Informed Consent: Its Legal History and Impact on Medicine

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The doctrine of informed consent dictates that a physician has a legal duty to disclose to a patient sufficient information regarding the inherent risks and benefits of a proposed course of treatment, and alternatives to the proposed treatment so the patient can intelligently exercise his or her judgment about whether to undergo that treatment. The development of the law regarding informed consent both nationally and in Hawaii is examined along with the current status of the law and its potential impact on physician behavior and health care delivery in Hawaii.

When a physician fails to obtain informed consent from a patient before proceeding with treatment, he or she has failed to practice up to the professional standard of conduct expected of physicians and can be sued under a theory of negligence. The basic elements of a cause of action based on negligence are: 1) a duty or obligation recognized by the law, 2) a breach of that duty, 3) a legally recognized causal connection between the conduct and the injury, and 4) actual loss or damage to another. Element four, actual loss or damage, is an essential part of a plaintiff's case, and without that element, there is no cause of action.[1]

National Case Law

Schloendorff v. Society of New York Hospital[2] is the initial case involving the physician's requirement to obtain informed consent. It was in that case that Justice Cardozo said, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault."[2] The court made no distinction between informed consent and consent. Forty-three years later, *Salgo v. Leland Stanford Jr University Board of Trustees*, established the legal duty of a physician to provide a "full disclosure of facts necessary to an informed consent."[3] The *Salgo* court said physicians had a duty to disclose, but allowed the physician to use his or her best discretion as to what disclosure was necessary for informed consent. The court said:

> Each patient presents a separate problem...the patient's mental and emotional condition is important and in certain cases may be crucial, and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent.[3]

Several years later in *Natanson v. Kline*,[4] the court adopted the *Salgo* standard and held that the decision as to what to disclose was primarily a medical judgment; therefore, the duty was limited to disclosures that a reasonable physician would make in similar circumstances. The court concluded that under this professional standard "the patient is properly protected by the medical profession's own recognition of its obligations to maintain its standards."[4]

Canterbury v. Spence,[5] a federal court decision, changed the professional standard rule and developed a patient-centered standard of disclosure. The *Canterbury* court decided that "respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves."[5] The court, however, recognizing that a physician would be hard-pressed to know exactly what each-and-every patient might deem relevant in a given situation, adopted what has come to be known as the "objective patient standard," based on "the average reasonable patient...with due regard for the patient's informational needs and with suitable leeway for the physician's situation."[5]

The court also acknowledged several exceptions to the disclosure requirement, including risks inherent in any procedure (such as infection), hazards that the patient is already aware of, and emergencies where there is no time to obtain consent and waiting for consent would greatly endanger the patient.[5] In addition, the *Canterbury* court recognized the "therapeutic privilege" exception to disclosure of risk information. According to the *Canterbury* court this privilege occurs when a patient might become "so ill or emotionally distraught on disclosure as to foreclose a rational decision, or complicate or hinder the treatment, or perhaps even pose psychological damage to the patient."[5]

In keeping with the negligence theory, the *Canterbury* court determined that, in addition to breach of duty, there must also be evidence of a causal connection between the breach and the injury, and that without injury or harm there was no actionable negligence unless the disclosure of risk information would have led the patient to opt for a different treatment, the failure to provide that information, while a breach of duty, is not sufficient for a cause of action under negligence theory. This should be objectively determined, ie, "what a prudent person in the patient's position would have decided if suitably informed of all perils bearing significance."[5]

In summary, *Salgo*, *Natanson*, and *Canterbury* established failure to provide informed consent as negligence, ie, malpractice. *Salgo* and *Natanson* said that the decision as to what to disclose was a professional decision, while *Canterbury* said it was to be based on what the patient would view as important. While *Salgo* and *Natanson* did not need to address the issue, *Canterbury* said that causation, ie, whether the information would have changed a decision, was to be based on an objective "prudent patient" standard.

The court's hesitancy to trust the accuracy of the plaintiff's memory and judgment is well supported by empirical studies. Research demonstrates that people do not accurately remember even their own predictions, and therefore, end up exaggerating what they thought they knew at a previous time. "This research does not imply that hindsight is a knowing misrepresentation of fact, for individuals will be truthful in their hindsight recall. The

hindsight bias arises from cognitive limitations on people's ability to recall past perspectives accurately."[6] A recent study done in Hawaii confirmed the unreliability of patients' memories. Ninety percent of 144 patients who had been informed of the risk of death from gallbladder surgery were able to correctly recall that warning prior to surgery. However, only three weeks after surgery 54% of those who correctly remembered before surgery stated that they had *not* been told that death was a potential risk.[7]

Hawaii Law

In Hawaii, both statute and common law make failure to obtain informed consent a medical tort.

In 1970, two years before the landmark *Canterbury* decision, the Hawaii Supreme Court, in *Nishi v. Hartwell*,[8] established its position on the doctrine of informed consent. The court, citing the *Salgo* decision, stated:

> The doctrine of informed consent imposes upon a physician a duty to disclose to his patient all relevant information concerning a proposed treatment, including the collateral hazards attendant thereto, so that the patient's consent to the treatment would be an intelligent one based on complete information...However, the doctrine recognizes that the primary duty of a physician is to do what is best for his patient and that a physician may withhold disclosure of information regarding any untoward consequences of treatment where full disclosure will be detrimental to the patient's total care and best interest.[8]

The court held that the standard to be used in determining whether adequate disclosure had been made was a professional standard, ie, "by reference to relevant medical standards."[8] This meant the plaintiff had to prove with expert medical testimony that the relevant medical standard had not been met.

In 1976, in response to what was perceived as a medical malpractice crisis, the Hawaii legislature, to lend some potential protection to the physician, enacted legislation that attempted to develop standards for informed consent. The act stated: "The standards established by the board shall be *prima facie* evidence of the standards of care required but may be rebutted by either party."[9] The legislation also codified the common law exception to risk disclosure in the case of emergency treatment. The law did not directly address the standard of disclosure or the standard of causation.

In 1983 the legislature amended the statute to more clearly identify the scope of the disclosure. The statute stated:

> If the standards established by the Board of Medical Examiners include provisions which are designed to reasonably inform a patient, or a patient's guardian, of:
> 1) The condition being treated;
> 2) The nature and character of the proposed treatment or surgical procedure;
> 3) The anticipated results;
> 4) The recognized possible alternative forms of treatment; and
> 5) The recognized serious possible risks, complications and anticipated benefits involved in the treatment or surgical procedure, and in the recognized possible alternative forms of treatment, including nontreatment, then the standards shall be admissible as evidence of the standard of care required of the health care providers.[10]

Again, the legislative language was ambiguous as to whether the standard of disclosure was patient centered or professional.

In 1985, in *Leyson v. Steuermann*,[11] the Intermediate Court of Appeals examined the doctrine of informed consent. The *Leyson* court, noting ambiguity in the language of *Nishi* and HRS §671(3) (1976), did not address the standard of disclosure. The court did reaffirm, however, the previously discussed exceptions to the informed consent doctrine.

Applying the facts of the case to its interpretation of the law, the *Leyson* court described the tort of negligent failure to disclose risk information as:

> 1) duty to disclose...risks...2) breach...[of the] duty; 3) injury; and 4) breach of duty was a cause of injury in that: a) [the] treatment was a substantial factor in bringing about [the] injury and b) [the patient], acting rationally and reasonably, would not have undergone the treatment had he been informed of the risk of the harm that in fact occurred; and 5) no other cause is a superseding cause.[11]

By defining element 4 b in terms of the specific patient "acting rationally and reasonably," the court broke with previous courts by blending objective and subjective aspects of a patient oriented standard of causation:

> [W]e opt for the application of a modified objective standard that determines the question [of causation] from the viewpoint of the actual patient acting rationally and reasonably.[11]

This new "modified objective" standard examined causation from the view of the "actual patient [subjective component] acting rationally and reasonably [objective component]."[11]

In *Mroczkowski v. Straub Clinic & Hospital, Inc*,[12] the Intermediate Court of Appeals then held that before a plaintiff can argue that the duty to disclose a risk was negligently performed, he or she must prove that the harm complained about was a probable risk of the operation and that the defendant knew or should have known of that fact. The risks to be disclosed were "all recognized serious possible risks of harm and complications that the physician knew or should have known of, plus other information."[12]

Once again the court declined to address whether the question of seriousness of the risk was to be "answered from the point of view of the patient, the physician, or otherwise."[12]

Keomaka v. Zakaib[13] is the most recent decision by the Intermediate Court of Appeals regarding the doctrine of informed consent. It then reaffirmed the need for causality to be established vis-a-vis both the treatment rendered and the nondisclosure of the risk, ie, that the injury was caused by the treatment and that if the risk had been disclosed the patient would not have undergone the treatment. The court also addressed the question of whether a patient can be contributorily (or more correctly comparatively) negligent when a physician attempts to obtain informed consent. This issue could turn out to be the most important aspect of *Keomaka*.

The court held, in firm and unequivocal language, that "contributory negligence has no place in an action for failure to obtain informed consent."[13] The court stated the argument that Keomaka's failure to read the informed consent form was contributory negligence was without merit, and the duty to inform rests with the physician:

> [B]ecause of the superior knowledge of the doctor with his expertise in medical matters and the generally limited ability of the patient to ascertain the existence of certain risks and dangers that inhere in certain medical treatments, it would be unfair and illogical to impose on the patient the duty of inquiry or other affirmative duty with respect to informed consent.[13]

The court specifically stated that the mere signing of a printed

consent form (even one that said that the doctor had discussed all risks and alternatives) would not fulfill the physician's duty and "is not a substitute for the required disclosure by the physician."[13]

The court did not discuss whether or not the physician's duty could be carried out through affirmative acts of other hospital personnel such as nurses or pharmacists, and if so, what duty the physician had to make sure that the information had been understood by the patient. This point is of more than academic interest because many hospitals now use nurses and pharmacists to provide patient education regarding disease and treatment.

Summarizing Hawaii law: Failure to provide informed consent is a tort, with the parameters of the tort defined in statutory and common law. Treatments, alternatives to treatment, and all recognized serious possible risks are to be disclosed. While ambiguous, it seems that a professional standard is to be used to decide what to disclose. A *modified objective* standard (the actual patient acting rationally and reasonably) is to be used to determine if the disclosure would have changed the patient's decision. The plaintiff must prove both that a risk was not disclosed *and* that if it had been disclosed, the patient, acting rationally and reasonably, would not have undergone the treatment. Finally, in Hawaii the patient cannot be contributorily negligent by failing to ask questions, by signing a form that he or she has not read, or any other act of commission or omission related to the informed consent process.

Discussion

Current Hawaii law, pointing to the importance of protecting patient autonomy, requires physicians to obtain informed consent from their patients before proceeding with treatment. It is commendable and appropriate that Hawaii's legislature and courts are interested in protecting patients. However, some of their assumptions about the role of informed consent in protecting a patient's autonomy (and even what autonomy is) are open to examination. The autonomy rationale for informed consent argues that all human beings have a right to make their own decisions, and that any limitation on the information provided to patients is an affront and infringement on that right. Yet the Hawaii courts ignore at least two significant realities with their rulings:

First is the relationship between autonomy and responsibility. Hawaii law holds that the patient has *no* responsibility relating to the process of informed consent. Ironically, the court bases this idea of no responsibility on the very thing that it seems to question: The professional expertise and judgment of the physician. The court feels that the physician's expertise vis-a-vis the patient places all responsibility for initiating, maintaining, and structuring informed consent on the doctor. This appears contrary to the idea that the patient is an autonomous individual, for if that were so, he or she would have some responsibility for the choices made, ie, to sign or not sign a form indicating that something had happened when in fact it had not. More important, the *no responsibility* standard negates the idea that the patient has any responsibility for the nature of the doctor-patient relationship and the communication that exists in that relationship. It seems the courts' perception of the patient is passive, noncontributing, and not responsible is itself a paternalistic and demeaning view of the patient. If it is paternalistic of physicians to think that they know what is best for the patient, it is equally paternalistic of the courts to proclaim patients incapable of and not responsible for shaping the discourse between them and their doctors. It is this relationship between doctor and patient that is the key to true informed consent, and both parties must take responsibility for their part in that relationship.

The courts also continue to treat informed consent as an event rather than a process. They seem to think that medical decision making occurs at a fixed time and place, and that a course of treatment, once decided, is an essentially fixed recipe. The reality is that clinical decision making is an ongoing process that is constantly altered by numerous sources of feedback, including the disease and its response to earlier treatment interventions. A better view of informed consent is that it is a process between two people who are involved in a relationship with each other.

Burt[14] and Appelbaum[15] have discussed this view of informed consent and present a perspective that it much more relevant and meaningful to the actual context within which informed consent discussions occur. As they point out, the process of disease and death creates fear, anxiety, and/or uncertainty in both doctor and patient. As humans, both react to these emotions with attempts to control the situation, the doctor through prescribing a treatment and the patient through controlling what will be prescribed. Thus what is needed between physician and patient is less acquiescence of one to the other, but rather more dialogue, discussion, and understanding of the nuances of the bio-psycho-social situation in which the two people find themselves. In this manner each participant's fears and uncertainties can be exposed and confronted. While the ultimate decision might or might not be the *best* or most rational, it will be made the way many decisions are made—on the basis of a relationship between two people who recognize the humanity of the other.

Finally, and from a somewhat different perspective, whatever is thought of the courts' logic, its current ruling on the role of contributory negligence in informed consent cases may in fact affect aspects of patient care. By holding that the routine consent forms patients often sign on entering a facility have no legal significance in the absence of evidence that the physician actually performed his or her duty to disclose risk and alternative treatment information, it signifies a need to move away from the *paper consent* documentation via various forms, and instead to focus on physician documentation of actual discussions with patients. It should also lead to increased use of interpreters, so as to make sure that language limitations don't result in lost information. Note that this action would also be consistent with Burt and Appelbuam's views of informed consent processes.

In addition, adherence to both the spirit and letter of the law can improve patient care. First, physicians will be required to more clearly justify their clinical interventions, rather than to rely on the old saw that *it's the usual procedure.* Instead they should be more reflective about their treatment recommendations and the effect on their patients. This may in turn change patient choices. For example, a program at Dartmouth Medical School documented that after viewing a video that gave information on watchful waiting versus surgery for benign prostatic hypertrophy, one-third of the patients who had favored surgery changed their minds.[16] Second, because the process of informing patients often requires education about diseases, treatments and procedures, it is likely that other professionals will become involved. With their developing professionalism, nurses and pharmacists have increased their teaching activities with patients. For example, critical-care nurses[17] and pharmacists are becoming more involved in patient education, and thus contributing to the process of informed consent.

However, hospitals might negate these gains if they interpreted the court's holding on the physician's duty to provide informed consent as insulating the hospitals from any liability for failure to obtain informed consent. It would be ironic indeed

if, in attempting to protect patient autonomy, the court's holding negatively affected this move toward increased patient autonomy by allowing hospitals to decrease nonphysician patient education activities.

In the past hospitals generally have not been held liable by courts in informed consent cases.[17-21] However, recently there has been the suggestion that medical malpractice, including informed consent torts, should be viewed as enterprise liability. Under this theory, hospitals would become liable for the torts of the physicians on their medical staffs, and physicians would not need malpractice insurance for their hospital-based activities. Given the increasingly accepted view of a health care team and moves toward integrated delivery systems, it would be quite reasonable for the legal (and medical) system to focus on institutional liability and prevention.

> The best vehicle for identifying and dealing with such incidents is the organization in which the doctor practices. The memory of the institution can serve to record and piece together patterns in a host of apparently idiosyncratic incidents. The collective wisdom of the hospital team can be pooled to devise feasible procedures and technologies for guarding against the ever-present risk of occasional human failure by even the best doctors...Not only does the organization have a greater capacity to establish such quality assurance programs, but is also more likely to be influenced to do so by the incentives created by tort liability.[22]

The third potential benefit associated with the imposed duty to inform patients of risks and alternatives was alluded to previously. Providing additional information may result in a decrease in unnecessary health care expenditures. As noted previously, the provision of additional information resulted in an increase in the number of patients choosing the less expensive medical treatment option.

The hidden dangers in excessive informed consent procedures are at least twofold. First is that out of defensiveness physicians and hospitals might expend precious physician and other personnel resources trying to achieve a level of informed consent that is attainable only in the world of law review articles and court pronouncements. The second is the real possibility that by providing excessive information on rare but possible risks, patients will be frightened away from procedures where the actual risk benefit ratio is highly positive.

Conclusion

The aim of Hawaii's legislature and courts has been to protect patient autonomy and to ensure that medical choices are made from an informed position. However, the nature of the legislative and litigation processes have kept them from addressing broader questions relating to how patients actually get information about their medical treatment, how that affects physician-patient relationships, and how we should work to change those relationships to provide better medical care while at the same time meeting our obligation to respect each patient's individuality.

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