Understanding Potential Barriers to the Informed Consent Process

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Introduction

The doctrine of informed consent has progressed from one involving a paternalistic physician-patient relationship to a legal principle largely based on patient autonomy. The evolution has primarily occurred through state common law. Various states have modified the scope of the process. Although desirable in theory, true informed consent is difficult to measure.

The objective of this paper is to provide a brief history of the evolution of the informed consent process by examining the evolving framework of important court holdings that led to the current state of informed consent. Research is based on major legislative actions and judicial rulings in the United States. Additionally, this paper will highlight the differences in the informed consent process among states by using the historical timelines of two states, Wisconsin and Pennsylvania.

Wisconsin attempted to broaden the limits of required disclosure but faced significant backlash from the medical community. Pennsylvania, in a recent court case, Shinal v. Toms has narrowed its application to information provided to the patient solely by the physician in anticipation of a mutual exchange of information and has made it a non-delegable duty of the physician. This may result in significant changes in the way informed consent is obtained in Pennsylvania.

The basis of informed consent is to provide the patient with information necessary and adequate to make a medical decision. The MGMA acknowledges that “well-informed patients are generally more willing to participate in their healthcare management and more compliant with physician directives” (MGMA, 2017). It goes on to say that the job of the medical practice manager is to ensure that patients “have easy access to accurate, up-to-date materials that are simple to understand” (MGMA, 2017). However, difficulty can lie in the scope of information needed by the patient and in what context that information is delivered.
Medical practice executives must understand how their particular state defines and enforces the process of informed consent. The history of informed consent in Wisconsin shows how processes evolve and change through case law and illustrates the need for medical practice managers to monitor for and adopt to these changes. The recent ruling in Pennsylvania serves as a reminder to medical practice managers that judicial and legislative changes can occur swiftly, necessitating broad and rapid adjustments to practice procedures and policies. The current national trend toward a more diffuse distribution of information and patient autonomy may be at odds with the judicial interpretation in certain states.

**Brief History of Informed Consent**

The theory of informed consent is based upon the principle of self-determination or autonomy. It has undergone extensive modification during the past century, primarily through the evolution of state common law which has imposed significantly more responsibilities on the physician. Initially, the medical profession held a highly paternalistic view of the physician-patient dyad. Informed consent is not a part of the Hippocratic Oath. Sir Oliver Wendell Holmes has stated: “Your patient has no more right to all the truth you know than he has to all the medicine in your saddle bags...He should get only so much as is good for him.” (Campbell, 2017).

The notion of patient consent was introduced in a landmark case, *Schloendorff v. Society of New York Hospital*. Judge Cardozo wrote: “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”. Unconsented treatment was considered a simple tort of battery with two elements, intention and a harmful or offensive contact. Medical battery is established either when the clinician acts without any consent or acts outside of the
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scope of the patient’s consent, regardless of whether the intervention is performed skillfully or successfully (Pope, 2017). A standard of care need not be established, obviating the need for expert witnesses. Punitive damages can be assessed without the need to demonstrate compensatory damages. Tort reform procedures such as a pre-filing review are not necessary (Pope, 2017).

Forty years later, a legal delineation was made of the crucial parameters of the information necessary to be disclosed to the patient for that voluntary consent to be an adequately informed one (Derse, 2017). In Salgo v. Leland Stanford Jr. Board of Trustees, the California Appellate Court stated that “a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment”. Although no malpractice was found, the plaintiff was awarded a favorable verdict because the physician failed in his duty to disclose details of the procedure. In fact, it was in this case that the term “informed consent” first appeared. Currently, many states have enacted statutes mandating physician disclosure of certain elements, namely a description of the procedure, its risks and benefits as well as its alternatives including no treatment. Although a patient could not claim a tort of battery if he consented to a procedure, a medical negligence claim for lack of informed consent could be supported in the absence of proper disclosure (Ginsberg 2017).

Initially the standard of care was based upon what a “reasonable physician” would do. In Canterbury v. Spence, the burden was shifted to a “reasonable patient” standard. The court wrote that “a risk is...material when a reasonable person...would likely attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy”. This objective patient standard has been adopted by many states. It does not require expert testimony as does the professional standard.

The doctrine of informed consent has evolved from the tort of battery to one requiring both voluntary consent and a disclosure of information. Where the courts have had difficulty is in deciding
whether the process is satisfied by mere disclosure or, if to be effective, it “requires patient understanding, suggesting something more than only a physician disclosure” (Ginsberg, 2017).

Lessons from Wisconsin

Wisconsin serves as an example of how a state judiciary can modify the informed consent process. In 1975, the Wisconsin Supreme Court adopted the objective patient standard in *Scaria v. St. Paul Fire & Marine Ins. Co.*, finding that “the need of a particular patient...should not necessarily be limited to a self-created custom of the profession”. This statement signaled a movement away from physician paternalism towards patient consumerism by acknowledging the patient’s participation in the decision-making process. Later, in *Martin v. Richards*, the court found a physician negligent for failing to inform a family about an alternate means of diagnosis. “The information that was required to be disclosed had moved away from mere information about risks and benefits of treatment that an objective patient would want to know as required by statute, and now had expanded into the areas of availability of alternate methods of diagnosis as well as potential definitive treatment available only at other institutions” (Derse, 2017).

The objective patient standard was further expanded in *Johnson v. Kokemoor*. The defendant neurosurgeon was found to have failed to disclose either his experience or comparable morbidity and mortality rates to his patient. The Wisconsin Supreme Court found that a physician’s experience, “if substantially different from an average practitioner, may be admissible and determined by a jury to be informational material to an objective patient, and thus failure to disclose this information may be determined by a jury as evidence of an inadequate informed consent” (Derse, 2017).

The expansion continued in *Bubb v. Bruske* in which a patient discharged from the emergency room (where a CT and a neurological consult were obtained) suffered a stroke two days later. The
plaintiff argued that not all available testing was performed and that the alternative of hospital admission was not presented. The Wisconsin Supreme court held that the physician had a duty to inform the patient about all “alternate, viable medical modes of treatment” which included the risks and benefits of admission.

In *Jandre v. Wisconsin Injured Patients and Families Compensation Fund*, a patient filed suit claiming that an Emergency Room physician failed to disclose his differential diagnosis and other possible tests that could have been ordered. Although no negligence in diagnosis and treatment was found, the Wisconsin Supreme Court found that informed consent requires information about the alternative diagnoses the physician considered, and the tests that can rule out these diagnoses (Derse, 2017).

Essentially, the Wisconsin Supreme court expanded the informed consent doctrine to include not only information regarding the procedure, its risks benefits and alternatives, but also a physician’s differential diagnosis, his experience, the range of available diagnostic testing and a discussion of whether to admit the patient or treat as an outpatient. Given the expected response from the medical community, the Wisconsin legislature enacted a statute in 2013 to revert to the reasonable physician standard (2013 Wis. Act 111). Also contained was language exempting a physician from discussing alternative treatments not within his differential diagnosis. However, the issue of determining whether a patient has been given adequate information to formulate an informed decision remains elusive (Siegal, 2012). Mandated disclosures suffer from insufficient resources and a focus on content rather than clarity and explanation (Pope 2017). Many healthcare advocates are calling for “informed patient choice” as a standard of practice in which ancillary providers and patient decision aids play a large role in the process (O’Connor, 2007).
Informed Consent in Pennsylvania

The Pennsylvania Medical Care Availability and Reduction of Error (MCARE) Act was legislated in March 2001. Section 1303.504(a) states:

Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient’s authorized representative prior to conducting the following procedures.

Subsection 1303.504(b) further provides:

Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to the procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted medical standards of medical practice would provide.

The Pennsylvania courts have held that a physician’s consent must be based upon adequate information without which the physician is liable regardless of whether he was negligent. In Grey v. Grunnagle, the court held that “since the agreement between a physician and his patient is contractual in nature, for there to be valid consent it must be clear that both parties understand the nature of the undertaking and what the possible as well as the expected results might be…it will be no defense for a surgeon to prove that the patient had given his consent, if the consent was not given with a true understanding of the nature of the operation to be performed.”

In Gouse v. Cassel, the court held that doctors were not required to disclose “all known information”, but were required to “advise the patient of those material facts, risks, complications and alternatives to surgery that a reasonable person in the patient’s situation would consider significant in deciding whether to have the operation.”
A Superior Court also found, in *Kelly v. Methodist Hosp.*, that “the physician is in the best position to know the patient’s medical history and to evaluate and explain the risks of a particular operation in light of the particular medical history”.

However, in *Bulman v. Myers*, a Superior Court upheld a trial court’s ruling that informed consent was valid when obtained by a nurse assistant. The state’s primary interest was in ensuring that the patient was informed of the “material facts necessary from which he can make an intelligent choice as to his course of treatment.” The court believed that the “sufficiency of the information communicated” rather than the “identity of the person making the decision” supported informed consent.

Likewise, in *Foflygen v. Allegheny General Hosp.*, a Superior Court held that “the validity of a surgical patient’s informed consent depends upon the pretreatment information relayed to the patient, regardless of whether the disclosures are made by the treating physician or another qualified person such as a nurse or other assistant”.

The Pennsylvania Supreme Court, in *Valles v. Albert Einstein Medical Center*, determined that “a hospital could not be held liable under a theory of corporate negligence based on its failure to promulgate policies and procedures relating to informed consent”. The court wrote that “our lower courts have recognized that the duty to obtain informed consent belongs solely to the physician...Informed consent flows from the discussions each patient has with his physician, based on the facts and circumstances each case presents. We decline to interject an element of a hospital’s control into this highly individualized and dynamic relationship...Thus we hold that, as a matter of law, a medical facility lacks control over the manner in which the physician performs his duty to obtain informed consent as to render the facility vicariously liable”.
Shinal v. Toms

Procedure and Facts

Megan Shinal was a patient with a recurrent pituitary tumor who met with Dr. Steven Toms, a neurosurgeon for an initial consultation on November 26, 2007. During that encounter, Dr. Toms “reviewed the alternatives, risks and benefits of total versus subtotal resection” and shared with her “his opinion that, although a less aggressive approach to removing the tumor was safer in the short term, such an approach would increase the likelihood that the tumor would grow back”. He advised her that “total surgical resection offered the highest chance for long-term survival”. Mrs. Shinal agreed to undergo surgery, although the surgical approach had not been decided.

On December 19, 2007, Mrs. Shinal had a telephone conversation with Dr. Toms’ physician assistant regarding surgical scarring, the potential for post-operative radiation and the date of surgery. On January 17, 2008, she met with the physician assistant who obtained a medical history, conducted a physical and provided her with information relating to surgery. A consent form was signed which identified the risks of surgery as well as the advantages and disadvantages of alternative treatments, but did not “purport to address the specific risks of total versus subtotal resection”.

On January 31, 2008, Mrs. Shinal underwent an open craniotomy total resection during which Dr. Toms perforated her carotid artery resulting in hemorrhage, stroke, brain injury and partial blindness.

On December 17, 2009, Mrs. Shinal and her husband filed a medical malpractice action in the Court of Common Pleas of Montour County against Dr. Toms and the hospital alleging lack of informed consent. A motion of partial summary judgement was granted in favor of the hospital, a co-defendant, based on Valles v. Albert Einstein Med. Ctr. The Shinals alleged that Dr. Toms failed to explain the risks of surgery and did not offer her the lower risk surgical alternative of subtotal resection followed by radiation.
The trial court instructed the jury that they “may consider any relevant information” from Dr. Toms or his physician assistant in determining whether Dr. Toms satisfied his requirement to obtain informed consent.

The jury found in favor of Dr. Toms. The Shinals filed for post‐trial relief, arguing inter alia that the court erred in its instructions to the jurors that they may consider information provided by Dr. Toms’ physician assistant as relevant. The court denied post‐trial relief and the Superior Court affirmed, relying two of its prior cases, Foflygen v. Allegheny General Hosp. and Bulman v. Myers, to opine that “information communicated to a patient for purposes of obtaining informed consent may be conveyed by a qualified professional acting under the attending doctor’s supervision”. An appeal was accepted by the Pennsylvania Supreme Court.

**Issue**

The issue is whether the trial court had misapplied the MCARE Act and Pennsylvania common law in instructing the jurors that they may consider information provided by the physician assistant in determining whether Dr. Toms had properly obtained informed consent.

The Pennsylvania Supreme Court, in a 4-3 decision, reversed the Superior Court’s order affirming the trial court’s denial of the Shinal’s motion for post‐trial relief and remanded a new trial.

**Rationale**

The Pennsylvania Supreme Court relied upon its holding in Valles in which “the duty to obtain informed consent rests solely upon the healthcare provider performing a medical procedure, and not upon a hospital”. This “duty of disclosure” rests upon the physician who “is in the best position” to evaluate and explain the risks. “For these same reasons, we hold that a physician cannot rely upon a
subordinate to disclose the information required to obtain informed consent.” Thus, “the duty to obtain informed consent belongs solely to the physician and that it is non-delegable”.

The Court also felt that Valles was consistent with Section 1303.504(a) of the MCARE Act which states that a physician owes a duty to a patient to obtain the informed consent. “Nothing in the plain language of the Act suggests that conversations between the patient and others can control the informed consent analysis or can satisfy the physician’s legal burden.”

Finally, the Court held that the Superior Court rulings, Bulman and Foflygen, pre-date Valles and the MCARE Act. “To the extent that those decisions permit a physician to fulfill through an intermediary the duty to provide sufficient information to obtain a patient’s informed consent, we overrule them.”

In its interpretation of the informed consent doctrine, the Court held that “informed consent requires direct communication between physician and patient, and contemplates a back-and-forth, face-to-face exchange, which might include questions that the patient feels the physician must answer personally before the patient feels informed and becomes willing to consent. The duty to obtain the patient’s informed consent belongs solely to the physician.”

Amicus Brief

The American Medical Association (AMA) and the Pennsylvania Medical Society (PAMED) filed an amicus curiae in support of Dr. Toms. They argued that although both common law and MCARE have made it the physician’s duty to see that the proper information was conveyed to a patient in order to obtain informed consent, the “imposition of duty is quite different from mandating that the physician provide all the information”. Furthermore, they point out that “physicians’ delegation of some of their duties to other healthcare professionals while maintaining liability if those delegated services are not properly performed is commonplace, recognized in the Medical Practice Act, P.S. § 422.17. They
believe that the trend of delegating will become commonplace as healthcare looks to become more efficient.

They further argue that Pennsylvania common law and the MCARE Act have maintained their focus on the “patient’s receipt of information” rather than who provided it. Both 40 P.S. § 1301.811-A of the CAT Fund Act, enacted in 1996 and 40 P.S. § 1303.504(b) of the MCARE codification have stated that consent is informed if the patient “has been given” a description of the procedure, its risks and alternatives. The central requirement was written in the passive tense indicating what must be done, without identifying who must do it.

There was no contention that Dr. Toms physician assistant provided inaccurate information. If the information provided was satisfactory for the patient to provide an informed consent, then the statutory requirement that the “patient has been given” the appropriate information was satisfied. The imposition of duty does not describe how the duty is to be carried out or by whom.

Dissenting Opinion

In his dissenting opinion, Justice Baer agreed with the majority that a physician owes a duty to his patient to obtain the patient’s informed consent, consistent with both common law and the MCARE Act. He also agreed that the physician cannot delegate or assign the duty to obtain a patient’s informed consent to an assistant. However, he disagreed with the Majority which concluded that a physician is prohibited from utilizing his qualified staff to aid him in performing his duty.

He also referenced the MCARE language in 40 P.S. § 1303.504(b) that explained that consent is informed “if the patient has been given” the specified information. He argues that “the Act conspicuously does not mandate that only physicians themselves can provide information to patients to inform their consent”. The Legislature had crafted the language in the passive voice leaving open the method of informing a patient’s consent to the professional judgement and discretion of the physician.
“To hold otherwise improperly injects the judiciary into the day-to-day tasks of physicians such as Dr. Toms and fails to acknowledge the reality of the practice of medicine.”

He finds the Majority opinion impractical as it suggests that physicians must address all their patient’s surgery-related calls and would be responsible for becoming personally involved with “every conceivable aspect of their practices that may assist them in informing their patients’ consent”.

He concludes: “I fear that today’s decision will have a far-reaching, negative impact on the manner in which physicians serve their patients. For fear of legal liability, physicians now must be involved with every aspect of informing their patients’ consent, thus delaying seriously ill patients access to physicians and the critical services that they provide. Courts should not impose such unnecessary burdens upon an already strained and overwhelmed occupation when the law does not clearly warrant this judicial interference.”

**Implications of Shinal v. Toms**

The decision will most likely impact regulatory interpretation of the MCARE Act requirements, invalidating any previous sub-regulatory guidance on the use of qualified staff (Hospital Association of Pennsylvania, 2017). After Shinal, the Pennsylvania Department of Health rescinded its past guidance related to obtaining consent for peripherally inserted central catheter (PICC) line insertion and blood transfusions. (PSPA, 2017). For example, 49 Pa. Code § 18.157(a) states that “the physician assistant may order or administer, or both, controlled substances and whole blood components if the authority to order and administer these medications and fluids is expressly set forth in the written agreement”.

Nursing staff typically perform PICC line insertions at a hospital. However, subsection 1303.504(a) of the MCARE Act assigns the duty of informed consent for “inserting a surgical device or appliance” and
“administering a blood transfusion” to the physician. The DOH stated that “to the extent the guidance conflicts with the June 20, 2017 ruling of the Pennsylvania Supreme Court in Shinal v. Toms, it is no longer valid”.

*Shinal v. Toms* sets a new legal precedent in Pennsylvania. It is possible that other states will adopt this rule significantly restricting the informed consent process. As of the June 2017 ruling, there were more than 234,000 licensed nurse practitioners in the United States. Thirteen states recognize full independence practice authority (Scope of Practice Policy, 2017). For example, Nurse Practitioners in New Hampshire have full independent practice authority and are recognized in state policy as primary care providers in the advance practice categories of family practice, internal medicine or pediatrics (N.H. Admin. Code §Ins 2701.05). Many activities such as administering vaccines could involve an informed consent process. Additionally, areas experiencing physician shortages may be hampered in their ability to utilize other healthcare providers if additional states adopt the Pennsylvania Supreme Court’s ruling that only a physician is uniquely qualified to obtain a patient’s consent.

Currently the Pennsylvania legislature is contemplating a bill which would allow certified registered nurse practitioners (CRNP) to practice independently without physician supervision. If passed however, the Pennsylvania Supreme Court may not allow them to obtain informed consent for procedures.

The ruling also carries broader implications for research. The FDA states that informed consent for a clinical trial must be obtained by an “investigator”, but does not clarify that the investigator need not be a medical doctor. In the context of clinical trials, this has traditionally been a study coordinator or a nurse (Kulkami 2017). Again, subsection 1303.504(a) of the MCARE Act assigns the duty of informed consent for “administering an experimental medication” as a non-delegable responsibility of the physician per the *Shinal* ruling. Not only will this place an unexpected burden on clinical research facilities, but also may result in less sponsorship of clinical trials in Pennsylvania.
Conclusion

The doctrine of informed consent has evolved from mere voluntary consent to a process involving the exchange and understanding of information between a physician and the patient. Although simple in theory, its practical and universal application remains elusive. Wisconsin failed in its attempt to improve the process by broadening the information required to be disclosed for informed consent. Pennsylvania is attempting to improve the process by delegating the responsibility solely to the physician in the hopes that a “back-and-forth, face-to-face exchange” will give the patient the best understanding of the proposed intervention.

Both Wisconsin and Pennsylvania may have reacted slowly and incompletely to recent trends in the dissemination of medical information. Patients have more ready and easy access to an exponentially growing amount of medical information made available through diverse and often non-physician channels. Wisconsin sought to limit the amount of information necessary to make an informed decision and Pennsylvania sought to restrict the diffusion of information by mandating a physician-patient channel. This assumes that physicians are the best source of health information and that patients are not knowledgeable enough to obtain and process information on their own.

This theory, however, runs contrary to recent findings. First, many studies suggest that physicians do a poor job of conveying information to patients and that proving that a comprehensive discussion and exchange of information was made is difficult. One study of over 1000 physician-patient encounters involving over 3,500 medical decisions found that only 9% met the minimum standards for informed decision making (Braddock, 1999). Second, more states are adapting patient decision aids (PDAs) which have been demonstrated to improve patient understanding and which do not involve
direct physician communication. Furthermore, significant savings in healthcare costs can be realized from their use. Washington State found a 26% reduction in hip replacements, a 38% reduction in knee replacements and a 12-21% reduction in overall costs after implementing PDAs for joint replacement surgery (Arterburn, 2012).

Several assumptions underlie the doctrine of informed consent. First, is that it is “shared” decision making rather than “transferred” medical decision making in which a “collaborative process” occurs, rather than an event in which the patient simply exercises his right to choose. Second, the assumption is that physicians possess current and accurate knowledge of the procedure and its accompanying risks, benefits and alternatives. Third, it is also believed that physicians can effectively and objectively communicate the information to their patients (Kapp, 2007). Previously, it was believed that physicians “retained gatekeeping authority by virtue of their monopoly power over medical information and most medical resources” (Kilbride, 2018). Recently however “widespread access to the internet and social media has reduced physicians’ dominion over medical information and, increasingly over patients’ access to medical products and services” (Kilbride, 2018).

It has been long recognized that valuable information can derive from non-physician health care providers. In 2005, CMS instituted a pilot program to allow chronically ill patients access to health coaches who advise beneficiaries on medical choices and help reduce patient’s confusion in making treatment choices (Kapp, 2007).

Patient decision aids are evidence-based educational tools which can assume various forms including decision-grids, videos, and web-based interactive programs. They not only assist in a patient’s understanding of the available treatment alternatives, but also incorporate beliefs and preferences into the decision process. They are up-to-date, accurate, complete, balanced and patient-centered. They are effective and allow the patient to control the pace and timing of their education. More than 130 randomized controlled studies have demonstrated their benefit. Their use has been shown to reduce
healthcare liability for informed consent claims (Pope, 2017). The Institute of Medicine in its 2001 *Crossing the Quality Chasm* report called for development of support tools to help clinicians and patients in applying evidence and in making decisions.

Section 3506 of the 2010 Patient Protection and Affordable Care Act (ACA) is specifically dedicated to establishing a program to facilitate shared decision making. The act is intended “to facilitate collaborative processes between patients...and clinicians that engages the patient...in decisionmaking, provides patients...with information about trade-offs among treatment options, and facilitates the incorporation of patient preferences and values into the medical plan”. It directs HHS to develop, make grants for and implement PDAs. “The federal certification of PDAs may soon displace these inadequate state standards and impose much needed consistency and uniformity to informed consent processes” narrowing the persistent gap between the theory and clinical reality of informed consent (Pope, 2017). PDAs are currently being utilized by non-physician health providers in non-physician locations such as nurse call centers, insurance plans and research facilities (O’Connor, 2004).

Both state and federal governments are providing more physician specific data online for patients. Medicare.gov has a link to Physician Compare which provides performance information on individual physicians and allows them to “compare their care against care provided by other clinicians”. ProPublica publishes a Surgeon Scorecard which compares death and complication rates for individual physicians for eight elective procedures. Although intended for patient use, the *Shinal* ruling may prevent consideration of this information, even if positive, in the informed consent process in Pennsylvania unless presented to the physician. The material contained in these public sites would need to be vetted with the patient’s physician possibly biasing the information originally intended to be impartial.

Finally, governmental intervention in consumer-driven healthcare, such as the individual mandate under the ACA, may be at odds with the concept of individual autonomy. “In place of the self-
determination commitment characterizing the informed consent discussion in the clinical sphere, many health policy analysts and policy makers would substitute governmental paternalism and protectionism when the conversation shifts to the context of consumer-driven healthcare” (Kapp, 2007). Attempts to repeal the individual mandate are consistent with this movement towards more patient consumerism and autonomy in health care decisions.

The irony of Shinal v. Toms is that the Pennsylvania judicial system may have pushed the informed consent process back towards the older paternalistic model by failing to recognize a patient’s autonomy in seeking alternative methods of information through other knowledgeable health care providers, online resources (such as published government outcomes data and disciplinary actions) and patient decision aids. Unfortunately, more studies are suggesting that the physician may not be the optimal source of information in terms of knowledge or ability to convey an informed understanding. By establishing the foundation for informed consent on the physician as a non-delegable provider of information, the Pennsylvania Supreme Court may unintentionally have reduced patient autonomy.

Medical practice managers are faced with several challenges. First, patients are seeking more autonomy in their medical care. Second, patients have access to a broader range of medical information. Clinicians may no longer be the primary or initial source of medical information. The medical practice may assume more of a consultancy role. As discussed, many studies have shown that physicians may not be the optimal source of patient information. Managers are faced with federal governmental initiatives which encourage the dissemination of medical information through non-physician providers. However, medical practice managers must be keenly aware of how informed consent is applied in their jurisdictions. Modifications in how information is provided and with whom it is reviewed must be made to accommodate judicial interpretation of informed consent. For example, the MGMA Body of Knowledge section on Patient Centered Care states that “supplementing verbal communication with written information and instruction is an essential part of establishing effective
patient communication protocols. Written material affords a patient the opportunity to read and reflect on information when opportune, not just when he or she consults with the physician” (MGMA, Vol 4, 2015). Additionally, MGMA acknowledges that “well-informed patients are generally more willing to actively participate in their healthcare management and more compliant with physician directives” (MGMA, Vol 4, 2015). However, the Shinal case in Pennsylvania dictates that information regarding informed consent come directly from or be reviewed with the patient only by the physician. This requires the medical practice manager to develop, implement and track standards of care in the practice. Additionally, he or she must be attentive when developing clinical pathways which satisfy legal requirements. Finally, as demonstrated, the process of informed consent continues to evolve and an effective manager must remain alert to any unanticipated changes. Because “laws and their interpretations are insidious”, the MGMA Body of Knowledge recommends that it is “essential that the medical practice executive with risk management responsibility have a relationship with a respected, ethical and efficient law firm” (MGMA, Vol 5, 2015).
Summary Paragraph

Informed consent, a process involving providing information to patients to obtain permission to undergo a procedure, has evolved over time. Additionally, the elements involved in the process have been interpreted differently in various jurisdictions. Traditionally, the physician had been the gatekeeper of medical information. The trend towards the use of more diverse medical providers, the exponential growth of health information and its ease of access, as well as the patient consumerism movement have all challenged this doctrine. The medical practice manager must be aware of the continuing evolution in informed consent and be prepared to modify policies and practices to accommodate these ongoing changes.

Key Words

Informed consent, patient autonomy, physician-patient, medical consumerism, judicial rulings
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