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SYMPOSIUM: EVOLVING MEDICOLEGAL CONCEPTS

What to Disclose? Revisiting Informed Consent

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Abstract

Background The requirement of obtaining informed consent before medical procedures is well established. With patients having greater access to information through information technology and owing to other factors, disclosure that goes beyond the traditional elements of the risks, benefits, and alternatives to an intervention is demanded from physicians.

Questions/purposes We asked if modern informed consent doctrine encompasses such physician-specific variables like professional experience, health, disability, training, qualifications, disciplinary history, FDA-regulatory status pertaining to a medical device, physician research and financial interests, and statistics related to medical outcomes.

Methods We searched two major legal databases and identified court opinions and legal reviews that have examined the scope of physician disclosure while obtaining informed consent. From this information, we summarized the prevailing state of informed consent law.

Results Despite the expansion of information available to patients, courts have been hesitant to expand the informed consent doctrine to encompass physician-specific variables. Exceptions involve cases in which such variables directly impacted medical care and the patient could demonstrate their relevance in the informed consent process.

Conclusions Judicial decisions have subtly expanded the doctrine of informed consent beyond its traditional limits, at least in some cases. As informed consent law continues to develop, physicians should ask if information would be material to a reasonable patient while making medical decisions; if so, such information should be disclosed.

Introduction

The law of informed consent is familiar to all orthopaedic surgeons. The basic requirement of consent before a surgical operation was set forth in the 1914 legal case of Schloendorff v Society of New York Hospital [43]. In Schloendorff, a woman consented to having a fibroid tumor examined under ether anesthesia to see if it was malignant. The doctor, on finding that the tumor was malignant, chose to remove it contrary to the patient's wishes. The plaintiff said that the operation constituted medical battery; Justice Benjamin Cardozo agreed that "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 for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained."

The 1972 legal case of Canterbury v Spence expanded the scope of informed consent by focusing on information disclosure [10]. In Canterbury v Spence, the Court of Appeals in the District of Columbia considered the complaint of a patient who was seriously injured after elective

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thoracic spine surgery for a herniated disc. The surgeon had chosen not to tell the patient about the risk of paralysis; he argued that the risk was small enough and that disclosure might provoke unnecessary patient anxiety that could result in the harmful postponement of a medically necessary procedure. The court disagreed; its opinion clarified the disclosure requirement that is now a well-recognized element of the informed consent process. The Court said "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 … it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie."

With dramatic advances in information technology, patients now have easier access to medical information. The emerging model of patients as consumers of medical services has led to a reexamination of what needs to be disclosed during the informed consent process. Traditional informed consent has focused on the risks, benefits, and alternatives to a planned procedure. Physician disclosure has never addressed the quality of the physician, physician performance, potential physician economic and research conflicts, physician illness and disability, operative logistics and operative devices, and variables related to resource availability.

The purposes of this review are to: (1) describe the perspective of professional medical associations concerning information that member physicians should disclose while obtaining informed consent; (2) examine whether physician-specific variables such as professional experience, health, disability, training, qualifications, and disciplinary history must be disclosed to patients when obtaining informed consent; (3) investigate if FDA-regulatory status pertaining to a medical device is relevant information requiring patient disclosure; and (4) inquire whether information concerning physician research, financial interests, and statistics related to medical outcomes should be disclosed during the informed consent process.

Search Strategy and Criteria

We searched the two major legal databases, Westlaw and LexisNexis, and law review articles [22, 24] and identified 178 legal citations related to the law of informed consent in the context of a medical procedure. Of these, 40 case law citations were identified that were relevant to the question of how much information a physician should disclose to a patient when obtaining informed consent; those cases form the basis of this review. Review of case law is important because the legal principles that govern informed consent have been shaped by the judicial decisions of courts. Those decisions can therefore provide valuable insights into how the law in this area is developing and offer useful guidance to practicing physicians.

Perspective of Professional Medical Associations

The published perspectives of physician professional associations as they relate to informed consent are important because these are often cited in court decisions as practical guidelines and a summary of the law of informed consent available to practicing physicians. Before examining case law therefore, it is worthwhile to examine what physician organizations such as the American Medical Association (AMA) have said about informed consent and how much information they recommend disclosing to patients while obtaining consent. The AMA characterizes informed consent as requiring a "dialogue between patient and physician in which both parties exchange information and questions culminating in the patient's agreement to a specific medical or surgical intervention" [30]. Beyond dialogue, however, the AMA states that informed consent requires voluntary disclosure of information by the physician, even absent patient inquiry. However, AMA opinions on this matter have not required member physicians to disclose personal risk, performance, or quality measures to help the patient make an informed choice [4, 47]. In contrast to the AMA, the American College of Surgeons (ACS) has addressed variables related to choice of surgeon, surgeon safety record, surgeon training, and success rates [24]. The ACS view on informed consent implicates physician-specific variables such as performance, quality, and disability in a patient inquiry-driven model whereby the doctor must disclose information if so urged by the patient. From the physician standpoint, the informed consent doctrine, even in the ACS model, remains limited to disclosure of the classic procedure-related risks, benefits, and results; the ACS simply encourages the patient to inquire further if so desired [42].

Recent reports and teaching aids from the American Academy of Orthopaedic Surgeons (AAOS) emphasize that informed consent is a process and educational endeavor [22]. AAOS publications are helpful in understanding the legal perspective, research use, and pitfall avoidance related to the informed consent process, but like the AMA and ACS models, the AAOS guidelines do not specify what physician-specific information, if any, must be volunteered to the patient.

In summary, although most physician associations have published guidelines advising member physicians about informed consent law and the amount of information to disclose, this information is usually vague when it comes to disclosure of physician-specific information. Most physician

association websites list legal cases that have dealt with informed consent law and encourage member physicians to familiarize themselves with the relevant case law. The next several sections of this article examine court opinions that have addressed the scope and extent of physician disclosure during informed consent. However, this inquiry has its limitations. First, most legal cases are appellate opinions that are limited to particular issues before the court; the opinions rarely offer expansive pronouncements that can educate medical professionals. Second, most medical negligence cases are treated at the state level, creating some randomness and inconsistency in the rulings. Even so, court opinions in one state are often cited by lawyers as legal authority, which, although not dispositive, can still influence judicial deliberations in similar cases in the courts of other states. Accordingly, despite the limitations of case law, a review of court opinions is helpful in determining how the doctrine of informed consent may be reshaped in the modern, information-rich age. Specific elements related to physician disclosure of information are examined in the sections that follow.

Disclosure of Physician Experience

Meaningful disclosure of physician experience would address how many times a surgeon has performed a procedure and the attendant success rate of that surgeon with the procedure. In Degennaro v Tandom, a defendant dentist neglected to tell the patient that she had no experience with the equipment used and that she typically relied on an assistant when performing the procedure [14]. The patient sustained a serious tongue injury, and the Connecticut court held that provider-specific information such as inexperience must be disclosed to obtain consent "where the facts and circumstances of the particular situation suggest that such information would be found material by a reasonable patient in making the decision to embark on a particular course of treatment, regardless of whether the patient has sought to elicit the information from the provider."

In Barriocanal v Gibbs, a medical negligence/wrongful death action involved a defendant neurosurgeon who failed to disclose that he had not done that type of surgery recently, that the hospital was thinly staffed over a holiday weekend, and that other nearby hospitals had more expertise in that type of brain surgery [7]. The plaintiff's expert witness argued that such nondisclosure violated the standard of care; the court permitted this evidence into the case. The importance of this decision is that the court interpreted the Delaware informed consent statute to encompass the disclosure of provider-specific information.

In Goldberg v Boone, a Maryland court considered a medical negligence claim against a surgeon who performed a revision mastoidectomy that led to brain injury [9]. The issue was whether the surgeon should have told the patient that he had performed just one similar operation in the past 3 years and that more experienced surgeons were available nearby. The court used a "reasonable patient" test and decided that jurors should determine if a reasonable person, in the plaintiff's position, would have considered such information material to the decision whether to have the surgery performed by the relatively inexperienced defendant surgeon.

Other courts have adopted a more conservative posture toward disclosure of surgeon experience. Duttry v Patterson was a Pennsylvania case in which an injured patient claimed that the surgeon was questioned about his experience and that the surgeon had misled the patient [18]. The court acknowledged that related judicial decisions in other states had expanded the requirements of disclosure to include surgeon experience but refused to join those opinions. In Avila v Flangas, a Texas Court held that nondisclosure of surgeon experience cannot form the basis of an informed consent claim because it is not a risk inherent to the procedure [6]. However, even the judicial rulings that have adopted a restrained posture have left the door open to future expansion of the informed consent doctrine either through reexamination of the relevant state statute by the legislature or by requiring that injured plaintiffs must prove, by expert testimony, that failure to disclose information related to surgeon experience constituted a deviation from the standard of care.

In practice, the definition of surgeon experience or inexperience is fraught with practical difficulty; for example, a surgeon may be well experienced in performing surgery around a given anatomic location although he or she may not have performed the specific procedure in question. Some authors have argued that hospital staff privileging and credentialing data should be the dispositive standard by which surgeon qualifications and experience are judged instead of compelling physician disclosure to the patient [46].

In summary, recent case law suggests disclosure of surgeon experience is not always necessary, but in cases of substantial inexperience or disadvantage, failure to disclose may be construed as a breach of informed consent.

Disclosing Physician Health and Disability

Should physicians be required to disclose matters pertaining to personal health, especially if matters related to physician health may increase the risk of harm to the patient? Several court decisions have tackled this issue. In Albany Urology Clinic v Cleveland, the court dealt with a negligence claim against a urologist with a history of

cocaine use outside of work and while not on call [1]. The patient, unable to have intercourse after surgery for penile cancer, argued that the doctor had a duty to reveal his drug use history. The court agreed that the history of drug use may be relevant to the alleged negligent conduct but that a strict construction of the statute governing Georgia law of informed consent did not support an independent cause of action against the doctor. The opinion cited some interesting hypothetical situations, noting the "impossibility of defining which of a professional's life factors would be subject to such a disclosure requirement."

In Hidding v Williams, a Louisiana court considered a negligence claim against an orthopaedic surgeon in which the patient sustained neurological injury after spine surgery and alleged that the doctor should have disclosed his alcohol abuse history that had led to a prior medical license suspension and divorce [29]. The court affirmed the lower court ruling that the physician's failure to inform the patient about his personal alcohol abuse voided the surgical consent. The court reasoned that alcohol and drug abuse constituted a material risk that increased the risk of injury from surgery and that if disclosed, the patient probably would have sought treatment elsewhere. In Kaskie v Wright, parents sued a doctor after their son died in his surgical care when they discovered the doctor had alcohol problems and did not possess a state medical license [33]. The court, reluctant to expand the informed consent doctrine, chose to implicate credentialing bodies and hospitals by noting that "matters such as personal weakness and professional credentials of those who provide healthcare are the responsibility of the hospital employing them, the professional corporations who offer their services, or the associations which are charged with oversight. Their failure to fulfill their obligations in this regard becomes a matter of negligence, and it is from them that recovery must be sought." Alcohol use is pervasive in society, and physician opinion is divided on whether to tell patients about alcohol use before treating them; a study on this subject addressed informed consent and concluded that patients would want to know about a physician's use of alcohol while on duty [15].

Where disability of the surgeon directly impacts surgical performance, the issue of disclosure is more straightforward. In Hawk v Chattanooga Orthopaedic Group, a patient injured during a THA later discovered that the surgeon had Raynaud's syndrome that affected his hand [27]. The court recognized this as a proper basis for an informed consent medical malpractice action. In contrast, in which physician medical history is unrelated to increased risk to the patient, courts have generally held that physician health, drug, or alcohol use history is not subject to disclosure. Thus, in May v Cusick, a surgeon was accused of failing to share his history of strokes; he had two minor strokes in the past with full recovery [38]. In Mau v Wisconsin Patients Compensation Fund, the accused surgeon had a history of drug use but had been clean for several months, as evidenced by random drug testing [37]. In both cases, Wisconsin courts ruled that the physician's medical history was irrelevant to the chosen course of treatment and therefore could not be implicated in an informed consent claim.

The relationship between disclosure and alleged injury was examined by the court in Halkyard v Mathew; the surgeon was accused of negligently performing a hysterectomy that led to complications [25]. The patient, a nurse, said that if she had known of the doctor's history of epilepsy, she would have picked a different doctor. The surgeon had not had an epileptic seizure, and the outcome was unrelated to epilepsy or the use of medications to treat such. The court ruled that no liability in negligence existed because although undisclosed, the doctor's health history was unrelated to the harm sustained by the patient. This requirement of a nexus between the undisclosed condition and patient injury has been criticized by legal scholars who argue that the patient is not required to be injured by the health risk; the injury is lack of disclosure itself that constricted patient choice in either refusing treatment or going to a different doctor [23].

Informed consent cases related to physician HIV-positive status have led to much debate and case law. Professional medical organizations have issued varying positions on this subject. The Centers for Disease Control and Prevention recommendations of 1991 advise physician disclosure of HIV seropositivity to patients [11], whereas a statement by the ACS neither discourages HIV-positive surgeons from performing invasive procedures nor requires that they disclose their HIV status to patients while obtaining informed consent [48]. The American College of Obstetricians and Gynecologists states that if HIV-positive physicians avoid procedures that place their patients at risk of disease transmission, then no obligation arises to inform the patients of their HIV serostatus [3].

In Faya v Almaraz, a Maryland court ruled that a HIV-positive oncology surgeon who performed breast surgery was negligent in not disclosing his HIV status during the informed consent [21]. The foreseeability of disease transmission was central to the court's opinion, although the risk was remote. The plaintiffs could recover for mental anguish and fear during the limited window from the time of discovery of the surgeon's illness to learning of their own HIV-negative test results. In Estate of Behringer v Medical Center of Princeton, a HIV-positive otolaryngologist was required by the medical center where he had staff privileges to report his HIV status to surgical patients as a condition of obtaining consent [19]. When the doctor challenged this requirement, the court used a reasonable patient standard to rule that the doctor's

seropositive status would be material in deciding whether to choose that surgeon.

In Scoles v Mercy Health Corp, a Pennsylvania court considered the claims of a HIV-positive orthopaedic surgeon against healthcare institutions that prohibited him from performing surgery without the patient's informed consent regarding his HIV status [44]. Although the case did not invoke issues related to informed consent directly, the court noted that the institutions had reasonably decided that the surgeon's patients should not undergo an invasive procedure without knowledge of his HIV status.

In summary, in the several legal cases that have examined the disclosure of physician health status, the decisions appear to be turn on the nexus of physician health conditions and how they affect the ability to deliver health care. Cases in which physician health directly impacts the risks of healthcare delivery such as Raynaud's syndrome in a surgeon or HIV seropositive status in a practicing surgeon likely require disclosure for informed consent. Indirectly related conditions such as well-controlled epilepsy or HIV seropositive status in a nonsurgical physician are likely not required for disclosure.

Disclosure of Physician Training and Qualifications

The issue of whether a surgeon should offer details of qualifications and training pertaining to the surgeon and to the operating room personnel during informed consent has been encountered in a number of legal cases. In Ditto v McCurdy, a Hawaii court relied on the state's informed consent law to determine that a surgeon had no duty to reveal his qualifications to the patient before surgery [17]. Likewise, in Zimmerman v New York City Health and Hospital Corp, the court held that the doctrine of informed consent, under the facts before the court, did not include the disclosure of details related to the qualifications of operating room personnel [51]. At issue was whether informed consent required the disclosure of a nurse anesthetist, and/or a student physician, and/or a resident physician to administer anesthesia during surgery.

In Thomas v Wilfac, a Washington state court considered the case of a radiology resident moonlighting in a walk-in emergency facility; at issue was lack of disclosure that the resident was not a specialist in emergency medicine [49]. The court invoked the state informed consent statute and held that disclosure of physician qualifications was not required. Other case law dealing with the participation of resident physicians and physician assistants during surgery has reached similar conclusions. In Dingle v Belin, for example, a Maryland court considered an informed consent claim based on resident participation in gallbladder surgery; the court found no obligation to disclose the resident role in obtaining the classic informed consent [16].

Likewise, in Prissel v Physicians Ins Co, a Wisconsin court was faced with an experienced coronary bypass surgeon who had failed to disclose the role of a physician assistant during the operation [41]. The court referred to the relevant state statute and found no disclosure requirement, observing that the use of an assistant did not increase the risk to the patient. In Henry v Bronx Lebanon Medical Center, the court considered postdelivery complications that occurred when a second-year resident performed the delivery under the supervision of an attending doctor [28]. The court observed that it was hospital custom for residents to perform complicated deliveries and that by seeking care at that facility, the patient had consented to the practices and customs of that hospital.

In summary, case law indicates that physician experience and information related to specific qualifications and training of operating room staff, residents, and personnel assisting during a medical procedure do not need to be specifically disclosed. This information can be efficiently captured in a generic consent form, in which the patient is informed, for example, that residents and other personnel who are in training stages may help during the procedure under the supervision of the attending physician.

Disclosure of Physician Disciplinary History

Judicial decisions related to disclosure of physician disciplinary history are sparse, and most have assumed that such information is subsumed in the practice privileges and credentialing process such that no physician disclosure is required during informed consent. Thus, in Curran v Buser, a Nebraska court interpreted the state statute regarding informed consent as encompassing a professional-friendly theory of the underlying doctrine [13]. Disclosures related to physician disciplinary history, the court said, are required only when mandated by the standard of care, and in the case in question, the standard of care did not require such a disclosure.

In Ex parte Mendel, a court in Alabama considered a dental negligence claim in which the accused dentist had an extensive history of license suspensions and revocations [20]. The injured patient requested discovery of this information from the Alabama Dental Board. The court held that the requested discovery was appropriate under the state Medical Liability Act and commented that "we will assume, but need not decide, that Dr. Mendel owed [plaintiff] a duty to disclose 'multiple' suspensions or revocations; reprimands by 'numerous' dental review boards; or suspensions or revocations in 'numerous' states."

In summary, physician misconduct can range from improper recordkeeping at one end of the spectrum to criminal conduct on the other. Case law suggests that if physician disciplinary history directly relates to professional competence and patient safety, a court could reasonably find that disclosure is required before treatment of a patient but not otherwise.

Disclosure of FDA Status of a Medical Device

A patient enrolled in an experimental study concerning a device not yet approved by the FDA is entitled to full disclosure of the experimental nature of the study. However, if a patient's surgical procedure uses the implantation of hardware that is not FDA-approved, or is FDA-approved for another purpose, or is experimental, must the patient be so advised by the surgeon to provide informed consent? Courts have wrestled with this matter in a number of legal opinions.

In Orthopaedic Bone Screw Products Liability Litigation, a Florida court held that disclosure of FDA status is not required, because such status is not a medical risk of surgery [31]. This reasoning was also articulated in Alvarez v Smith, another Florida case involving the alleged implantation of surgical screws in the patient's spine, in which such pedicle screws were not FDA-approved for that procedure [2]. In favor of the surgeon, the court noted that the terms Class III, investigational, and substantial risk pertaining to the device are for administrative or regulatory purposes and cannot be extrapolated to specific risks of the surgical procedure. Likewise, in Blazoski v Cook, a New Jersey court held that disclosure of FDA status was not required during informed consent when a patient sustained injury from failure of implanted pedicle screws that were not FDA-approved for the procedure [8]. In Klein v Biscup, an Ohio court considered the off-label use of bone plates and screws and also found that such use was not a material risk that required disclosure before obtaining informed consent [34].

In contrast to the previously mentioned cases, in Corrigan v Methodist Hospital, a federal trial court heard the claims of a patient injured from lumbar spine surgery in which a plate and pedicle screws were used [12]. The patient argued that informed consent was not obtained because she was not advised of the investigational nature of the system nor of the physician's financial interest in the manufacturer of the system. The court found that the undisclosed risk of the investigational status of the VSP bone screws raised an issue of material fact that should be referred to the jury. Not long after this opinion, the court considered the aforementioned case of Orthopaedic Bone Screw Products Liability Litigation and distinguished the findings from those in Corrigan. The court observed that FDA-regulatory status is not a risk of the procedure and therefore not a subject of disclosure related to informed consent. However, the participation of the patient in a clinical investigation, which was invoked in Corrigan, requires disclosure of the investigational status of a product pursuant to FDA regulation, not state informed consent law.

In Southard v Temple University Hospital, the Supreme Court of Pennsylvania revisited the nondisclosure of the FDA-regulatory status of bone screws and rods [47]. The court affirmed previous case law by commenting that the category into which the FDA places the device for marketing and labeling purposes simply does not enlighten the patient as to the nature or seriousness of the proposed operation. Accordingly, FDA-regulatory status is not a topic for mandatory disclosure under the doctrine of informed consent.

Although FDA-regulatory status may not be relevant during informed consent, FDA status can be admissible into evidence as one factor to be considered by the jury, especially if the plaintiff raises issues relating to the standard of care prevailing at the time of surgery or courts may permit examination of evidence related to FDA status pursuant to the rules of the procedure used in that jurisdiction. In Shadrick v Centennial Medical Center, for example, a Tennessee court found a disputed issue of material fact as to whether the prevailing standard of care at the time of patient injury required disclosure of the lack of FDA approval and the experimental nature of the use of pedicle screws [45]. The court did not discuss the purpose of FDA-regulatory status; the importance of the ruling is that FDA status pertaining to the device could be presented before the jury by the plaintiff in addition to other disputed facts.

In summary, although most court opinions related to disclosure of FDA status of a medical device have clarified that FDA classifications are for regulatory purposes only, a number of legal cases have in fact allowed admissibility of FDA status as one factor to be considered during litigation. Therefore, a prudent rule that emerges from this review is that FDA-regulatory status of a device should be disclosed during informed consent, especially if the device is not FDA-approved for the particular application in which the physician plans its use.

Disclosure of Statistics Related to Outcomes

Should the patient be informed about the probabilities of success versus failure during informed consent for surgery? Taken to an extreme, should doctors be required to tell patients about the small but foreseeable risk of negligent performance of surgery? This issue has been disposed of by courts; for example, Colorado courts in Mallett v Pirkey [35] and more recently in Hall v Frankel [26] have ruled that doctors have no duty to disclose the risk of negligence

in the performance of a medical procedure. To decide otherwise would mean that every informed consent would have to capture a discussion of negligence as a risk of the procedure. However, should a physician be required to present known statistics, related to the success, failure, complication rate, and mortality of a procedure, during informed consent? Case law suggests that with few exceptions that address specific factual situations, there is no general duty on the part of the doctor to disclose statistical outcomes related to an operation.

In Arato v Avedon, the Supreme Court of California considered an informed consent claim based on the defendant's alleged failure to disclose life expectancy rates for patients with pancreatic cancer [4]. A pancreatic tumor was incidentally diagnosed during kidney removal surgery, and the patient was referred to an oncology practice for treatment. Before starting therapy, none of the physicians specifically disclosed the high statistical mortality rate associated with pancreatic cancer. The court declined to endorse the mandatory disclosure of life expectancy probabilities, noting that these statistics are impersonal and unreliable when applied to the fate of the individual patient. Wlosinksi v Cohn reflects a variation of this theme; there, a Michigan court encountered a patient who had postoperative complications and failure of a transplanted kidney [50]. The transplanted kidney was removed, dialysis was started, and the patient died after stopping dialysis. The suit alleged that the defendant physician had not disclosed his kidney transplant success rate to the patient. The court found that the defendant's success rate was not a risk related to the medical procedure and that a physician's raw success rates do not constitute risk information reasonably related to a patient's medical procedure.

In Johnson v Kokemoor, the Supreme Court of Wisconsin considered an informed consent claim in connection with a surgery to repair a brain aneurysm [32]. The patient sustained postoperative neurological complications. One issue in the case was whether the inexperienced physician was obligated to disclose surgical morbidity and mortality rates to obtain informed consent. Expert testimony said that the morbidity and mortality rate expected when a surgeon with the defendant's experience did the surgery substantially exceeded the rate expected when a more experienced physician performed the same surgery. The court reasoned that an informed patient might well have elected to forego surgery with the defendant. Although reluctant to adopt a mandatory informed consent comparative risk statistics disclosure rule, the court nonetheless said that "when different physicians have substantially different success rates with the same procedure and a reasonable person in the patient's position would consider such information material, the circuit court may admit this statistical evidence" for the informed consent analysis.

In summary, court opinions have held that there is no general duty on the part of physicians to share statistics related to the odds of success of a procedure. The relevant cases recognize the uncertainty attendant to the outcome of any medical procedure and the difficulty in relating variables such as survival rates, physician experience, and statistical odds in predicting the success or failure of a specific procedure.

Disclosure Related to Research and Financial Interests

Must physicians disclose their potential conflicts in terms of underlying financial interests or research goals when signing patients for surgery? Moore v Regents of the University of California is the classic legal case in this field; a patient with leukemia being treated at UCLA gave blood, tissues, and other samples, including the spleen, as part of a treatment protocol [39]. Unknown to the patient, retrieved tissues were used in research that led to a patented cell line with the university's assistance. Defendants successfully negotiated agreements for commercial development of the cell line and products derived from it.

The Moore court had no trouble expanding the doctrine of informed consent to include the disclosure of "personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment." The court remarked further that "this cause of action can properly be characterized either as the breach of a fiduciary duty to disclose facts material to the patient's consent or, alternatively, as the performance of medical procedure without first having obtained the patient's informed consent."

The Moore ruling has limitations; specifically, physician incentive schemes such as those based on surgical productivity and patient volume may not be subject to disclosure. In Neade v Portes, the Supreme Court of Illinois refused to recognize a breach of fiduciary duty claim against a physician for failure to disclose his financial incentive derived from the patient's HMO [40]. The court noted that the Illinois Managed Care Act "requires that managed care organizations disclose physician incentive plans to patients"; this disclosure requirement does not pertain to the physician. However, in a more recent decision, the Appellate Court of Illinois approved the introduction into evidence of physician financial motive, in a limited and specific manner, insofar as it addressed compliance with the standard of care [36].

In summary, court opinions suggest that information related to research and financial interests should be disclosed during informed consent, particularly if that information has any relationship to the professional activity of the physician. With changing physician-hospital

relationships, and the emergence of new healthcare delivery models such as "accountable care organizations," physician incentives, loyalties, and financial alignments will change in the future. An honest disclosure of these relationships while obtaining informed consent is prudent.

Discussion

This review has examined specific types of nonmedical information that have been the subject of legal litigation and asked whether or not the relevant case law can guide physicians in terms of recognizing what information to disclose while obtaining informed consent.

Readers should be aware of the limitations of our review and certain distinctions in scientific literature and case law. First, we used only two databases and law reviews to identify cases. There are likely additional cases, although we presume they would not change our conclusions. Second, outcomes of case law may appear to be arbitrary and random to medical readers, but in fact, judicial reasoning relies on well-established principles such as stare decisis, whereby judges respect the precedents established by prior legal decisions, even those in the courts of other states. Thus, a limitation of this work is that judicial cases offer only a guide to identifying trends in legal developments rather than firm guidelines. Also, published cases reflect case law that has been litigated at an appellate level; trial litigation and settled cases are not usually published and may offer valuable insights that cannot be identified in a review study. Third, the available literature related to the disclosure of nonmedical information suggests that the law has attempted to strike a balance between the impossible goal of disclosing all possible information versus that information that is likely to influence patient decision-making while being fair and equitable to all parties. As such, the notion of materiality is relevant to a functional model of informed consent, ie, information that a reasonable patient would find material to consenting to a medical procedure must be disclosed, whereas all other information need not be disclosed. As case law continues to develop in this area, the goal of identifying that information that would influence the decision-making of a reasonable patient provides an objective standard that physicians may find useful in identifying the limits of disclosure during informed consent and one that may guide further inquiry into this field.

Given these limitations, we make some general observations. First, we found that the perspective of professional physician associations is limited to the familiar elements of disclosure as they relate to the risk, benefits, and alternatives of a medical procedure. Professional societies have yet to develop clear guidelines about what physicians should disclose beyond these de minimis requirements of traditional informed consent. Nonetheless, the published opinions of professional medical associations are important because courts have inquired whether or not any guidance about what information should be disclosed during informed consent available to the defendant physician. It is possible that professional medical associations have a key role to play in constructing clear guidelines pertaining to the scope of such disclosure that could be used by courts in future cases.

Second, physician-specific variables such as those related to experience, skill, qualifications, and related factors have been the subject of many lawsuits, in which patients have alleged that such information should have been disclosed by the doctor while obtaining informed consent. With few exceptions, courts have been reluctant to allow such physician-specific variables to be admissible into evidence; the rationale for this nuanced approach is that such variables are very difficult to quantify. In contrast, a number of legal cases have permitted, to varying degrees, admission of information related to physician alcohol and/or drug use and relevant disciplinary history as it directly impacts professional conduct. Furthermore, courts have generally allowed admission of information related to physician illness and disability with the exception of disclosure of HIV seropositive status and those disabilities that directly impinge on the performance and outcome of surgery.

Third, this review found that disclosure of FDA-regulatory status of a medical device is generally not required by courts, because FDA-regulatory classes pertain to administrative activity rather than indications for proper use of the device. In selected cases, however, FDA-regulatory status has been allowed into evidence by courts as one of several factors to be considered by a jury.

Fourth, and finally, the requirements of disclosure related to financial and research interest are uncertain in the limited case law available; most legal cases have found such information to be material in patient decision-making and, hence, subject to physician disclosure.

There is an intense focus on investigating patient safety, physician and healthcare institution performance, and quality measures in health care today. This focus is unlikely to recede in the near future as medical care becomes more depersonalized and patients seek more information related to the odds of success and failure of surgical procedures and variables related to surgeon training, personal characteristics, motives, and outcomes. The notion that a doctor has something other than the best interests of his or her patients at heart goes directly to the core of the concept of informed consent. In the model of the patient as a healthcare consumer, patients will increasingly seek more information from their doctors, especially because there may be no other means of obtaining that information.

Although physician associations such as the AMA have encouraged a dialogue with the patient during obtaining informed consent [30], other professional associations have identified factors such as choice of surgeon, surgeon safety record, training, and success rates as relevant to informed decision-making by the patient, but only if the patient initiates and drives that inquiry [23]. AAOS guidelines emphasize dialogue and patient education during informed consent [22], but no professional association so far has squarely addressed the extent to which nonmedical information must be shared with the patient as part of the informed consent process.

Case law has held that physician experience and qualifications are not relevant to obtaining informed consent, except where the facts suggest that such information is material and relevant to the decision-making process [14]. Thus, factors such as a lack of surgeon experience, particularly with a complex surgical procedure, the adequacy of hospital resources, and the availability of alternatives are not admissible at trial unless the patient can convince the court that such factors were material in deciding whether to have a medical procedure [7]. Courts have been cognizant of the perils in trying to quantify surgeon experience and the availability of resources, and some decisions have held that hospital staff credentialing and privileges should be sufficient evidence of experience and ability. In summary, physician-specific professional attributes are generally inadmissible in medical malpractice litigation unless the circumstances are particularly egregious and the patient can establish the relevance of such attributes in the decision to proceed with surgery [45].

Like professional credentials, variables related to physician-specific illness or disabilities are ordinarily not admissible at trial. Exceptions involve cases in which surgeon disability directly impacted the performance of a medical procedure. For example, a history of drug and alcohol use in an otherwise qualified surgeon is not material to obtaining informed consent when the record shows that such problems occurred in the past [36]. HIV seropositivity represents a special line of cases in which the general stance is one of requiring disclosure of physician HIV status as part of informed consent before an invasive procedure [19].

In terms of physician training and expertise in a subspecialty area of medicine, the general rule is that no disclosure is required [48, 50]. Courts have also reasoned that there is no general duty to disclose the role of a resident physician [16] or that of an otherwise qualified physician assistant [40] while obtaining informed consent; the rationale is that qualifications of personnel do not necessarily increase risk to the patient and that such variables are not a component of the doctrine of informed consent. Taken further, when physician disciplinary history is at issue, rather than physician training and expertise, courts have reluctantly found a duty to disclose, but only in cases of egregious physician misconduct with multiple episodes of physician discipline [20]. The rationale behind no general duty to disclose a history of disciplinary sanctions is that such information is already subsumed under physician licensing and credentialing mechanisms [13].

Where a physician uses a device in an application that is not expressly approved by the FDA, prior disclosure is generally not required. Courts have reasoned that such off-label use does not constitute a material risk to the patient, because the FDA classification system is designed as a regulatory mechanism rather than a mechanism for patient risk stratification. Exceptions to this general rule include instances in which the patient participated in a clinical trial and was not told of the FDA status of the device [12] or the investigational nature of the device to be used [44]; in such cases, courts have allowed FDA status as a relevant factor to be considered by the jury.

Courts have held that there is no physician duty to disclose statistical data related to individual surgeon performance or the odds of success or survival after a medical procedure [5, 49]. The reasoning is that such raw success data do not constitute meaningful risk information that relates to informed decision-making. The rare exception to such reasoning is the case in which surgeon inexperience is so egregious that the performance of a complex operation by an inexperienced versus a readily available experienced surgeon has dramatically different outcomes that are well known to the medical community [22]; even so, courts have been very reluctant to articulate any general rule that mandates disclosure of the odds of success of a procedure.

The prevailing posture concerning financial interests and related conflicts of interest is that there is a duty of full disclosure, particularly if the physician stands to benefit personally in terms of research or economic interests that are unrelated to patient welfare [38]. Although physician incentive schemes such as those related to surgical volume and financial productivity are excluded from such disclosure requirements, financial incentives offered by managed care programs may be admissible in court [39]. Evolution of case law in this area suggests that there is a trend toward requiring disclosure of physician financial incentive, at least in a limited and specific manner, as part of the general standard of care in obtaining informed consent [35].

This article has examined legal cases that can offer guidance as to what elements of information should be discussed with the patient and under what circumstances. Although the outcomes of court rulings may appear haphazard, a common theme in case law is the reluctance of courts to expand the traditional boundaries of the informed consent doctrine, which is enshrined in statutory law in

many states and typically addresses the traditional elements of risks, benefits, and likely outcomes of surgery. Where courts have taken a broad view of the informed consent doctrine to encompass physician health, training, qualifications, and other physician-specific variables, judicial opinions have invoked the concept of materiality of the information as measured by a reasonable patient standard. In other words, a court may decide as a matter of law, or allow the jury to decide as a matter of fact, whether the disputed disclosure would be relevant to decision-making about a planned procedure. If disclosure is deemed to be material, then at trial, information related to a lack of such disclosure would be admissible evidence in support of the plaintiff's case.

Legal scholars have argued that if patients are to be efficient consumers of health care, they need access to quality, performance, and other information personal to their physicians [22]. There is a balance between a patient who is adequately informed and a doctor who is not so busy worrying about disclosure that he or she cannot practice medicine. Professional medical associations have a responsibility to be proactive in answering the demand for more transparency and information-sharing during the informed consent process. Position statements by medical associations could guide physicians, and courts, in determining how much information to disclose during informed consent. Physician associations can also help shape informed consent statutes encompassing the disclosure of provider-specific information. Absent such engagement, sporadic judicial opinions will continue to shape the doctrine of informed consent.

For the individual physician concerned about the scope of disclosure, a useful strategy is to understand the concept of materiality used by courts. The practical inquiry is that if a family member were having surgery, what information would be deemed relevant and important in affecting the decision to have surgery performed by the selected physician. This inquiry will help identify the extent and types of disclosure relevant to the situation such that the patient has all the resources to make an enlightened decision while avoiding information overload. Clearly, this is an area of healthcare law that will continue to expand in the years ahead as consumer access to professional information continues to grow.

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