Informed Consent and its Implications in Family Practice

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The doctrine of informed consent has had its practical introduction to medical malpractice litigation in the past five years. Its definition has not changed since the days when its definitive application was only a fond dream of the malpractice plaintiffs' attorneys. However, with new methods of presenting this theory to the courts, and with the newly emerging practice of having rulings on matters of law substituted by judges for prevailing standards of medical practice, the implications for family physicians have become tremendous. Hopefully, by understanding the principles involved in its application in the pertinent landmark cases, family physicians will be better able to avoid the pitfalls engendered by the doctrine of informed consent.

In the summer of 1967, a six-week seminar on Law and Medicine was held in Crested Butte, Colorado, sponsored by the Law Science Academy of America. This seminar consisted of a detailed discussion, somewhat plaintiff-oriented, of the field of law and legal medicine and there was much discussion of the fringe or frontier areas of the interface between law and medicine. At that time, "whiplash" injuries were in vogue as regular fare for plaintiffs' attorneys. A new concept called "informed consent" was also mentioned. We were all quite interested, but we discovered that there was much speculation about this subject with little factual knowledge. We recognized that the plaintiffs' bar constantly explores new theories of recovery and, with the burgeoning emphasis on medical malpractice litigation, it seemed that this new theory would come into its own in the not-too-distant future.

In 1967 those of us present at the Law and Medicine seminar were unable to recall a single case in which the decision had been solely based on the theory of informed consent. Today there are several of them, and there will be many more. At one time, no one—not the patient, not the courts, and generally not even the attorneys—would question the treatment judgment of the physician. Moreover, it was unheard of that the entire medical profession could be called to task for a therapeutic approach or for withholding information from patients.

Today, with the rise of consumerism and of the "patient's rights" movement, the therapeutic decisions of the physician are no longer sacrosanct. There is probably no area of medical malpractice litigation in which this phenomenon will be more clearly demonstrated than that of "informed consent." This article will outline the theory of informed consent, discuss recent landmark cases on which current definitions of informed consent have been based, and point out some areas of present and future concern for the family physician.

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Nature of Informed Consent

What is "informed consent"? We can begin with what it is *not*. It is not a rule which requires that you tell the patient every conceivable complication or side-effect which has been demonstrated. It is not required that you read the entire package insert of a given drug to every patient prior to administering that drug. Prior to giving a penicillin injection, assuming you have satisfied yourself that there is no history of hypersensitivity reaction to this drug, it is not necessary that you read "Reports indicate an increasing number of strains of staphylococci resistant to penicillin G, emphasizing the need for culture and sensitivities studies . . . " or "The most common reactions to oral penicillin are nausea, vomiting, epigastric distress, diarrhea, and black hairy tongue . . . ." We are all familiar with such entries as this in the PDR and we recognize their usefulness and necessity in the practice of medicine. However, we, and even most courts, realize that there is a line between what *might* be told to the patient and what *must* be told to the patient.

On the other hand, the doctrine will require that you relate to your patient all information required by him on which to base an intelligent and rational decision concerning his medical therapy. In the words of the Canterbury Court, the court will "measure the required disclosure by the patient's need."[1] Moreover, the courts are more and more willing to decide whether any information we have withheld from our patient would have been material to the patient's decision. Some courts have, therefore, ruled out the need for expert medical testimony in determining what information would be medically indicated and legally required. Most physicians and many attorneys recognize the great potential for irrationality by the courts when legal principle allows the judge to decide what the best medical practice should have been. We must, however, recognize that this is an element of medical practice today and it will most certainly expand in the future.

Let us return to Washington, DC, in 1959 to review the facts of the Canterbury case, which has thrown such an ominous cloud over the practice of medicine and the potential liability of its practitioners. The 19-year-old patient was, at that time, a clerk typist employed by a government agency. It is interesting to note, and this proba-

bly represents an all-too-common occurrence, that the patient had been labeled with various psychiatric diagnoses prior to consulting a neurosurgeon with a chief complaint of severe pain in the interscapular region of his back. Two family physicians had tried to manage the pain with medication but had been unsuccessful. Thus, the patient was referred to Dr. Spence. It is also interesting to note that the plaintiff had been hospitalized for various other complaints prior to development of the pain for which he contacted Dr. Spence.

In the words of the Canterbury Court, "Dr. Spence examined the patient in his office at some length, but found nothing wrong. On his advice, the plaintiff was x-rayed, but the films did not identify any abnormality. Dr. Spence then recommended that the patient undergo a myelogram . . . ." The patient subsequently underwent the myelogram which revealed a "filling defect" in the upper thoracic region. Based on this abnormal finding, the surgeon defendant suggested that the patient undergo a laminectomy for correction of a suspected ruptured disc. The patient did not, at that time or at any subsequent time, voice any objection to the proposed procedure, nor did he in fact inquire as to its exact nature or ask for any clarification of what was involved. This point, of course, proved to be one on which the court ruminated at length.

The plaintiff's mother, who did not have adequate finances for making the trip to Washington, was contacted by Dr. Spence and was told that the suspected condition was a ruptured disc and was told the proposed procedure. When the mother inquired as to whether or not the recommended operation was "serious," Dr. Spence replied, "Not any more than any other operation." When his subsequent testimony revealed that "even without trauma, paralysis can be anticipated 'somewhere in the nature of one percent' of the laminectomies performed," a risk he termed "a very slight possibility," his fate was sealed. The court felt that this risk was certainly great enough to require disclosure to the patient. Of course, at the time of this trial the patient was still a minor, so the court held that such disclosure should have been made to the parent. We all realize that the patient would today be considered an adult for all purposes, as he was over 18 years of age at the time of surgery. To reiterate, the standard for adequate informed consent is not that *all* information be given, but that all information be given which is pertinent to the making of the patient's decision. The plaintiff subsequently suffered some postoperative complications and ultimately became a paraplegic and remained so at the time of the trial, the appeal of which was finally heard in 1972. At the risk of clouding the issue, it must be reported that the reading of the court's opinion reveals that there were several intervening factors which probably played a large part, including negligence of nursing personnel in allowing the plaintiff to fall from bed in the immediate postoperative period. However, that did not have any apparent effect on the court's ruling.

The trial court directed a verdict for both the physician and the hospital; both, of course, were sued as is the general practice. The Appeal's Court reversed, basing its opinion almost entirely on the theory of informed consent. The critical factor which should be noted is not so much that the doctrine of informed consent was applied to this case, but that the court was unwilling to accept the requirements of expert medical testimony in reaching its decision. In the past, the testimony of an expert medical witness was required in order for a medical malpractice case to even reach the jury. This is consistent with any type of malpractice litigation, against physicians or other professionals. There must be some other member of the profession who is willing to state that the defendant's conduct was not up to the standards required of such a professional. The Canterbury Court, and several other courts since, indicate that informed consent will often fall into that gray area in which the court is willing to rule as a matter of law that adequate standards were not upheld. This is the most important principle which we should remember from this case.

Discussion

We are in an era of consumerism, an era of close scrutiny of our day-to-day medical practice by individuals and institutions outside the medical profession. The implications for present and future involvement of family physicians under this concept are great. You will almost always see that the landmark cases, the million dollar recoveries, and the most horrible results will be in cases concerning surgical and related specialties. However, the extension of the Canterbury-type thinking to the area of family practice is virtually certain. Under almost any situation, someone will be willing to assert that there is a higher standard of care which should have been followed. There will always be a surgeon who will state that the family physician should not have done surgery; there will always be an internist who will state that the internist should have managed a myocardial infarction or other serious medical problem. In addition, there will be some courts who will be willing to make those assumptions even without expert medical testimony, as we have just seen.

Even without the sensational type of result such as seen in the Canterbury case, the future will probably bring lawsuits based on theory of failure of informed consent against family physicians. There are various factors which limit the number of suits brought against family physicians, such as close patient-physician relationships, the frequent rural or semi-rural practice environment, and other factors. A discussion of these, however, is beyond the scope of this article. There will be areas in which these protective factors break down. It is in those circumstances that various types of cases will be engendered.

The now famous Darling case was the case on which is based the theory that the hospital has a duty to monitor standards of practice within the hospital.[2] There was also one area concerning informed consent upon which recovery in this case was based. The defendant was not an orthopedic surgeon and, in fact, had done very little work of the type involved in the case, which concerned a fracture of the tibia in a young football player. In the future, in most jurisdictions we will probably be taken to task for overstepping the limitations of our training and experience. Hopefully, we are still some distance from being held liable on the basis of simply carrying out a procedure which is normally reserved to the specialties, but the presence or lack of informed

consent will play a major role in the case-by-case determination of the results of suits involving the family physician and such procedures. Thus, when it comes time to do an appendectomy, hysterectomy, herniorrhaphy, or cesarean section, or when we attempt the medical management of a serious problem such as myocardial infarction, severe congestive heart failure, or other problems, we will have opened ourselves to potential liability if we have not informed our patient either on that occasion or by our previous relationship with him that there might be a specialist in that particular area who could also deliver the service. By this I do not mean to state that we should say there is someone who can do the job better, but the patient must be aware that his family physician is not the only physician to whom he has access.

The logical extension of this concept will be malpractice litigation based on a failure to refer. There are numerous cases already on the books concerning this failure, but all of them, to my knowledge, have required expert medical testimony. A case bearing on this point could involve a general surgeon who had a poor result from a vascular surgery procedure. He could be held liable for this result if it were shown that a vascular surgeon had his office directly across the street from the general surgeon's office. The court could hold that although a better result could not have been guaranteed by the subspecialist, nevertheless the general surgeon has a duty to refer when it appears that the added expertise would be to the patient's benefit. Although many of us feel completely comfortable in handling problems which in some contexts are reserved to the specialist or the subspecialist, we will be required more and more to refer in questionable cases.

Another extension of this doctrine into the area of family practice, and one which perhaps is open to more argument pro and con, is that concerning the alleged failure to follow the best manner of therapy, or the most accepted manner of therapy, or even the most recent advance in therapy in dealing with a specific problem. I expect that the doctrine of informed consent will be extended to include this type of argument in the future. Thus, if the family physician is not able to keep up with improved methods of carrying out a procedure, and he is aware that such advantage could be found in the patient's same area, there will be some enterprising attorneys and some more liberal judges who will say that the patient should have had it explained to him that there is perhaps a better or more convenient management for his problem than that offered by the family physician. In the majority of cases, those we see every day, the patient will prefer to stay with "his doctor." That is not the issue. The issue is that the patient be given adequate information on which to base that decision.

We are indeed in the midst of a medical malpractice litigation crisis. This, of course, has resulted in a liability insurance premium crisis for which no one seems to have the solution. However, it does appear that the most fertile field for even further growth of malpractice litigation, from the point of view of the litigation-prone patient and the plaintiff's attorney, is very likely to be family practice. There are questions concerning the definition of a family physician, the scope of expertise of the family physician, and, as we have seen, the potential liability of the family physician. The family physician can protect against the invoking of the doctrine of informed consent by conducting his practice and educating his patients in keeping with the changing definition and application of informed consent.

References

1. Canterbury vs Spence, 464 F 2d 772 (DC Circuit) 1972
2. Darling us Charleston Community Memorial Hospital, 33 Ill 2d 326, 211 NE 2d 253, 1965