, almost every participant repeatedly reasoned in ways that seemed at odds with his own aspirations. More specifically, participants frequently seemed swayed by unexamined assumptions, which led them to ignore or misunderstand the information they were given. More specifically still, the interviewees relied crucially on what might be called principles of folk wisdom. An examination of some of these principles will reveal much about the way these men thought about the problem they confronted.

Prevention is good. Public health and cancer education seemed to have done their job almost too well. Participants had fully imbibed the principle that "prevention" is better than treatment, that nothing is more crucial to combating cancer than catching it early, and that screening is the first step in early detection. Thus one respondent said,

My mother is a retired registered nurse. I've got a lot of health professionals in my family. I've been aware of health and healthcare all my life. . . . I've been blessed with good health, for the most part, and I just did not want to run the risk. I didn't want to do something stupid. . . . [I]f there's a test, or an exam, or something, I'm going to take it. . . . I just want to be preventive, instead of [regretting] after the fact.

And another:

[My body's] like a machine. . . . [I]f there's a flat tire, I'll go ahead and change it. If the oil's low, I'll go ahead and change it. . . . It's by taking preventive measures like this [test] I've been able to maintain a reasonable amount of good health. . . .

And in like vein:

***Respondent:* I honestly believe that knowing, and having the option of prevention, outweighs all the other risks [of PSA screening]. . . . [I]f you do the proper things, it's just like starting a car. You can have the key, and if you don't unlock the door and stick it in the ignition, you're not going anywhere. But if you do the proper things: stick the key in the door, unlock the door, stick it in the ignition, put the seatbelt on for safety, . . . you're going to go somewhere. . . . This is good sense, this is good medicine.**

***Interviewer:* So you've said that 'prevention' really overrides this uncertainty about PSA?**

***Respondent:* The availability of prevention has to be part of the system, part of the schedule of benefits [for an HMO]. . . . I mean, I think of prevention. I'm not always that way, but prevention — you're always in control of prevention.**

Of course, the interviewees were commonly doing more than applying the general lesson of prevention and screening. The advocates of PSA screening have had much the better of the controversy in the media, and the blessings of PSA screening seem to have been well preached by celebrities like Robert Dole and Arnold Palmer. As one of the participants remarked, prostate cancer "is all over the TV now." That has had its effects.

It is of course entirely reasonable to believe that PSA screening is wise because it makes it possible to detect disease early and thus to treat it more effectively. The controversy over screening exists precisely because many estimable authorities accept that view. But such a position is reasonable only after one has grappled with the proposition that, in the particular case of PSA screening, the general argument in favor of screening does not work. Many of these men seemed so powerfully driven by an idealized version of "prevention" that they had difficulty hearing, understanding, and analyzing a reason PSA screening might be desirable.

To put the point a bit differently, screening often works just as it is supposed to. It works for easily apprehended reasons. The virtues of screening have been drummed into the public over many years of virtuous advertising. As the passages quoted a moment ago suggest, screening is easily analogized to familiar and desirable practices, like routine maintenance of one's car. All one's educated intuitions, in short, make PSA screening seem like common sense and the arguments against screening seem foolish. Taking those arguments seriously requires an uncomfortable and burdensome re-examination of what seem like settled questions. Personal experience suggests to most people that such re-examinations are rarely worth the effort, and they are thus resisted.

Many of these men were also diverted from thinking clearly about their choices by their tendency to call PSA screening "prevention." But PSA screening does not prevent disease, it reveals it. Effective prevention relieves people of any of the consequences of disease and treatment, and prevention is often virtually free of risk. On average, then, prevention is much more effective than screening, and conflating the two makes screening more attractive than it will often deserve.

Control is Good. Some years ago, "control freak" was a term of disparagement. Today, Americans feel with increasing conviction that people need to take and maintain control over their circumstances. Control even takes on a moral dimension, for taking responsibility often means taking control. PSA testing appealed to a number of these men because it was a way of taking control and responsibility for their health: "[T]here are a limited number of things that you can control in your life. . . . I like to keep as many of those as possible." PSA screening looked attractive because it was seen as a form of "prevention" and prevention was seen as a way of having control: "[P]revention — you're always in control of prevention." More than half our participants used negative stories about other people who had failed to assume responsibility for their health by using PSA screening.

Now, if they don't get a PSA, and then they get [cancer], I have no sympathy for 'em. That's just stupid on their part, they could have prevented it, but didn't. They could all die for all I care. . . . [W]hy should we pay for their unnecessary medical care? No doubt it's their doctor's fault, too; a doctor is supposed to prevent things, not ignore them.

The association of PSA screening with "control" suggests another reason men may be reluctant to grapple with the argument against screening. That argument disturbingly suggests that, in the present state of knowledge, medicine fights prostate cancer ineptly. Taking that argument seriously means confronting medicine's limits with disquieting directness. In addition, that confrontation challenges another idea of psychological importance — that if you live right, you will live long, that you can avoid all harm if you are just careful enough. As one interviewee said, "If you avoid all these things that are bad they got these days, you'll be rewarded with life. You have to take care of yourself, get the proper checkups and tests." In short, the desire for control provides another reason to accept PSA screening with little thought and to resist examining the argument against it.

Information is Good. The survey literature now insistently suggests that most patients believe they want a good deal of information about their illnesses. The participants in this study shared a nearly axiomatic belief that information is always good to have. Some of these men had quite plausible reasons. One common reason for wanting information is wanting good news. Some men see PSA testing not as a way of detecting cancer but as a way of hearing comforting news: "[I]f you have a negative test, then you say, hey, you're really reassured that nothing is going to happen."

Another common reason for wanting information is a belief that forewarned is forearmed.

Everything affects our life, but that [prostate cancer] affects the end of your life, so you need to know. . . . Nobody anticipates when they're gonna die. . . . If it happens, it happens, but if you know it's going to happen, you put yourself into an advantage situation of being able to accomplish things that you've put off, things that you've wanted to do, or . . . maybe experimental medication. . . .

Or, as another man put it,

I would rather know what information's available, and which way to go, so I've got all the information to make some kind of a sensible decision of what I'm gonna do with myself. . . .

Other men seemed committed to "more information" even if its usefulness might be obscure. These men might acknowledge the possible disadvantages of PSA testing but then suggest that even a misleading PSA is better than no test. One man said that a PSA test is —

> **Not a gamble. I mean, do it. It's silly not to. . . . [L]ogic would dictate the tests are there, they're available, and they're reasonably accurate, even if they're not 100 percent.**

As another interviewee said,

> **You're attempting to try and find out what's going on [with the prostate]. . . . [T]he PSA may not be exact, but at least it is some measure, and as time goes on it will become more precise, but nonetheless, it's something.**

These men are recruiting a standard aphorism from common sense — that half a loaf is better than none, that some information is always better than none. The aphorism is inappropriate, however, since the uncertainty lies not just in the accuracy of the test, but also in what to do if cancer is diagnosed. Few things seemed more counter-intuitive to many of these men than the suggestions that a lack of knowledge could be better than knowledge.

Even participants who seemed to acknowledge some of the arguments against PSA screening emphasized how important "knowing" is.

> **I didn't understand [PSA statistics before], to be honest with you. I didn't realize about all these numbers, and it may sound silly, but I still like the idea of doing the blood test, only because I'm always curious about these things, I just like to see.**

The same man said,

> **But if I get a positive result, I'm not sure I'll do anything. The potential [adverse effects of treatment] here, would make life very unpleasant, [and] outweigh the small possibility of dying.**

He saw PSA screening, then, as a way of putting off a decision about how to respond to prostate cancer until the evil moment of knowledge actually arrived.

> **But if I start to get a positive result, then that's something I should find additional information about, look into, you know, really make a decision about.**

Other participants put their preference for information in yet starker terms. As one frankly said, "I can't explain why [I want screening]. I just like to see tests." And another participant felt so intensely that information is good and ignorance bad that he saw the argument against PSA screening as part of a conspiracy to keep him in ignorance.

> **You can't put the genie back in the bottle. The awareness is there. People like myself are spreading the word, of advantages of PSA. I don't care [if the cancer] is latent or active. . . . [W]ho do you think shows up at those meetings [on cancer screening nights]? Opinion leaders, people that want the information. Now, you [showed] your statistical work [to me], but it's the opinion leaders that tell 10 others. You unleashed the dragon. [The speaker at the screening night] said, pure and simple, just like that — . . . he knows how many other groups are talking about [PSA].**

There is, or course, much to be said for having information about one's health. However, here as with the other two axioms we have explored, the danger is that the simple principle "information is good" operates so powerfully and is accepted so uncritically that men do not hear and consider the arguments that suggest that the information provided by PSA tests may be bought at a high price (because the PSA test itself produces so many false positives) and is unexpectedly uninformative (because there is — in the mind of PSA skeptics — no satisfactory evidence about what men with prostate cancer should do and thus reason to think they should do nothing).

Technology is Good. Another common element of folk wisdom in American culture is the steady progress of technology and medical science. Some of the interviewees saw PSA screening as the "state of the art" and believed they should take advantage of the best medical science had to offer.

> **We already know about heart disease. We already know about certain forms of cancer that are caused by smoking. We know about emphysema, that's usually a byproduct of smoking. Right now, prostate cancer is a treatable problem. You know, [PSA] is a good. Right now there isn't anything else.**

Some saw being screened as a necessary best step toward the next technology:

> **If I were presented with a positive PSA test, I guess the most logical thing is to get a second confirming PSA test. But there will be another test that the medical community will come up with in the future, and that will work better than the PSA. . . . If I don't get the PSA, then I won't know to get that [other] test, I won't be able to benefit from the advance. . . . There was a time when the PSA didn't exist, after all, and men were subject to cancer without warning. Now, the PSA is here, and something else will be discovered soon.**

Statistics are Lies. A number of the participants scorned the arguments against PSA screening because they shared the common American skepticism of, and even contempt for, statistics. That skepticism is summarized by one man's use of the cliché "you can prove anything you want with statistics." Similar doubts led other men to such conclusions as a belief that all statistical uncertainty was automatically a "50-50 chance," so that either choice was appropriate, or a "toss-up."

> ***Respondent:*** **The numbers [don't matter] . . . . I don't want to take chances with all that stuff. I might die, I might not. I might get those [side effects of impotence and incontinence], I might not. Either way, I got a 50-50 chance, you know, I might as well guess.**
>
> ***Interviewer:*** **Hmm. Remember those numbers here aren't exactly 50-50, your chances could be worse, maybe of getting a side effect, or maybe a lot better, like living for years without problems [from the cancer].**
>
> ***Respondent:*** **Yeah, I hear you. But I figure it's a gamble, an even chance either way, you know, 50-50. Since you don't know, you know you're saying 30 percent here, you might as well guess either way. You got an even chance of good or bad.**

This skepticism of statistics could shade into an acid distrust of those who purported to use them:

> **Now the person [who is] saying the PSA tests aren't that valid. . . . What would happen if their mother went in and got a pap smear, and it was positive, or their father went in and got a PSA that was a 5? . . . Right then and there they'd want to do everything possible to see what was going on. Yet it's very easy for them to say, "Joe Blow down there, he may not have it 'cause he's got a PSA of 5." When you start throwing statistics around, I think it's a cop-out, in a way, for these people. I always say, "[I]f I was your mother or father, or your son or your daughter, what would you do?" And if they're telling the truth, they're gonna say, "[W]ell I'd do everything possible."**

"I knew someone once who . . ." One of the best-studied defects in human reasoning is the tendency to prefer a few vivid examples to systematic but dry statistical data. The participants in this study were as prone to this failing as

anyone else. The interviews were strewn with stories of friends and relatives who had been saved by testing.

> **I think my impression initially was that [my physician] didn't want to do the test, and I insisted that we do it. You know, I'll make the decision about what I'm going to do. . . . I think about Bo Schembechler [one-time University of Michigan football coach and a sainted name in Ann Arbor], he had a prostate operation, and [a friend of mine], and somebody else, a pretty renowned citizen — oh! Schwarzkopf, General Schwarzkopf.**

Often these stories did not involve PSA screening, but rather involved quite different kinds of cases, from other blood tests such as cholesterol to decisions about children with congenital heart disease.

> **You know, a one in 1,000 chance may not sound like much, but I had an aunt that was told she had a one in 1,000 chance of having a blood clot go to her brain through a procedure she was going to have, and it happened. . . . [I]t's all risky, but I still think it provides a framework for decision making even if it's not totally accurate, because you can't have complete accuracy.**

"If it weren't for bad luck, I'd have no luck at all." Finally, some men implicitly relied on old beliefs about a purposive fortune. At least six complained quite seriously about their bad luck. From this they concluded that PSA testing might be bad for the general population but necessary for themselves.

> ***Respondent:*** **Oh, I understand you all right, and I don't think most people should have a PSA. . . . I still want it because bad things happen to me. I'm the guy with bad luck, the one percent.**
>
> ***Interviewer:*** **You told me you don't have a family history of cancer, right?**
>
> ***Respondent:*** **Yeah, but I'm just like [the men with a family history]. . . . I'll get cancer because I get everything else.**

This PSA study does not, of course, prove that people make medical decisions badly. It does, however, suggest a hypothesis that may help explain how patients so often seem to be able to make medical decisions with more rapidity than the complexity of their choices might seem to justify. Often, the participants seem to have short-circuited their consideration or fallen back on axiomatic principles current in American culture. These principles are not necessarily problematic in themselves although some of them were (like the facile dismissal of all statistics). The problem, rather, is that these principles seem so right (and may in the proper circumstances be so unexceptionable) that they make it seductively easy for the participants confronted with an unappealing and counter-intuitive proposition (PSA screening is not a good bet) to dismiss the information without reflecting on it and instead to leap to a conclusion.

The cure for the ills of informed consent

The problems patients have in understanding and retaining what they are told are well known. And evidence is beginning to accumulate about the difficulty patients have in analyzing the information they are given and making a sound decision about it. The hypothesis we investigated in the preceding section helps substantiate the suggestions that patients often seem to resolve medical questions with a speed that would inhibit thoughtful consideration of the information presented to them. Added to the other doubts we have already reviewed about how patients receive and process information, the hypothesis raises questions about what can be hoped for from informed consent.

The conventional response to concerns of this kind has most typically been: "The only cure for the ills of informed consent is more informed consent." Many of these suggestions have to do with ways of conveying information more effectively, as by improving the way forms are worded, or by having people other than doctors explain choices to patients, or by making videos part of informed consent. As it has become clear that such changes do less than had been hoped, doctors have been urged to expand the range of information they impart and the range of situations in which they offer informed consent. (The movement away from guidelines and toward patient choice in PSA screening exemplifies the latter tendency.) A sense of the ambition — one might almost say desperation — of these proposals is to be found by examining a recent article by Geller *et al.* (Gail Geller, *et al.*, "'Decoding' Informed Consent: Insights from Women Regarding Breast Cancer Susceptibility Testing," 27 *Hastings Center Report* 28, March/April 1997). Among its recommendations:

> There should be an "in-depth exploration by providers of patients' affective and cognitive processes," since "[p]roviders who rely on a discrete or short-term approach to informed consent are unlikely to succeed at understanding fundamental patient beliefs and preferences and thereby have little hope of obtaining truly informed consent."
>
> "It is particularly important in the area of genetics and genetic testing for provider-patient interactions to explore uncertainties and limitations both in the provider's own knowledge and in the state of the science."
>
> "[I]f they are to facilitate truly informed decision making on the part of their patients, providers must understand and disclose their own motivations, beliefs, and values to patients."
>
> "Concerns about autonomy should be broadened from a sole focus on the voluntariness of the decision itself to include a focus on the voluntariness of the decision making *process*. . . providers ought to explore what kind of role expectations the patient has for herself and her provider."
>
> Finally, "informed consent ought to be individualized . . . and take place in the context of an ongoing relationship with a trusted healthcare provider."

People are driven to such effulgent visions of informed consent in part by the strength of the autonomist ideal in American life, law, and medicine. More particularly, they are not insubstantially motivated by the rise of the view among some bioethicists and even some doctors and patients that, as a matter of good medical practice and even as a matter of moral duty, patients ought to make their own medical decisions even if they would rather delegate them to someone else. Those who espouse this "mandatory autonomism" must hope to perfect informed consent for want of a better way of achieving their goals.

The limits of informed consent

One interpretation of the PSA study this paper describes is that informed consent was a success, that the men took the information they were given and applied their own "values" to it, with the results we have seen. This is true at least in the narrow (but not trivial) sense that people formulate and evince their values by making decisions. It is also true in the sense that these men genuinely subscribe to the culturally axiomatic ideas on which they relied.

But there is an important sense in which this interpretation of the study seems false. It is unlikely that the men wanted to make decisions in the way they seem to have done. Indeed, when asked about how they wanted to make decisions, the men in the study tended to espouse quite conventional views of how decisions ought to be made. Most people want to make decisions as well as they can. Most people believe that making good decisions requires listening to the arguments on both sides carefully enough to understand them. One might even wonder whether these men were aware of how they were making decisions. Possibly, but probably not, since the psychological mechanism at work is one which ordinarily does not reveal itself to its user.

Nor is the way the men often seemed to be reasoning consonant with the principles of informed consent as they have ordinarily been understood. Those principles assume that patients will grapple as directly with the advantages and disadvantages of their medical choices as possible. Why proffer substantial amounts of difficult information about difficult choices if consideration of them is thus to be short-circuited? Furthermore, there is a public interest in having them reach sound decisions, both because the cost of medical care is generally shared and because the lives of patients are valuable to the people around them and even society at large.

This paper has expressed doubts about how well patients hear and remember what they are told and about how well they are able to reflect on the choices presented to them. But what is to be concluded from these doubts? Should informed consent be abandoned? Of course not. This is not the place for a full-scale reconsideration of informed consent; this paper will have done its job if it directs attention to the grotesquely understudied issue of how patients make medical decisions. But a few words of clarification are no doubt needed.

The doubts this paper has expressed about informed consent do not require anything like abandoning informed consent. There are many reasons for this but space for only a few. First, sometimes informed consent works in something like the way bioethicists and courts envision. Some people are well situated to make medical decisions. Some "medical" decisions can be well made by many patients. Second, most people want at least some of the information the doctrine of informed consent intends for them to have. Third, some of the information given in informed consent helps patients care for their illness better even if it does not help them make medical decisions. Fourth, informed consent may have value even if it is only a ritual, for it reminds doctors of their duties of concern and deference to their patients, duties it is easy for them to forget and neglect in the press of the other duties that surround them.

The question, then, is not whether to discard informed consent, but what to expect of it. The material surveyed in this paper raises the possibility that there are real limits to our ability to solve the two problems of informed consent and thus to what it is reasonable to hope for from it. The PSA study illustrates a number of those limits. Not the least of these is time. In the artificial setting of this study, time could be lavished on a single medical question in a way that would be flatly impossible in almost any ordinary medical situation. Yet interviewees still came away from this educational extravagance without having fully understood and confronted the arguments presented to them.

But why is this surprising? Teaching and learning are both humblingly difficult, as any student and any teacher knows. Yet teachers and students teach and learn in virtually ideal settings compared to those in which doctor and patient must labor. And when the subject of the teaching and learning is as fraught with disturbing ideas and with unrecognized and unreliable assumptions as medical decisions, it is hardly surprising that people should almost struggle to avoid the task of learning.

Indeed, a substantial number of patients expressly say, when asked, that they do not want to make their own medical decisions. And the sicker patients are, the less likely they are to want to make their own medical decisions. The task of education is always daunting. How much more daunting must it be when the learners do not wish to use what is being taught?

The PSA study suggests another practical limit on the scope of informed consent. The participants in that study seemed often to be relying on powerful cultural axioms that allowed them to dismiss much of what they were being told. They may not fully have realized what they were doing, and it seems likely that physicians trying to inform them would often not realize all that was going on in their minds. Furthermore, there is good reason to think that patients will often be influenced by misapprehensions of whose existence or strength their physicians are unaware. For example, it seems not to be generally thought that patients who have agreed to become research subjects considerably over-estimate their chances of benefiting from the experimental treatment even when they have been told what those chances actually are. These research subjects "systematically misinterpret the risk/benefit ratio of participation in research because they fail to understand the underlying scientific methodology" (Paul S. Appelbaum *et al.*, "False Hopes and Best Data: Consent to Research and the Therapeutic Misconception," 17 *Hastings Center Report* 20, 21, April 1987). And like the participants in the PSA study, they are saved from difficult choices by misplaced reliance on a cultural truth: "Most people have been socialized to believe that physicians (at least ethical ones) always provide personal care. It may therefore be very difficult, perhaps nearly impossible, to persuade subjects that *this* encounter is different. . . ."

What is more, it appears that even willing physicians have had trouble in overcoming this kind of misapprehension:

> **The investigator in one of the projects we studied offered his subjects detailed and extensive information in a process that often extended over several days and included one session in which the entire project was reviewed. Despite this, half the subjects failed to grasp that treatment would be assigned on a random basis, four of 20 misunderstood how placebos would be used, five of 20 were not aware of the use of a double-blind, and eight of 20 believed that medications would be adjusted according to their individual needs.**

Doctors should surely do their best to give patients the information they want. But it is time to consider the possibility that doctors will never be able to communicate to patients all the information they need in a way that they can use effectively. It is the rare physician who has the skill and the time to probe deep enough into the patient's mind to discover the misapprehensions of fact and the inapt reliance on truths that distort what patients hear and think about the problems they face. It may therefore be time to acknowledge the limits of informed consent and to search elsewhere for ways of helping patients secure what they want from medicine.

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Professor Schneider continues his study of the interaction between American law and American culture in an influential series of articles on moral discourse and family law. In those articles, he contends that family law has increasingly abandoned moral language in analyzing the issues it confronts and has increasingly sought to transfer responsibility for moral decisions to the people the law seeks to regulate.

Professional education is another of Professor Schneider's interests. He has lectured and written about legal education in several countries. He is the author (with Margaret F. Brinig) of an innovative family law casebook – An Invitation to Family Law *(West, 1996) – a second edition of which is about to appear. And he is currently preparing a law and bioethics casebook (with Marsha Garrison).*

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