Practical Risk Management Principles for Physicians

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Abstract: Most medical schools and postgraduate residency programs do not focus adequate attention on risk management and quality management issues. This article will prepare physicians with an adequate working knowledge of risk management and quality management information, which will enable them to practice more effectively in today's litigious and regulatory climate.

“We all know here that the law is the most powerful of schools for the imagination. No poet ever interpreted nature as freely as a lawyer interprets the truth” (ref. 1).

Introduction
Only history, not medicine, resembles an exact science. This, coupled with the plaintiffs' attorneys' penchant for overexuberance related to hindsight, creates a legal environment that is uncomfortable for most physicians.

The first reported case of medical malpractice in the United States occurred in Connecticut in 1794.

Although one may believe the issue of medical malpractice is a phenomenon of the 20th century, the origin of medical-legal issues can be traced as far back as the Hippocratic oath in approximately 460 BC. The first reported case of medical malpractice in the United States occurred in Connecticut in 1794, more than two centuries ago (ref. 2).
Although quality management and risk management techniques are being incorporated into medical school curricula and residency training (refs. 3, 4), risk management is not addressed fully. Therefore, this article is designed to provide physicians with a basic, yet practical, guide to risk management issues.

Since healthcare law is a complex field of legal expertise that often generates opposing opinions not fully supported by substantial case law or statutory law, readers of this article are cautioned that the views expressed herein are those of the authors and do not constitute legal advice. When additional information or clarification is needed, please consult your attorney.

**Basic Risk Management Principles**

Recent legal literature abounds with volumes concerning medical malpractice or, as it is sometimes called, professional negligence. It is not the intent of this article to collect and annotate all cases about physician negligence, but rather to provide a broad general outline of basic principles of physician liability.

Physician negligence is almost always a matter of state law. Consequently, the various injuries for which a cause of action exists vary from state to state, as do the evidentiary standards of proof to establish such a case. Even the basic standard of care by which the alleged negligent physician is measured varies. There simply are few truly uniform rules.

Physician liability may arise from many causes of action, including medical malpractice, informed consent, intentional infliction of emotional harm, breach of contract, etc. Most physician liability is predicated on legal theories of negligence as opposed to the intentional causing of harm.

Essentially, for a person to be guilty of negligent conduct, there must be some duty or obligation recognized in the law, which requires conformity to a standard of conduct for the protection of other individuals. Further, the person who is alleged to have committed a negligent act must be found to have breached the required duty or standard of conduct and that breach must be found to have predicated a causally related injury producing legally cognizable damages (ref. 5).

Translating legal theory to medical practice, what we find is that there generally is a duty owed by physicians to patients, which arises from the physician-patient relationship. When the physician breaches this duty and fails to meet the standard of care, i.e., when the physician does not bring to the practice of medicine that degree of care and skill ordinarily employed by the medical profession under similar conditions and circumstances, he or she has been negligent. Negligence in and of itself, though, does not give rise to legal liability. In addition to the breach of duty, there must be a cause-and-effect relationship between the breach of duty and some injury to the patient. Lawyers call this relationship “proximate cause” or “direct cause.” Finally, if a breach of duty occurred and it can be proved to be causally related to some injury to the patient, there still must be legally cognizable damages as a result. These attributes are sometimes referred to in the risk management field as the Principle of Four Ds, which are listed in Table 1.

As an example, consider the situation wherein a surgeon negligently leaves an instrument inside the body of a patient causing an infection and requiring a second surgery for removal of the object. The duty owed by the surgeon is to bring to the practice of medicine the degree of care and skill employed by like surgeons. It could not be argued seriously in the medical community that a surgeon who
Table 1. The Principle of Four Ds

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<tr>
<td><strong>Duty Owed:</strong></td>
<td>A physician-patient relationship must exist.</td>
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<tr>
<td><strong>Duty Breached:</strong></td>
<td>A duty that was owed must have been breached.</td>
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<tr>
<td><strong>Damages:</strong></td>
<td>The patient must have damages that usually must be physical.</td>
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<tr>
<td><strong>Direct Cause:</strong></td>
<td>The damages must be a direct result of the breach of duty.</td>
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leaves an instrument in a body cavity has exercised that degree of care and skill ordinarily employed by surgeons under similar circumstances and conditions. The duty is therefore breached. Further, it could not be argued seriously that an infection in the area of the retained surgical instrument is not causally connected to the breach of the surgeon’s duty. Proximate or direct causation is established. Finally, there are legally cognizable damages, both with regard to the cost of the second surgery and the pain and suffering of the individual who is caused to undergo such surgery.

A different situation is presented, however, when an obstetrician/gynecologist negligently performs a tubal ligation resulting in a subsequent pregnancy and birth of a child with Down’s syndrome. A duty has been breached, and the pregnancy is deemed proximately caused by the failure of the physician to perform the surgical procedure properly. There are damages legally cognizable to the mother for her delivery costs and certain other items, but the law generally does not recognize damages to the child for a genetic disorder. In most states, the law does not recognize the birth of a child as an injury entitling one to damages, even if damages could be ascertained. There simply is no cause of action in most states for wrongful life (ref. 6).

In cases involving physician negligence, there are several areas that deserve more explanation. First, although practically all jurisdictions in the United States recognize the standard of care as the exercise of that degree of care and skill ordinarily employed by the medical profession under similar conditions and circumstances, there is no universally recognized rule on how that standard is determined. Many state courts recognize a national standard of care, whereas many other state courts apply a local standard of care. The trend probably is toward the national standard, but, as stated, the states are split. It is important for each physician to know the standard of care required in the state wherein he or she practices.

Further, in the context of a lawsuit involving allegations of physician negligence, the standard of care is a matter of proof. Expert testimony is required to establish the standard of care except in cases of res ipsa loquitur, which means “the thing speaks for itself.” Expert testimony also is required to establish that there was some deviation from the standard. Generally, this expert testimony must come from a professional trained in the same school of medicine, i.e., allopathic or osteopathic. However, some states allow evidence to be given by an osteopath against an allopathic physician and vice versa if it can be shown that treatment modes for both schools are the same. Also, some states require that the testimony come from someone practicing in the same specialty. In other states, specialty-based testimony is not required.
Generally, though not always, expert testimony is required to establish that the breach of the standard of care proximately caused the injury. Lay witnesses simply are not competent to testify as to the medical consequences of a physician’s breach of the applicable standard of care.

Finally, it must be remembered that in any lawsuit based on alleged physician negligence, the burden of proof is on the person claiming that the negligence occurred. In some states, there is a presumption of appropriate treatment. This presumption must be overcome by competent evidence to the contrary.

The proof of the standard, the deviation therefrom, proximate causation and damages, being the essence of a civil lawsuit, generally must be proved by what the law calls a preponderance of the evidence. Many judges, in explaining the concept of preponderance of the evidence, still use the analogy of a scale, stating that when the balance shifts in favor of one party, then proof by a preponderance of the evidence has been established. But, if after hearing all the evidence, the jury believes that the evidence is equal or that the shift is in favor of the defendant, then there can be no recovery for the plaintiff.

**Patients’ Reasons for Suing**

Patients often judge the quality of medical care rendered to them not by objective, scientific criteria, but rather by subjective, personal beliefs. From something as non-threatening as a patient satisfaction survey to something as threatening as a lawsuit, patients’ reasons for dissatisfaction with medical care can be viewed best as dependent on two variables: predisposing factors and precipitating factors (ref. 7).

Predisposing factors include events, which, when evaluated individually, appear to be of little consequence to patient satisfaction, yet, when evaluated collectively, significantly influence a patient’s opinion about the quality of care provided. Predisposing factors may be either real or perceived and include such events as rudeness, delays, inattentiveness, miscommunication, apathy, uncleanliness and minor errors.

While predisposing factors initially appear to be inconsequential to patient satisfaction, precipitating factors may have a significant influence on the patient’s tendency to initiate a claim, even if the precipitating factor is an isolated, single event. Precipitating factors often occur after a number of predisposing factors have been experienced by the patient. Precipitating factors tend to be more consistent with reality than predisposing factors and may include significant adverse patient outcomes, especially those attributed to iatrogenic injuries, i.e., caused by the action or inaction of medical personnel.

Levinson and her colleagues (ref. 8) found that primary care physicians with low claims experienced several common characteristics that were less common among primary care physicians with high claims experience. Some of these characteristics included longer routine patient visits, better patient orientation about the visit process, active listening skills on the part of the physician and a warmer, friendlier, more humorous physician personality. These characteristics are consistent with a personable communication style.
Although communication is extremely important, lack of communication is not the only reason patients and their families decide to pursue legal action. A relatively small study was conducted by surveying mothers whose infants had experienced adverse outcomes and whose legal cases had been closed. The mothers were asked why they decided to file a suit. The mothers generally responded either that (1) they were advised to file a suit by knowledgeable acquaintances, (2) they believed there was a cover-up, (3) they needed money, (4) they recognized their child would not have a future, (5) they needed information, or (6) they decided to seek revenge or protect others. In addition, they believed physicians would not listen to their concerns, would not talk openly, deliberately attempted to mislead them, or did not warn them about long-term neurodevelopmental problems (ref. 9). Most but not all of these matters involve communication issues.

Oftentimes, the patient's upbringing or beliefs influence the patient's predisposition to sue. "Incidents, like seeds, may fall on sterile or fertile ground" (ref. 10), and it is important not to fertilize the ground if at all possible.

There is a belief that nice doctors do not get sued as frequently as good doctors. Although practicing the ABCs of defensive medicine, i.e., being accessible, benevolent and compassionate, may insulate a physician from frivolous litigation, serious adverse patient outcomes often will result in litigation regardless of whether the physician practices in a personable manner. This should not minimize, however, the importance of the ABCs of defensive medicine. The perceptions of patients and their families play an integral role in the decision-making process related to litigation, and there is much truth in the epigram, "It's not what one says, but how one says it that matters."

**Claims History**

In response to requests from Congress, the U.S. General Accounting Office (GAO) undertook a major effort to review the medical malpractice situation in the United States. To perform this review, the GAO analyzed data from a random sample of malpractice claim files closed in 1984 by 25 insurers that were selected randomly from a total of 102 insurers (ref. 11). Other studies of malpractice data from 1992 to 1995 demonstrated results similar to those in the 1984 study (refs. 12, 13).

The malpractice experience of 9,250 physicians insured for at least two years from 1977 to 1987 in New Jersey was analyzed. After adjusting for years at risk, physician claims per year were categorized into low, medium and high. The study showed that male physicians were three times as likely to be in the high-claims group as female physicians, even after adjusting for other demographic variables. The authors of this study stated the most likely explanation for this finding was that women interact more effectively with patients (ref. 14).

In the 1987 GAO study (ref. 15), physicians were named in 71% of medical malpractice claims, and hospitals were named in 21%. Malpractice claims were filed against physicians practicing in more than 43 specialty areas. However, more than half of the physicians named in claims practiced in six specialties. Obstetricians/gynecologists (12%) and general surgeons (12%) were the physicians most often named in claims.
These were followed by orthopedic surgery (8%), internal medicine (8%), general practice (6%) and family practice (6%).

The leading causes of malpractice claims are surgical mishaps, followed by failure to diagnose, misdiagnoses, incorrect treatments, medication errors and obstetrical mishaps (ref. 16-18). This information is illustrated in the figure below. Eighty percent of lawsuits resulted from injuries that occurred in hospitals. Approximately 30% of the patients suffered minor temporary disabilities, 15% of the patients died and 6% of the injuries were emotional (ref. 19).

According to Jury Verdict Research, the median of medical malpractice awards during the years 1991 through 1995 fluctuated and ranged from approximately $350,000 to $500,000 (ref. 20). Also, the percentage of medical malpractice awards that resulted in million dollar verdicts was approximately 30% per year for the same period (ref. 21).

The incidence of, and relationship among, adverse events, negligence and medical malpractice lawsuits have been debated for years, and recent studies have yielded some interesting findings. One study of 30,121 hospitalized patients showed that adverse events occurred in 3.7% of the cases, and 1.0% of hospitalized patients experienced adverse effects as a result of negligence (ref. 22). In a related study, Localio and others (ref. 23) found that of 280 hospitalized patients who had an adverse event caused by medical negligence, only 8 (3%) filed malpractice lawsuits. Therefore, one might conclude that many factors affect whether a patient files a medical malpractice lawsuit.

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**Principal Allegations Prompting Medical Malpractice Lawsuits**

*as a percent of the total medical malpractice lawsuits filed*

- Surgical Mishaps 25%
- Treatment Related 19%
- Obstetrical Mishaps 8%
- Medication Related 8%
- Diagnosis Related 25%
- Other 15%

Adapted from GAO (1987), Kelsay (1994), and GAO (1995).
Levinson and her colleagues (ref. 24) were the first to identify specific communication behaviors associated with physicians' risk for medical malpractice claims. Some of the behaviors that were inversely related to the degree of risk included the length of time spent with the patient, orienting the patient about the care delivery process, facilitating conversations with the patient and conversing in a warm, friendly manner.

Another study showed that a physician’s risk of being a defendant in a claim was greatest for physicians between the ages of 36 and 55 and peaked at approximately age 40. No association between claims rates and a physician’s site of training or type of degree was evident in this study. There was no difference between physicians with an osteopathic degree and those with an allopathic degree (ref. 25).

A survey of 400 randomly chosen patients was conducted, and 149 (37%) of these surveys were returned. The survey consisted of patient responses to hypothetical scenarios involving physician error. The findings showed that patients desired disclosure when a physician makes a mistake. Patients were significantly more likely to either report or sue the physician when the physician failed to acknowledge the mistake. The risk of litigation nearly doubled in the moderate mistake scenario when the patient was not informed (ref. 26).

**Patients were significantly more likely to either report or sue the physician when the physician failed to acknowledge the mistake.**

Most risk managers believe quality is inversely related to risk. If quality is high, risk is low; if quality is low, risk is high. However, quality management and risk management overlap significantly (ref. 30), and it is recommended that there be operational linkages between the two.

Quality assurance, a reactive discipline, historically focused on removing “bad” doctors as a means of improving patient outcomes. Likewise, risk management normally focuses on adverse outcomes in order to protect assets. Conversely, quality management examines the processes that are so much an integral part of the healthcare delivery system, and the best programs are more proactive than reactive. Another advantage of a good quality management program is the desire for continuous improvement, not just responding to poor outcomes or trends (ref. 31).
There are many ways of performing quality and risk management studies. Sentinel events—single events that are significant enough to warrant close scrutiny—include occurrences such as maternal deaths, unexpected postoperative neurological deficits, hemolytic transfusion reactions and other events. General indicators screen for trends or patterns related to relatively minor occurrences, which, in aggregate, may signify a problem with either a process or a person. Examples of general indicators include unscheduled returns to the operating room, postoperative wound infections, medication errors and patient falls.

The results of these studies should be used to improve patient outcomes. Although some studies indicate that the appropriate action may be to address a specific individual, most studies identify process issues that warrant improvement.

Patients and families usually want as much information as possible as soon as possible.

Occurrences
All physicians should practice in a knowledgeable and skillful manner. Although such practice may lessen the chance of iatrogenic injuries, it may not guarantee that all iatrogenic injuries will be prevented. Healthcare providers may cause iatrogenic injuries in a number of ways, including unfamiliarity with an invasive procedure technique, inexperience with a specific medical condition or medication, a lapse in judgment due to excessive fatigue or hastiness and other various ways.

The biggest risk management issue with iatrogenic injuries involves deciding what information, if any, should be divulged to the patient or the patient’s family. This often is a judgment call on the part of the physician and hospital administrators, but the decision to divulge such information should be based on a careful analysis of the legal, ethical and moral dynamics. “Honesty is the best policy” is a phrase that has much application to the practice of medicine. Nevertheless, one might argue that the truth has many different shades, and choosing the right shade is an art that is difficult to master unless one has much experience with iatrogenic injuries.

After an iatrogenic injury has occurred, approaching a patient and the patient’s family should be performed in a cautious manner and only after collaborating with the other healthcare providers, the risk manager, and possibly legal counsel. Oftentimes in these cases, “when” something is said is as important as “what” is said.

Patients and families usually want as much information as possible as soon as possible. Yet giving information too soon in the process may lead to presenting information that is less than 100% accurate, creating a difficult situation in which someone must approach the patient or family later and explain why erroneous information was given originally. On the other hand, withholding information that should be communicated may look like a coverup and generally can be used effectively by the plaintiff to inflame a jury in a subsequent malpractice case.

Safe Medical Devices Act
Medical devices such as catheters, monitoring devices and invasive procedure equipment are used to treat patients. If one of these devices causes or contributes to the death or serious injury of a patient, it must be reported to the Federal Drug Administration (FDA) and/or the manufacturer. Under the Safe Medical Devices Act (SMDA) of 1990
(refs. 32, 33), device user facilities must report device-related deaths to the FDA and the manufacturer, if known. Device user facilities must also report device-related serious injuries to the manufacturer, or to the FDA if the manufacturer is not known. In addition, the SMDA also requires that device user facilities submit to the FDA, on a semiannual basis, a summary of all reports submitted during that time period. This law currently applies to hospitals and some healthcare facilities, but it does not apply to physicians' offices.

**Suspected Adverse Medication Reactions**

Although it is sometimes difficult for the physician to determine if a patient's signs or symptoms are consistent with an adverse medication reaction, the physician should have a high degree of suspicion and report any suspected adverse medication reaction via the appropriate mechanism, normally to the pharmacy department.

The pharmacists should investigate the patient's drug regimen and history to determine if the signs or symptoms are related to the medication. They should determine if the correlation is doubtful, possible, or probable, and they also should classify the reaction as mild, moderate, or severe (refs. 34, 35). Each case should be evaluated on a case-by-case basis, and the data should be trended to see if patterns develop in a particular drug or class of drugs.

**Suspected Blood Transfusion Reactions**

Although members of the nursing staff often are the first to suspect a blood transfusion reaction, physicians also should be cognizant of the signs and symptoms of a transfusion reaction and the need to report such suspicions. Whenever a transfusion reaction is suspected, the transfusion should be stopped, and the blood bank should be notified immediately. The blood bank, in consultation with the pathologist, should determine what laboratory tests need to be performed to determine what type of reaction, if any, occurred (ref. 36).

**COBRA and EMTALA**

The Consolidated Omnibus Budget Reconciliation Act (COBRA) is known as the antidumping bill because it contained the amendment called the Emergency Medical Treatment and Active Labor Act (EMTALA) (ref. 37). Although the complexities of the law are very extensive, a few of the intricacies of the law should be known by practicing physicians.

The COBRA rules require that hospitals and physicians ensure that patients who "come to the emergency department" have an appropriate medical screening examination and be stabilized prior to transfer. Patients who are transferred should have appropriate medical records sent to the receiving facility at the time of the transfer, the receiving physician must accept the patient in transfer from the transferring physician, and the nursing staff of the transferring facility must give a report to the receiving facility's nursing staff.

Physicians and facilities that commit a COBRA violation by transferring a patient inappropriately may be subject to a civil penalty up to $50,000, as well as possible termination from Medicare and state health programs. Physicians and facilities that receive an inappropriate transfer and fail to report the violation may be penalized, also. In addition, private causes of action may be asserted by individuals and facilities (refs. 38,39).
Although there are many technical and unsettled legal questions, physicians should make every effort to be in compliance with the law as well as the policies of the facility. To comply with the COBRA rules, the healthcare providers' major emphasis should be on stabilizing the patient prior to transfer and communicating thoroughly with the receiving physician and nursing personnel.

Patient Rights

Physicians, from ancient times, have recognized that they have a responsibility to ensure that the individual rights of patients are honored and that patient rights are restricted only as a last effort for the safety of the patient or others. Physicians realize that the health and well-being of patients are a joint effort between the physician and patient.

The Report of the Council on Ethical and Judicial Affairs, which was adopted by the American Medical Association House of Delegates in 1990, lists several rights of patients. These include the right of a patient to informed consent; to make decisions regarding the healthcare that is recommended; to courtesy, respect, dignity, responsiveness and timely attention to the patient's needs; to confidentiality; to continuity of healthcare; and to available adequate healthcare (ref. 40).

Informed consent is a legal doctrine that is a communication process, not simply a form or document (ref. 41). A patient has the right to receive information about healthcare treatment from physicians and to discuss the benefits, risks and costs of appropriate treatment alternatives. Informed consent frequently is regarded legally as a memorialization of an understanding between the patient and the physician. The law of informed consent varies significantly from state to state, and physicians should become familiar with the law in their state.

The elements of informed consent typically include the disclosure of the nature of the proposed treatment or procedure, material risks, alternatives and consequences of refusing the proposed care. Material risks that should be discussed include but are not limited to death, serious disability or dismemberment, extended pain and suffering, and prolonged hospitalization or recovery.

As a precautionary measure, after the procedure has been explained to the patient, the patient should be asked to summarize what he or she has been told. Sketched drawings of pathology and operative procedures may be helpful when they are explained to the patient and included in the medical record. If possible, a family member or other responsible adult known to the patient should witness the consent process. The consent should be obtained directly from the patient unless there is an emergency or the patient is a minor or mentally incompetent. In these circumstances, the consent should be obtained from the legally authorized representative.

Any patient has the right to make decisions regarding the healthcare that is recommended by the patient's physician, so patients may accept or refuse any recommended medical treatment. If a patient is reluctant to implement treatment or completely refuses treatment, the physician should encourage the patient to seek the opinion of another physician. This should be done discreetly at the first sign of noncompliance.

If the patient continues to refuse treatment, the refusal should be noted in the medical record along with notations that the patient was advised of the consequences of the refusal, and a formal written refusal should be obtained (ref. 42). This document should state that the patient, having been fully informed of all
consequences, refused the physician’s recommendation. Have a family member or other responsible adult known to the patient witness the written refusal, or, when this is not possible, have two responsible hospital personnel witness the refusal.

Although healthcare providers usually err on the side of preserving life, this is not necessarily applicable to the life of a fetus. The courts have ruled that a competent woman has the right to decline exposure to additional medical risks for the sake of her unborn fetus, regardless of whether the fetus is viable (ref. 43).

Jehovah’s Witnesses have biblical beliefs—based on Acts 15:28,29—which prevent Witnesses from being able to accept blood or blood products, either homologous or autologous. Some of the blood products are listed in Table 2. Such a belief does not mean that Jehovah’s Witnesses refuse all medical treatment. They simply prefer other alternatives, such as non-blood volume expanders and cell-saving technology. Many Jehovah’s Witnesses carry specific advance directives that give instructions specifying which products they refuse to receive (ref. 44).

The right to refuse care is not always absolute and has been the subject of considerable litigation. It is important to determine the legal requirements in a jurisdiction regarding the right to refuse care (ref. 45). The hospital ethics committee may serve as a source of guidance for the healthcare providers and the patient or the patient’s family. As a last resort, legal action can be initiated.

**Advance Directives**

Most states now recognize various types of advance directives, the most prevalent of which are living wills and healthcare powers of attorney—the latter allows a patient to name an agent to make healthcare decisions in the absence of the competency of the patient. Advance directives regarding end-of-life issues and agents who may make healthcare decisions in the absence of a competent principal generally are matters of state statutory law (ref. 46).

There are various state and federal definitions of competency and various statutory definitions of what is meant by “life support,” i.e., whether hydration and nutrition are included or excluded. Also, states differ as to the form of execution of such advance directives, with some states requiring only attestation by witnesses in the presence of the declarant of a living will or healthcare power of attorney and other states requiring notarization. It is beyond the scope of this article to make any attempt to detail the requirements of the various states regarding these documents. Each physician should consult his or her own state’s laws with regard to the matter.

**Table 2. Common Products Obtained from Blood**

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<tr>
<th>Usually Refused by All Jehovah’s Witnesses</th>
<th>Refused at Discretion of the Witness</th>
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<tr>
<td>Whole blood</td>
<td>Albumin</td>
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<tr>
<td>Red blood cells</td>
<td>Erythropoietin</td>
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<tr>
<td>White blood cells</td>
<td>Rh immune globulin</td>
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<tr>
<td>Platelets</td>
<td>Gamma globulin</td>
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<tr>
<td>Plasma</td>
<td>Streptokinase</td>
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<tr>
<td></td>
<td>Clotting factors and fibrinogen</td>
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<tr>
<td></td>
<td>Horse serum</td>
</tr>
<tr>
<td></td>
<td>Snake bite antivenom</td>
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<tr>
<td></td>
<td>Medications containing albumin</td>
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</table>
Also, in the transient society in which we live, it is common for an individual to present himself or herself to a medical practitioner with advance directive documents, which, while they may have been valid in the state in which they were executed, may be either valid or invalid in the state where the physician is practicing medicine. If possible, new advance directives should be executed in accordance with the laws of the state where treatment occurs. Although physicians should not practice law, it is recommended that the physician or someone on his or her staff have a working knowledge of the requirements of the laws in the state where the physician is practicing concerning advance directives and, if possible, maintain generally accepted statutorily prescribed forms for use by his or her patients.

The medical record can be a healthcare provider's best friend or most formidable enemy.

Medical Records

The medical record can be a healthcare provider's best friend or most formidable enemy. It really depends on how the medical record is managed. The primary purpose of the medical record is for documentation of the course of a patient's illness and the treatment that the patient receives. It is the prime communication medium for planning, coordinating and orchestrating patient care.

Although medical records are the physician's own work product, many other people have potential access to them with appropriate consent. The medical record also is a legal document. It provides the legal basis for birth, death, communicable disease and other public health reporting information. Another important use of the medical record is in malpractice claims, where both plaintiffs and defendants may find information either helpful or damaging.

The medical record is an official document of everything that was done, and it is sometimes used in an effort to show that something was not done. Without an accurate and complete medical record, the physician is left to his or her memory. This can be a crucial point in a court case several years later when there is disagreement between the physician's recollection and the patient's testimony. The medical record also is a basis for many other important healthcare activities such as documentation for patient care reimbursement, documentation for teaching and medical research, utilization review, performance improvement and peer review purposes. Therefore, although it is not always practical, it is best to document everything and omit nothing.

The information included in the medical record is important to both the physician and the patient. The physician or hospital owns the original record; however, due to the confidential nature of the information contained in the record, copies of the record usually cannot be released to any other person without appropriate authorization from the patient or the patient's legal guardian, or if other legally acceptable circumstances exist. The physician and the hospital's director of medical records are responsible for safeguarding the information in the medical record against loss, defacement, tampering and unauthorized access (ref. 47).

There is a legal and ethical basis for confidentiality of medical information. The legal basis for confidentiality is derived from the physician-patient privilege, which is set forth by statute in almost all states (ref. 48). The ethical principle of confidentiality originates from the idea that confidentiality encourages patients to seek needed medical care and to be candid with their physicians about their situation. Confidentiality also is necessary to protect the patient's inherent privacy interests (ref. 49).
Beyond state law, there is a body of case law that recognizes the healthcare organization's duty to protect the privacy of its patients. Patient confidentiality also is protected by codes of professional ethical conduct such as the Hippocratic oath, and even by standards issued by various accrediting bodies such as the Joint Commission on Accreditation of Healthcare Organizations.

Absent other legal authorization or requirements, physicians and their employees should not release privileged information about a patient's treatment or diagnosis without first obtaining a written authorization from the patient or, if a minor, by the parent or legal guardian. The requirements for valid authorization for the release of information are contained in Table 3.

A waiver of privilege for confidentiality may be made only by the patient or patient's legal representative. Waivers may be either expressed or implicit. Exceptions to the waiver requirements exist, however, in the context of active litigation where most medical records must be provided in response to a valid subpoena or request for production of medical records in accordance with state law.

The right of confidentiality and the physician-patient privilege are never without exception. Certain interests of society outweigh the physician's duty to maintain confidentiality of patient records even when there has been no waiver or authorization. Many states have laws mandating that physicians and hospitals report communicable diseases, cases of suspected child or elder abuse and neglect, incidents of cancer, gunshot or knife wounds, physician misconduct and incidents of adverse patient care. Patients with uncontrolled seizures or syncopal episodes create a reporting dilemma for physicians, because this information may be reportable to the department of motor vehicles or the police department. In addition, physicians must be aware of when they must report that a patient is a risk to identifiable third parties (ref. 50).

Table 3. Requirements for Valid Authorization for the Release of Information

| ✔ The authorization must be in writing. |
| ✔ The authorization must be addressed to the organization, facility or physician. |
| ✔ The authorization must be signed by the patient, parent or legal guardian. |
| ✔ Authorizations dated prior to treatment are not acceptable. |
| ✔ Authorizations must designate the name of the person, company or agent to whom the information is to be given. |
| ✔ The signature on the authorization should be verified if possible. |
| ✔ Authorizations should state specifically which information is to be released. |
| ✔ Authorizations should specify the illness and/or period of time to be covered. |
| ✔ Authorizations should be filed in the patient's permanent medical record. The record should contain the date the copies were sent and the initials of the employee who sent them. |
The statutes regulating disclosure usually contain a confidentiality statement restricting the ability of the public to gain access to that information. Patient authorization also is not a prerequisite to release information to either internal or external review organizations. Official agencies such as state health departments and professional or peer review organizations (PROs) assess patient records for the purpose of quality of care reviews (ref. 51).

Adequate documentation is one of the most important risk management skills. It has been found that in malpractice suits where documentation and record keeping were judged inadequate, damages were paid in two-thirds of the cases. When documentation and record keeping were judged adequate, damages were paid in only one-third of the cases. If a patient's file contains good documentation, the likelihood of a malpractice suit even being filed is generally reduced because the plaintiff's attorney knows that a settlement or winning in court would be difficult (ref. 52). There are many guidelines for appropriate documentation in the medical record. Some of these are listed in Table 4.

The length of time medical records should be retained will vary depending on the purpose for which the records are being kept. In some areas, a healthcare institution is not required by law to preserve its records for any given length of time. The appropriate period of retention may be affected by the statute of limitations for bringing a legal action for an injury or breach of contract. In most states, the period of the applicable statute of limitations is less than 10 years; however, medical records of minors should be retained for the period of minority plus the applicable period of statute of limitations as prescribed by the statute in the state in which the healthcare institution is located. If possible, the medical record should be kept indefinitely. If this is not acceptable because of the cost of storage space, then local legal counsel should be consulted to review the statutory or administrative law and suggest a reasonable alternative (ref. 53).

**Test Results**

It is the customary practice for physicians to order and interpret diagnostic tests, formulate a treatment plan, instruct the patient on treatment options and recommend a course of treatment and follow-up care. The American Medical Association's Risk Management Principles and Commentaries for the Medical Office suggests that "the physician ordering the tests bears the responsibility and should develop a mechanism for communicating test results to the patient should that patient leave the office before results are known" (ref. 54). Practices such as requiring the patient to call for results, or calling the patient only when results are abnormal, can leave patients unaware of the significance of tests and the need for follow-up care. This type of practice also increases the risk of the results not being communicated to the patient.

Boohaker and others (ref. 55) surveyed attending physicians and residents and determined that approximately 17% to 32% of physicians did not have any reliable method to ensure that the results of tests are reviewed. In addition, only 23% of physicians reported having a reliable method for identifying patients overdue for follow-up.
Table 4. General Documentation Guidelines

- Documentation must be legible, clear and concise. Patient identification must be on every page. A record that cannot be interpreted clearly is of little benefit to the subsequent treating provider and/or months or years later in the face of a professional liability lawsuit.

- The time must be noted on each entry. Military time or an a.m./p.m. should be used on all entries. This is particularly crucial in critical care records where multiple entries occur throughout the day.

- Documentation should be timely. Chart entries should be entered immediately after the practitioner sees each patient to ensure accuracy and prevent any later question regarding credibility of the entry. Every entry should be signed, and entries never should be made ahead of time.

- Documentation of all examinations should be made, and should include significant negative and positive findings. If a review of systems is done, it should be done consistently and include all systems every time.

- Documentation and communication among providers involved in a patient’s clinical course should include significant clinical events, significant interactions with the patient and telephone and/or informal consultations among providers.

- Documentation of telephone calls should be made. The healthcare provider should clearly delineate the complaint, assessment, advice, call taker’s signature, consulting physician’s signature, date and time.

- Documentation should include patient education and discharge instructions. This documentation should show what information has been provided to the patient or to the family member or other person responsible for the patient, and that the person who was instructed understood the information.

- Corrections in the medical records are acceptable but should follow appropriate protocol. Corrections should be made by drawing a single line through the error, leaving the original entry legible. The correct entry should be shown, along with the name or initial of the person making the correction, and the date. An explanation of the correction should be included if needed. If there is not enough room for the explanation, then a note should be added in a late entry. The time of the correction should be included if it might be critical to the patient’s subsequent treatment.

- A correction should be made as soon as the error is noticed but not after there has been a notice of possible litigation. A policy detailing how to make changes in the medical record should be developed.

- An alteration is a deliberate attempt to change rather than correct what has been recorded. Altering records can lead to allegations of spoilage of evidence and fraud. Alterations can result in a waiver of the statute of limitation and punitive damages. Pages that have an error should not be removed from the chart. Attempts to cover up errors through unexplained additions to the records have resulted in a plaintiff’s award even though the standard of care was met.

- Personal opinions or subjective comments should not be placed in the medical record. The medical record should contain objective information. In the face of a professional liability lawsuit, such comments are perceived as a lack of respect for the patient.

- Only institution-approved abbreviations should be used in the medical record.
Medications

Physicians should obtain and document an adequate history from the patient. This should include current medications, allergies to medications and allergies to anything else, such as eggs, which are used to manufacture some medications. The risks and benefits of prescribed medications should be discussed with the patient and documented in the medical record (ref. 56).

Physicians' offices should have an appropriate system for ordering, storing and dispensing controlled substances used in the office, and samples from pharmaceutical companies should be secured and controlled (ref. 57). Prescription pads should be secured and never should be presigned.

Residency Issues

Residents often are unsure which standards apply to their practice. Courts have held that it is unfair to hold residents to any standard other than the one requiring the same degree of knowledge and skill possessed by residents in the same specialty (refs. 58, 59).

Although the widely accepted practice and long-standing tradition of residents working shifts for more than 24 or 36 hours at a time is common, the Libby Zion case from 1984 brought the issue to public attention (refs. 60, 61). Some improvements have been made, but there will be defense difficulties whenever the length of a resident's shift becomes an issue in a medical malpractice case.

Residents who moonlight, and administrators and physicians involved in hiring and supervising the residents, are prone to criticisms related to the residents working when exhausted, unsupervised and outside their area of expertise (ref. 62). All these issues must be considered and monitored whenever residents are hired as independent or contract physicians.

Although residents may be involved in medical malpractice cases for a variety of reasons, some opportunities for improvement definitely exist. Some of the most troubling reasons include lack of continuity of care, shift change, telephone calls, lack of appropriate instructions and patients who leave against medical advice or elope without being examined by the physician. These areas should be managed cautiously with the guidance of a more senior physician.

Since the mid-1980s, body fluid exposures have become a significant issue for healthcare providers. Diseases such as hepatitis and autoimmune deficiency syndrome (AIDS) can be acquired through body fluid exposures. The study by O'Neill and others (ref. 63) revealed that 71% of fourth-year medical students who responded to their survey reported at least one body fluid exposure during the training year. Body fluid exposures should be reported to the infection control practitioner, if applicable, so an appropriate workup and prophylactic treatment can be initiated, if necessary.

Healthcare Quality Improvement Act

Congress recognized that the healthcare system depends on the willingness of professionals to participate in reviewing quality of care issues, so it adopted the Healthcare Quality Improvement Act (ref. 64) in 1986. Prior to the Act and following the U.S. Supreme Court decision in *Patrick v. Burget* (ref. 65), wherein the U.S. Supreme Court held that physician members of hospital peer review committees could be subject to suit under federal antitrust laws, physicians participating in peer review activities were not immune from liability for damages to physicians whose conduct came into question. Obviously, this lack of immunity severely undercut the peer review system.
What physician would serve knowing that an antitrust suit could be brought against the individual physician members of a hospital peer review committee? Under the Act, though, immunity for participation in professional review actions by professional review committees is granted from all federal and state law claims, except civil rights violations, if the review actions meet the standards of the Act. In addition, witnesses providing information with regard to peer review are immune, except when they knowingly give false information.

The Act provides that a review activity meets the standards of the Act for immunity purposes if it is performed in the reasonable belief that the action is in the furtherance of quality healthcare, a reasonable effort to obtain the facts is made, and notice and a hearing are afforded in the event that an action is warranted by the facts. The Act sets forth what lawyers generally refer to as “safe harbor” standards describing procedures that are deemed adequate if followed. These safe harbor standards set forth how notice of a proposed action must be given and the manner in which a hearing must be noticed and conducted (ref. 66).

In furtherance of the purposes of the Act, some states have provided their own immunity statutes granting immunity for members of a “medical review committee” when the committee functions as a committee of a hospital’s medical staff under written guidelines for the purpose of evaluating and improving the quality of care rendered by staff physicians. Since these statutes vary from state to state, state immunity statutes should be consulted for their breadth (ref. 67).

Physician Credentialing
A national data bank for the collection of data on adverse actions against physicians was established by the Act (ref. 68). Hospitals, in order to protect their immunity for peer review, must report adverse professional review actions to the National Practitioner Data Bank. Also, a hospital must request certain information from the data bank before granting practice privileges to a new applicant. During the recredentialing process, which normally occurs every two years, a hospital must request information regarding physicians who are already on staff.

In addition to the National Practitioner Data Bank information, hospitals also solicit proof of the physician’s education and training, insurance coverage, medical license, Drug Enforcement Agency license and other documents.

The American Medical Association estimates that approximately 10% of physicians practicing in the United States are impaired.

Impaired Physicians
The American Medical Association estimates that approximately 10% of physicians practicing in the United States are impaired (ref. 69). The Americans with Disabilities Act of 1990 has been instrumental in changing the perception of impaired physicians from castaways to potentially rehabilitative professionals.
Although the majority of physician impairment is caused by alcohol or other drug abuse, impairment can also be caused by aging, disease and other factors (ref. 70). Medical societies of each of the 50 states and the District of Columbia either have their own support system or participate in other support systems (ref. 71).

Managed Care and Case Management

During the past few years, the healthcare industry has been faced with pressures to reduce costs, improve profits and maintain quality. Organizations are changing to meet these challenges by acquiring, expanding, merging and restructuring operations. Out of these changes, managed care has emerged. Managed care is an alternative healthcare delivery system that influences utilization and cost of services, as well as encouraging measurements of performance (ref. 72).

As managed care grows and organizations shift their strategies to maintain a competitive edge in the marketplace, new risks emerge. Today, many physicians are entering into various forms of managed care arrangements, some of which are not wisely managed. Risks are no longer just clinical; they also relate to business and operations.

CNA HealthPro studied a sample of more than 200 managed care claims between 1992 and 1996 to get a glimpse of new and emerging risks in managed care. The top claim (36%) in the sample was vicarious liability. The top reasons for alleging vicarious liability against a managed care organization include medical negligence, failure to diagnose and failure to coordinate care. Other liability issues include bad faith/breach of contract (30%), benefits denial/utilization review (25%), medical malpractice (23%), contractual/business disputes (18%), fraud/misrepresentation (12%), marketing/advertising (8%) and credentialing (6%) (ref. 73).

With the advent of managed care, claims for failure to diagnose, misdiagnosis, delay in treatment and improper referral have increased significantly for physicians. Physicians can reduce managed care risks in medical practices by reviewing contracts thoroughly before signing, negotiating contract clauses that decrease liability, preventing referral/consultation liability, implementing malpractice prevention compensation formulas, improving documentation, improving follow-up systems, improving quality of care, and improving physician/patient relations.

An increase in lawsuits alleging delayed diagnoses of various conditions has been seen. The issue of diagnosis best highlights the potential conflict between managed care incentives and the practice of high-quality medicine. Many cases involving a failure to diagnose could be avoided if better follow-up and recall systems were in place. Office staff can help minimize the physician's malpractice risk by developing and implementing systems and procedures to reduce this risk. Such systems and procedures include follow-up for abnormal lab results, follow-up to ensure that the patient returns to the office to recheck conditions as indicated by the physician, and follow-up to ensure that the patient sought consultation after referral (ref. 74). Written policies, which can be introduced into evidence and supported by testimony that the policies were followed, can be helpful in litigation.
Before signing a contract with a managed care organization (MCO), a physician should assess the limitations a plan may place on his or her right to refer and his or her choice of hospitals or other facilities; the ability and willingness of a MCO to solve problems; and liability coverages of the plan, such as directors and officers and errors and omissions. The physician should have a high comfort level for the quality of the panel of approved providers, the process for credentialing them and the restrictions on his or her medical judgment (ref. 75).

There is a potential liability for physicians who knowingly make a referral to a physician and the referral results in patient injury, but not in all states. Physicians should insist that the managed care plan provides lists of participating physicians, and physicians should ensure there are enough providers on panels to give more than one referral. Primary care physicians should carefully document reasons for not referring to a specialist, document the differential diagnosis and have excellent follow-up systems to recall patients if necessary.

Referrals or services to a patient probably will be denied if the referral or service is not needed. If the MCO makes a decision with which the physician disagrees, the physician should avoid passive acceptance of the plan’s decision. The physician should follow these steps to support his or her treatment: follow the plan’s avenues for appeal and document efforts in the patient’s chart, advise the patient to obtain the recommended care and inform the patient of the risks of not following the prescribed care, document the advice given and any informed refusal, and document conversations with the plan reviewer and all efforts to get care on the patient’s behalf (ref. 76).

In reviewing physician compensation formulas in the managed care contract, the physician should look for positive physician compensation formulas rather than rigid physician incentive compensation formulas, which financially penalize a physician for recalling a patient for various conditions. Positive physician compensation formulas include point-based formulas, which measure physician performance in a variety of categories of value to the organization, such as number of compliments and complaints, results of patient satisfaction surveys, number of patient encounters, cost-effective care, number of outside referrals, participation in organization meetings and committees, liability claims involvement and quality of care as seen in chart audits (ref. 77).

A physician’s greatest defense weapon in any professional liability lawsuit may be the medical record. Adequate documentation not only will reduce liability exposure but also will aid the physician in optimal reimbursement. To ensure optimal reimbursement, the physician needs to learn the steps for properly identifying and reporting legitimate charges and diagnoses on the bill. Capturing charges and diagnoses on a daily basis is critical to efficient and timely billing.

The patient’s perception of quality has become significantly important to MCOs. As quality expectations and cost restraints are increasing, guidelines, parameters and pathways are proliferating; however, the scientific validity of these materials has not been proved conclusively.

Practice guidelines generally refer to standards and treatment recommendations developed from research findings, assembled by expert panels and used to help practitioners make healthcare decisions under specific circumstances. Most guidelines relate to physician interventions. Practice parameters are educational tools
that provide researchers with a practical way of staying abreast of medical research and assessing the clinical significance of research findings. Parameters are usually longer and more detailed than guidelines. Clinical pathways, also referred to as critical paths, typically have a wider scope than parameters or guidelines, as they coordinate the efforts of a multidisciplinary healthcare team and address care delivery as well as medical decision making (ref. 78).

Some experts contend that widespread use of guidelines may help reduce healthcare costs and provide protection from malpractice suits. This point is debatable (ref. 79). A clinical pathway may not carry much weight in defending a malpractice claim. To improve those chances, the pathway should be integral to the medical record and include outcome criteria and a variance record (ref. 80). The clinical team should use the pathway and document directly on it (ref. 81).

**One of the most important tools in medical risk management and practice development is good communication with patients.**

One of the most important tools in medical risk management and practice development is good communication with patients, especially since the increasing involvement of MCOs poses a significant threat to the quality of physician-patient relationships. To maintain good communication with patients, the office staff should be prepared and willing to assist patients with healthcare coverage questions. The physician and staff must understand the plan’s practice guidelines, and patient education and high-quality informed consent discussions should occur. The practice brochure should include specific information about the patient’s healthcare plan.

Patient satisfaction surveys should be performed because they are an indication of trends that may influence the patient or payers to take their business elsewhere. A patient satisfaction survey is considered an essential component of quality measurement to the payer community. They should be performed on a regular basis to identify trends and to see if improvement efforts generated positive results (ref. 82).

**Conclusion**

Although risk management is not a subject that most physicians will spend many hours learning, it is very important that physicians understand risk management (ref. 83). It has been demonstrated that physician education regarding their role in risk management efforts can facilitate early intervention, one of the main tenets in healthcare risk management (refs. 84, 85). To paraphrase Milton, “a complete and generous education allows one to perform justly, skillfully and magnanimously” (ref. 86).

Although the authors do not necessarily agree with the idea that a “lawyerectomy” is indicated to save billions of healthcare dollars (ref. 87), there are times when the legal system runs amok, as illustrated by the case in which three nurses were indicted on charges of criminally negligent homicide after committing a fatal medication error (ref. 88). As stated earlier, medicine is not an exact science, and human errors will be made. However, if a physician uses the principles discussed in this article (listed in Table 5), the physician’s risk exposure should be minimized significantly.
Table 5. Basic Risk Management Principles for the Practicing Physician

- Practice in a personable, caring manner so as to avoid generating predisposing factors.
- Precipitating factors should be handled in a honest manner tempered with sound judgment.
- Avoid working an excessive number of hours without an appropriate rest period.
- Manage only diagnoses, procedures and equipment that you feel comfortable with and for which you have received an appropriate level of training and experience. For all others, request a consult.
- Report unsafe devices to the risk manager so the manufacturer and/or the FDA can be notified.
- Report all suspected adverse medication reactions to the pharmacy department.
- Report all suspected blood transfusion reactions to the blood bank.
- Meet the requirements of COBRA and EMTALA by discussing the transfer with the patient and the receiving physician and facility, and document the information on the transfer sheet that is sent with the patient.
- Ensure all patient rights are protected.
- Obtain informed consent when required by law. Obtain informed refusal if necessary.
- Honor a patient’s advance directive or refusal of treatment to the best of your ability. Court intervention should be a last resort.
- Document objectively in the patient’s medical record. Avoid unnecessary changes and never alter the medical record.
- Have an appropriate mechanism for follow-up on test results.
- Manage office medications and prescription pads appropriately.
- Participate in peer review activities only as a means of improving patient care, never as a vendetta against a physician.
- Follow hospital guidelines and medical staff bylaws for all credentialing procedures.
- Avoid conflicts of interest in managed care cases, and always focus on doing what is in the best interest of the patient.
- Perform patient satisfaction surveys as a means of identifying concerns, then implement improvement efforts.

References
5. For those interested in a textual approach to negligence, as well as other torts, the standard law student reference Prosser & Keeton on Torts, 5th ed., edited by W. Paige Keeton and published by West Publishing Company, St. Paul, MN, is available in most law school book stores. For a historical approach, see Winfield, The History of Negligence in the Law of Torts, 42L.Q.Rev.184, 1926.
6. See, e.g., Fulton County-Dekalb Hospital Authority v. Graves, 252 Ga 441 (1984) and Atlanta Obstetrics & Gynecology Group v. Abelson, 260 Ga 711 (1990), both of which recognize the tort known either as wrongful birth, wrongful pregnancy, or wrongful conception as areas of medical malpractice allowing recovery by the parents for the expenses of an unsuccessful medical sterilization procedure, pain and suffering, medical complications, costs of delivery, lost wages and loss of consortium, but do not recognize a cause of action for the tort known as wrongful life, also sometimes confusingly called wrongful birth, as an action that may be pursued by or on behalf of the child for impairment. Atlanta Obstetrics & Gynecology Group v. Abelson, supra, presents a well-reasoned analysis of the approaches taken in several states in the development of the tort of wrongful life as well as citations to several good law review articles.


17. VA Health Care: Trends in Malpractice Claims Can Aid in Addressing Quality of Care Problems, op.cit.


19. Medical Malpractice, op.cit., p. 3.


24. Levinson, op.cit.


27. Headrick, op.cit.


31. Little, op.cit.

32. 21 U.S.C. Section 360:(b)(1).


42. Rozovsky, op.cit., p. 39.


44. There are numerous examples of case law in which the beliefs of Jehovah's Witnesses have been upheld by the courts. Some of these include Stamford Hosp. v. Vega, 674 A.2d 821 (Conn. 1996); In re Dubreuil, 629 So. 2d 819 (Fla. 1993); Norwood Hosp. v. Munoz, 564 N.E.2d 1017 (Mass. 1991); Fosmire v. Nicolet, 551 N.E.2d 77 (N.Y. 1990); In re E.G., 549 N.E.2d 322 (Ill. 1989); Public Health Trust v. Wons, 541 So. 2d 96 (Fla. 1989); In re Milton, 505 N.E.2d 255 (Ohio 1987); In re Brown, 478 So. 2d 1033 (Miss. 1985); In re Osborne, 294 A. 2d 372 (D.C. 1972); and In re Estate of Brooks, 205 N.E.2d 435 (Ill. 1965).


46. U.S. Supreme Court, in Cruzan v. Missouri Department of Health (497 U.S. 261; 110 S.Ct. 2841; 111 L. Ed.2d 224 {1990}; Internet: http://funnelweb.utcc.utk.edu/~scheb/cruzan.html), stated "It cannot be disputed that the Due Process Clause [of the Fourteenth Amendment to the United States Constitution] protects an interest in life as well as an interest in refusing life-sustaining medical treatment." The Court also stated, "The principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions."


49. Ibid.

50. For more information about "failure to warn," see Tarasoff v. Regents of the University of California, 551 P.2d 1378 (Cal. 1976).
52. Kelsay, op.cit., p. 49.
57. Ibid.
64. 42 U.S.C. 311101.
66. 42 U.S.C. 11112(b).
76. Ibid.
77. Phairas, op.cit.


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