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Informed consent in medicine: one physician's perspective

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The American physician is today besieged by economic and societal forces which conspire to weaken whatever equanimity he or she could once bring to the practice of medicine. In the latter realm, the threat of malpractice actions is ever-present. In this regard, negligence has long been the theory whereupon plaintiffs' attorneys seek to recover damages for patients' misfortunes in the medical system. However, when no physician negligence can be shown to be the cause of bad medical outcomes, lack of informed consent has become an alternative theory for attorneys to use in pursuing legal action. This development in the law balances a laudable effort to protect patients' autonomy rights against an often intolerable burden for physicians. What to tell patients is thus a matter of paramount concern in the era of risk management.

The issue of informed consent is a relatively recent development in the history of medicine. Traditionally the doctor-patient relationship has been paternalistic. In ancient Greece, Hippocrates advised physicians to

> ...[conceal] most things from the patient while you are attending to him,... revealing nothing of the patient's present or future condition. For many patients through this cause have taken a turn for the worse [because] of a forecast of what is to come. [1].

English common law, which nurtured the environment for the original development of principles of individual rights, sought to limit physician autonomy by providing a remedy in tort law for patients injured by medical practice. However, the British physician today still has considerable liberty to make unilateral deci-

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sions in patient care, including the matter of what risks to reveal to patients [2]. If a bad result ensues, the doctor is not liable for damages as long as (s)he has acted "in accordance with a practice accepted as proper by a responsible body of medical men skilled in the particular art" [3]. In deciding malpractice cases, British law places little importance on whether or not the patient consented to the course of treatment.

In contrast, the common law in America has been more concerned with preservation of individual rights. In this regard, courts require physicians to obtain the informed consent of a patient before beginning a course of therapy or diagnostic tests. Originally mere consent was required, beginning with Justice Cardozo's ruling early in this century that every competent adult has a right to refuse a course of medical treatment [4]. Subsequent case law deemed that consent alone was not enough, but rather had to be given by a patient who understood that to which he consented [5]. This meant the physician had a responsibility to educate the patient about the nature of a proposed course of action, its risks, and possible alternatives. Initially, the question of which risks to disclose was left to medical judgment [5].

Later, however, a doctor's discretion in deciding what to tell patients was qualified in *Canterbury v. Spence*, decided by the United States Federal Appeals Court in 1972 [6]. In this case, a surgeon operated on the spinal cord of a young man with back pain, after obtaining his consent but without warning that paralysis was a possible complication of the operation. The surgery itself was without complication, but the patient slipped out of bed during the post-operative period while trying to urinate on his own after no nurse would respond to his calls for assistance. The fall resulted in paralysis; the patient sued his physician on grounds of lack of informed consent to the spinal operation.

The court ruled for the patient and found that his consent to the operation had indeed not been informed. It further chose to put flesh on the bones of the concept of informed consent. It declared that a physician's duty is not limited to skillful diagnosis and therapy [7], but rather includes the additional obligation to "communicate specific information to the patient when the exigencies of reasonable care call for it" [8]. It stated that while a physician may have training which enables him or her to see a clear therapeutic choice, it is the patient's prerogative, not the physician's, to determine the direction in which the patient's interests lie [8].

The court stated that a patient's silence does not excuse the physician from offering the required information, because "caveat emptor" is not the norm for the consumer of medical services. The test for determining whether a particular peril required disclosure was its "materiality" to the patient's decision; a material risk was one which a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to in deciding whether or not to agree to a proposed therapy [8]. A therapeutic exception was stated, allowing the physician to withhold information when the patient's mental or physical health could be harmed by such disclosure. Trying to mitigate the physician's burden, the court exempted risks of which patients of average sophisti-

cation are aware, or those having no apparent materiality to patients' decision on therapy [8]. However, even a very small chance of death or serious disablement would require disclosure, as would a potential disability which dramatically outweighed the potential benefit of the therapy or the detriments of the existing malady [9].

However, these well-intentioned rules for informed consent follow from a fact situation that was not well understood by the *Canterbury* judges. The court case report states that "a youth troubled only by back pain submitted to an operation without being informed of a risk of paralysis" [10]. A myelogram ordered by the physician revealed a filling defect in the region of the "fourth vertebra" (sic) (thoracic or lumbar?). Apparently, the court was not aware that back pain with such a myelographic abnormality is a surgical emergency, for paralysis could result at any time. Without question, the physician should have warned his patient of the risk of paralysis from the operation, but the judges did not understand that the patient was also at great risk from delay.

In fact, there were no complications from the procedure in question, but rather paralysis resulted from a fall from bed the following day. This very decision holds that an unrevealed risk that should have been made known must materialize, or the omission is without legal consequence [11]. A strong argument can be made that the complication did not materialize from the operation itself. Furthermore, it is doubtful that the patient could show he would have refused the operation if he had been told that the risk of paralysis appeared to be greater without an operation than with it. Thus, the *Canterbury* decision is flawed by a failure of the court to properly understand the medical facts. This raises the question of the validity of the edicts on informed consent elucidated in this ruling, which formed such an important precedent for future cases.

Nevertheless, the principles the court enunciated have entered the common law, and were regarded as important precedent by the Massachusetts court in *Harnish v. Children's Hospital Medical Center* [12]. In *Harnish*, a physician operated on a young woman to remove a benign tumor from her neck for cosmetic reasons. She was not warned that her hypoglossal nerve could be injured by the procedure, resulting in damage to the function of her tongue. This risk did materialize, and she sued her physician on the grounds of lack of informed consent [13]; she did not allege that the operation was negligently performed. The court found for the plaintiff, stating that a physician has the duty to disclose all significant medical information that is material to an intelligent decision by the patient whether to undergo a proposed procedure [13]. The court stressed that every competent adult has a right "to forego treatment, or even cure, if it entails what for him are intolerable consequences or risks, however unwise his sense of values may be in the eyes of the medical profession" [14].

In a more recent Massachusetts decision, *Precourt v. Frederick*, a patient sued his ophthalmologist after he developed aseptic necrosis of his hips. Several years earlier, the Dr. Frederick had operated to remove a deeply buried metal fragment from his eye, suffered during an accident which destroyed vision in that eye. After the procedure, the physician placed the man on prednisone. He warned the patient

about several severe potential complications of steroid use, but not of aseptic necrosis of the hips. Vision was not restored. Several months later, the Dr. Frederick offered to operate again to remove scar tissue, stating that this operation had only a 10% chance of success, and the patient agreed. The patient was again placed on prednisone postoperatively, and the procedure again failed to restore vision. Three years later he developed aseptic necrosis of his hips and sued Dr. Frederick on grounds of lack of informed consent. The trial court found for the plaintiff.

The Massachusetts Supreme Judicial Court reversed the decision on appeal [15]. The court reasoned that a physician could not be held responsible for warning a patient of every conceivable unfavorable outcome of a treatment. A risk would not require disclosure if the chance of its materializing was so remote as to be negligible. Neither would disclosure be required of a very minor consequence even though the probability of occurrence was high [16]. The court stated that

> there must be a reasonable accommodation between the patient's right to know, fairness to physicians, and society's interest that medicine be practiced without unrealistic and unnecessary burden on practitioners. We observed (citing *Harnish* at 155) that remotely possible risks of a proposed treatment may be almost without limit, and we implied and now hold that a physician is not required to inform a patient of remote risks.

The SJC reversed the lower court because Precourt testified that he would have undergone the first operation even if he had been told of the risk of aseptic necrosis, but not the second operation. There was thus insufficient evidence that the hip disease was caused only by the second course of prednisone, rather than the combination of both treatments. The patient has no complaint if knowledge of the risk would not have led him or her to refuse a proposed procedure or treatment [17].

This development in the common law seems well-intentioned. No reasonable person could argue with the spirit of Justice Cardozo's concept of the inviolability of one's own body. The holdings of *Canterbury v. Spence* seem measured, equitable, and intelligent, even if the medical facts of the case do not support the decision.

Undoubtedly, this type of pressure from the legal system has had salutary effects on the practice of medicine. Over a span of years, old attitudes of paternalism have given way and patients are being involved ever more deeply in decisions regarding their care. Many patients appreciate the retention of control over their bodies that informed consent allows them, and therefore feel more positive about undergoing a procedure [18]. This is so even though many patients, particularly older ones, prefer at least some element of paternalism and do not welcome having to make such decisions (author's personal observation).

However, the ivory tower environment in which the courts deliberate does not always accurately reflect the situations in which physicians often find themselves. *Precourt v. Frederick* represents an excellent example of this problem. The physician warned his patient of several severe potential consequences of prednisone

use, but not of the remote risk that did materialize. The physician was dealing with an extremely difficult ophthalmologic problem, and treated his patient with the utmost skill he could muster, a fact not disputed by the plaintiff. He obtained informed consent to treatment from the patient in a manner he thought entirely reasonable. Medical data showed that few if any physicians using prednisone at the time in Boston thought of warning their patients of this remote risk (author's personal knowledge). Even in hindsight, the physician cannot fault himself for not mentioning this risk (author's personal knowledge). Yet, the physician found himself facing a judgment hundreds of thousands of dollars over the limit of his malpractice insurance coverage.

The *Precourt* case illustrates that there are so many medical decisions made each day by the average physician in which informed consent could be found wanting in hindsight that trouble in this area seems inevitable. The equivalent situation in legal practice would be to hold attorneys liable for adverse judicial outcomes if at every step of the litigation process they did not obtain informed consent from their clients regarding the risk inherent in each and every response to a problem. Thus, a client would need to be warned of the material risk of each answer to an interrogatory, each defense asserted, each decision to cross-examine or not cross-examine a witness, each juror challenged, and so on.

Lawyers like to believe that law is deferential to professional expertise, but insistent on its own beneficial role in enforcing the societal expectations that properly govern medical practice [19]. However, while the law defines lofty ideals to preserve individual rights of patients, physicians are left to apply these principles in real-life situations. When presented with a clear-cut decision to make and an intelligent patient, this is usually not difficult. It gets more complicated, however, when the decisions are complex, involve difficult concepts requiring detailed explanations, or are of an ongoing nature. Under these conditions, doctors often cannot be certain whether adequate informed consent has been obtained.

The physician thus often risks that if a bad outcome occurs, a court could find the consent obtained inadequate in hindsight. The plaintiff's lawyer may see in informed consent a litigation theory which still offers a chance for recovery if no negligence exists. The effect may be to sometimes hold the physician to a strict liability standard which makes the doctor responsible for a bad outcome despite absence of negligence.

Further, one legal author has even proposed that incomplete informed consent be considered actionable even if no harm materializes [20]. Katz states that interferences with self-determination occur in all situations in which a person's dignitary interests have been violated, and are not limited to those in which physical harm has occurred. He argues that lack of informed consent is itself a harm; the additional presence of physical harm only adds injury to the insult. In addition, the potential for further expanding physicians' legal risks exists. For example, a California patient who was repeatedly urged to have Pap smears by her physician, but who refused for financial reasons, successfully sued him after she developed cervical cancer. The California Supreme Court ruled the physician was liable for failing to inform the patient of the risks of refusing a procedure [21].

For many physicians, law is seen as "an alien intruder in their professional domain, displacing their judgment in favor of legal rules perceived as unreasonable, inflexible, and intrusive, bearing little relation to the complexities of clinical reality, and moving at a pace out of step with the demands of clinical practice" [18]. The medical profession feels that it strives for excellence of its own accord, and does not need the input of lawyers to improve.

The adverse effects of litigation on physicians are well documented in the psychiatric literature. Physicians who have not been sued tend to agree with popular notion that malpractice litigation affects only physicians who are guilty of negligence [23]. This makes being sued themselves a frequently devastating experience. Physicians in general do not understand the tactics of the adversary system and take the charges against them quite personally. Of four hundred and fifty sued physicians chosen at random for study, 20% reported pervasive anger and change in mood, inner tension, irritability, insomnia, fatigue, gastrointestinal symptoms, or headache [23]. Most (89%) felt that the plaintiff's suit was unjustified. Many perceived themselves as scapegoats of the legal profession [24]. Eighteen percent reported a "loss of nerve" in some clinical situations, with indecisiveness and an inability to concentrate. As a result of being sued, most (61%) ordered diagnostic tests for "protection" even when clinical judgment assessed these as "unnecessary", 42% stopped seeing certain kinds of patients, and 28% stopped performing certain high-risk procedures [25]. These effects lasted from weeks to years. More than half felt that they and their families had suffered as a result of the suit, and over a third entertained thoughts of retiring early.

A balance between the needs of patient and physician is needed. In this regard, Curran has suggested an approach to informed consent that derives from *Canterbury* [26]. In situations such as the *Harnish* case, which involved elective surgery which was important primarily in restoring a young woman's physical appearance, full disclosure is important because the procedure is neither urgent nor highly effective in combating disease or disability. Under such circumstances, the patient should consider the remote but serious risks in deciding to undergo elective plastic surgery of the neck. The *Precourt* case, on the other hand, involved a patient who was seeking restoration of sight, a goal for which considerable risk might be justified and disclosure of negligible, remote risks might be less necessary. The fact situation should thus be taken into account in determining the detail of risk disclosure required.

However, the complexity of medical decisions is such that patients often do not understand the issues well enough to make an informed decision [27,28], and some have called the very notion that informed consent can exist a delusion [29]. Patients must be informed not only about complex treatments for complex diseases but also about methods of analysis and decision-making which are often alien to them [30]. For example, patients choose surgery over radiation therapy for lung cancer when outcomes are expressed in terms of the probability of survival rather than the probability of death, but not the reverse [31]. Moreover, more detailed explanations may not help, because comprehension of medical information by patients is inversely correlated with the elaborateness of the material presented

[32], and it is actually possible to obtain patients' consent by overwhelming them with information [33]. In reality, medical decision-making is often not a mutual process but one undertaken by physicians, with information given to patients only after decisions are already made in order to obtain compliance with treatment regimens and satisfy the legal requirements [34].

There is a basic tension between law and medicine in the area of informed consent. Medicine regards the best outcome for the patient as the optimal result of a physician-patient interaction. Law, in contrast, views a patient's freedom to decide what shall be done with his own body as even more important than preservation of his health [35]. Proper informed consent is not only a legal but a moral ideal which physicians should always strive to achieve before treating patients. It is, however, a more complex matter than case law suggests; as Curran has suggested, different scenarios demand tailored approaches [36]. In situations such as *Harnish*, the law of informed consent is important to protect patients' autonomy rights. In more difficult situations such as *Precourt*, however, informed consent law should not provide yet another legal theory to pursue for damages when no negligence exists. *Precourt* is a welcome step toward recognition of this problem by American courts.

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