



# Informed consent: the third generation

a TMLT risk management publication

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Informed consent: the third generation  
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## **Preface**

Texas Medical Liability Trust is strongly committed to the prevention of professional liability claims. The TMLT Risk Management Department endeavors to present materials for physicians and their staffs to provide a foundation for basic risk management.

This handbook has been developed as a reference. The information contained herein is intended to enhance the knowledge of informed consent issues, thereby reducing the exposure to associated claims, and to assist in defense, should a claim occur.

The TMLT Risk Management Department staff is available to assist you and welcome your calls or questions.

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## Introduction and background

The legal doctrine of “informed consent” is not a static, carved in granite legal principle. Undergoing continuous refinement and definition, this doctrine is forever evolving and changing as new laws and new cases further shape the parameters and contents of what constitutes “informed consent.” This is something that, once learned, is not necessarily mastered. State of the art consent practices implemented at your hospital or office a few years ago may now be outdated. It is hoped you will approach this information with an open mind and willingness to take a second look at informed consent as it is in 2004.

An understanding of the doctrine of informed consent first begins with the legal notion of battery. You are most likely familiar with the common phrase “assault and battery.” They are legally different. Assault represents the attempt to injure, while battery represents the actual injury. More specifically, a battery occurs when there is an unauthorized touching or invasion of a person’s body. Although battery sounds suspiciously like “batter” or “battered,” it would be a mistake to conclude that an injury must occur. A battery represents any unauthorized invasion of a person’s right to privacy with respect to his or her body. Pinching a woman is not only a form of sexual harassment, it is also a battery, notwithstanding the absence of a physical injury.

As stated above, a battery occurs when the touching, invasion, or injury is unauthorized. If permission has been given, a battery does not exist. While permission may be expressly given in writing or orally, it may also be implied, such as when you step into a crowded subway or elevator conceding the inevitability of being jostled by fellow travelers. Still, the point to be made is that a battery does not exist in the presence of permission. And, of course, permission is but another way of saying “consent.”

Historically, in the context of medical malpractice, the patient deferred to his physician with respect to all treatment. It was not the patient’s role to second guess what was needed. With the expansion of the concepts of self-determination, patient’s rights, consumer advocacy, etc., it should come as no surprise that the historical notion of total deference to the physician has been abandoned. In its place has come the doctrine of consent, followed by the doctrine of informed consent, followed by

a more sophisticated and refined definition of informed consent, what we will now refer to as the third generation of informed consent.

A claim alleging lack of consent begins with patients complaining that they had not consented to the treatment rendered by their physician. The law traces these complaints to the turn of the century. For example, in 1906, an Illinois woman sued her doctor contending she had never given permission for the removal of her uterus; *Pratt v. Davis*, 79 N.E. 562 (Ill. 1906). Seventy-five years ago, a Texas doctor was held to account for operating on a child without parental consent, *Moss v. Rishworth*, 222 S.W. 225 (1920). These and other cases treated the doctrine of consent like a light switch. It was either on or off. Consent had either been given or it had not. Things were simple in those days and so was the law.

Beginning in the 1950s, consent was no longer so simple. It was not enough that the patient had given consent to a procedure or treatment. Now, the patient demanded that his decision to give consent be based upon facts and information necessary to render an intelligent decision. Hence was born the concept of “informed” consent. The hallmark case of *Salgo v. Leland Stanford, Jr. University Board of Trustees*, 317 P.2d 170 (Cal. App. 1957) recognized the duty of a doctor to tell the patient all the facts necessary to render his decision. As a consequence, informed consent litigation burgeoned and physicians quickly became the targets of claims that the consent obtained was not informed and, therefore, tantamount to no consent at all, reference *Gerety v. Demers*, 589 P.2d 180, 190 (NM. 1978) and *Wilkinson v. Vesey*, 295 A.2d 676 (RI. 1972).



## A Texas approach to informed consent

Texas recognizes that consent for treatment must be obtained and that such consent be “informed.” In 1977, the Medical Liability and Insurance Improvement Act (hereinafter referred to as “article 4590i”) became law. This statute was passed by the Texas legislature and was an attempt to put in writing the legal requirements of Texas physicians regarding informed consent. As will be explained later, the statute has since been the subject of many interpretations by the courts, further refining our understanding of this statute. In September 2003, the Informed Consent statute that was codified in article 4590i was moved to chapter 74, subchapter C of the *Texas Civil Practice and Remedies Code*.

The statute itself is rather simple. It states the following:

“In a suit against a physician or health care provider involving a health care liability claim that is based on the failure of the physician or health care provider to disclose or adequately disclose the risks and hazards involved in the medical care or surgical procedure rendered by the physician or health care provider, the only theory on which recovery may be obtained is that of negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent.”

You should first note that the statute views informed consent as a negligence issue. In other words, the law focuses on a hypothetical, reasonable physician and what that physician normally would or would not tell a patient regarding any treatment. This is not to say, however, that the statute has abolished any claims other than those alleging negligence. For example, a battery claim could still be filed if the physician got no consent whatsoever. Again, note the difference between consent versus informed or adequate consent. The statute is really addressed toward the adequacy of the consent. It requires the physician to properly inform the patient. The statute does not focus on the consequences of failing to get consent. That is left to the common law claim of battery.

Focusing upon the concept of the adequacy of the consent (informed consent), a Texas physician obviously needs to know what the patient must be told in order to satisfy the duty to properly inform that

patient. How do you know when you have told the patient enough so that his decision is now “informed?” The answer is a little complex. Article 4590i created the Texas Medical Disclosure Panel. It consists of six physicians and three attorneys. It is actually an administrative attachment to the Texas Department of Health. The panel is supposed to review all treatments and procedures to determine which procedures require disclosure and which do not. Those matters requiring disclosure are put on List A. Those matters that do not require disclosure are identified in List B. The panel periodically examines new treatments or procedures and assigns them to a particular list. You can acquire a current list, which is published in the *Texas Register* in the Texas Administrative Code, accessible on the Internet at [www.sos.state.tx.us](http://www.sos.state.tx.us).

As stated above, List A represents those treatments or procedures which the panel has decided require disclosure to the patient. The panel identifies the particular risks that should be disclosed to the patient. The panel also identifies the manner in which those risks are to be disclosed to the patient.

The panel created consent forms that must be utilized for certain List A procedures. Specifically, the Medical Disclosure Panel created consent forms for 1) General Disclosure and Consent (25 Texas Administrative Code, Section 601.4); 2) Radiation Therapy (Id, section 601.5); 3) Electroconvulsive Therapy (Id. Section 601.7); and 4) Hysterectomy (Id, section 601.8). Additionally, as of January 1, 2004, a patient contemplating an abortion must be provided informational materials created by the Texas Department of Health (TDH). Prior to obtaining an abortion, a patient must sign the informed consent form created by TDH.

The statute states that consent is effective if it is:

- in writing;
- signed by the patient or person authorized to give consent;
- signed by a competent witness; and
- the consent specifically states the risks and hazards involved in the care or procedure in the form and to the degree required by the panel.

If the physician complies with the panel’s requirements as to List A procedures, a substantial legal benefit is derived. The statute states that the jury will be made aware of this law and instructed that the law presumes in favor of the physician that he has properly obtained consent. By the same token, a physician who does not comply with the requirements of disclosure for List A procedures will find himself in the unfortunate position of hearing the jury told that the law presumes he did not comply with Texas law regarding informed consent. This is only a presumption. It is rebuttable. In other words, either side can come in and try to overcome that presumption by convincing the jury to the contrary. For example, even if a physician could produce a consent permit which meets the requirements for a List A procedure, the patient

could still come in to court and rebut the presumption by showing he could not read, was intoxicated or otherwise unable to comprehend what he had signed. On the other hand, a physician who was unable to produce the signed permit could still come into court and overcome the presumption against him if the jury believed through oral testimony that the patient had been informed and that perhaps the permit had simply been lost or misplaced.

List B procedures require no written consent. In other words, if a proposed treatment or procedure shows up on List B, there is no requirement that disclosure of risks be made to the patient.

What if the treatment or procedure does not appear on either List A or List B? The law states the physician is under the duty of disclosure “otherwise imposed by law.” That seems rather vague and most lawyers refer to this as the hypothetical “List C” procedures. Although there is no List C, it is convenient to refer to it for all those procedures and treatments not specifically identified on List A or List B.

So, what disclosure needs to be made for a “List C” procedure? What is the duty “otherwise imposed by law?” The law gives a little bit of guidance, but not too much. It states that a physician should disclose what a reasonable person would want to know in giving or withholding consent. In *Peterson v. Shields*, 652 S.W.2d 929 (Tex. 1983) the Texas Supreme Court held that this means the physician must identify “the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent.” It is extremely important for the physician to understand the focus of this law. It is on the patient, not the physician. In other words, it is not what the physician thinks the patient should know. It is what a reasonable patient would want to know in making the decision. Therefore, a benevolent physician, seeking to spare his patients from a discussion of grisly, but remote risks, cannot avoid liability by saying he withheld the information for the patient’s benefit. Even if most doctors would agree that a patient should not be told of a risk because it might unnecessarily scare the patient away, that is not relevant. What is relevant is whether the risk could have influenced a reasonable patient in making the decision, not whether a reasonable doctor should or should not disclose the risk to the patient.

So, the question arises — what needs to be disclosed to this hypothetical, reasonable patient? Remember, it is not what you think should be disclosed. It is what the hypothetical patient might need to know in making a decision, regardless of whether you think it is important or even prudent, to tell the patient.

Only “material” risks must be disclosed; *Barclay v. Campbell*, 704 S.W.2d 8 (Tex. 1986). This means two things. First, the risk must be inherent to the procedure undertaken. Second, it has to be the type of risk that

could influence a person in making a decision. Here is another way to state the rule. If a reasonable person could be influenced in the decision to undergo a treatment or procedure by disclosing a risk inherent to that treatment or procedure, then that risk must be disclosed.

What could influence a reasonable person must be determined on a case-by-case basis. A risk of one in a million probably could not. A risk of one out of a thousand probably could, where, in between, is no man's land. Most physicians would be well advised to err on the side of caution and let each patient decide what is, or is not, material to him.

In summary, Texas informed consent practice is now governed by statute; article 4590i. When offering any treatment or procedure to a patient, the physician must make these determinations:

- If the treatment or procedure appears on List A, then the disclosure specified by the panel must be followed.
- If the treatment or procedure appears on List B, no disclosure is legally required.
- If they appear on neither List A nor List B, the physician must then disclose all material and inherent risks which could influence a patient in making a decision.

Although List A procedure disclosures must be in writing, nothing is said with respect to "List C" procedures. It is respectfully suggested that the prudent physician will follow the List A approach to the "List C" procedures and put the disclosure in writing, taking care that it is witnessed by at least one competent individual.



## Barriers to “informed” consent

You are now aware that Texas law requires not just consent but informed consent. You should also know that Texas doctors who comply with article 4590i are presumed to have obtained informed consent but that this presumption can be overcome if the patient produces evidence to the contrary i.e., that he was not properly informed even though his signature appears on the permit. The purpose of this chapter is to explore some of the positions taken by patients seeking to establish that their permission was truly not informed and, therefore, permission had not been given.

### Impaired mental status

Lawsuits have been filed in which the patient contends his mental status was such that he was not in a position to comprehend the explanation of risks and benefits. This mental handicap may be permanent (as in the form of retardation), transient (as in the form of intoxication or drug impairment), or somewhere in between (as in the form of a severe but treatable mental illness). In these cases, the plaintiff interjects doubt as to his mental acuity at the time the consent was signed. It is a variation of the “temporary insanity” defense you may have heard of in criminal murder trials.

These scenarios are not far fetched. All too often, patients may sign the operative permit while under the influence of narcotics or other mind-altering drugs administered during their inpatient stay. Even patients seen in the office may be on medication (legal or otherwise) known to cause cognitive impairment. To protect against those contentions, a physician can safeguard himself by considering the following prophylactic measures:

- *Be aware of the timing of signature.* If it is in the hospital, try to make sure the permit was not signed 15 minutes after a mood altering medication had been given.
- *Document the patient’s mental acuity at the time of the risks/benefits discussion.* A brief note reflecting that the patient was awake, alert, participated in the discussion and asked appropriate questions, comprehended the discussion, etc., could save you a lot of trouble down the road.
- *Consider incorporating a brief statement within your forms to the effect that the patient fully comprehends the risks to the procedure and is not subject to any medication, illness, or other impairment which might affect his ability to comprehend or understand.*

- Consider including an addendum above the witness' signature by which the witness certifies not only the fact that the patient signed the document, but also that the patient was alert, comprehended the discussion and voluntarily signed the permit.

## Language

Understandably, it is difficult to maintain the presumption of disclosure when the patient presents evidence that he cannot speak English whatsoever and the permit is entirely in English. The jury is apt to believe the patient just signed whatever was placed in front of him.

In California, one appellate court has ruled that failure to supply a Spanish language warning of hazards associated with aspirin might be the basis upon which liability could be predicated. In *Ramirez v. Plough, Inc.*, suit was brought on behalf of a child who contracted Reye's syndrome after he was given aspirin for a respiratory ailment. The child became blind, quadriplegic and severely mentally retarded. Although the aspirin package contained a warning in English about the danger of Reye's syndrome, it was not understood by the child's mother who could only read Spanish. The court held that the defendant manufacturer is not immune from liability when an English-only warning does not adequately inform non-English literate persons likely to use the drug. The plaintiff was able to show the court that, although the FDA only required an English warning, it did encourage manufacturers to print the warnings in other languages.

This is not a novel decision. Two Hispanic workers were injured in Florida by a product with an English only warning label. Whether warnings should be in Spanish or English was held to be a question for the jury in *Stanley Industries, Inc. v. W.M. Barr*, 784 F.Supp. 1570 (Fla. 1992).

Texas law requires that the consent form for hysterectomy be available in both English and Spanish. The Spanish version is available from the TDH. The Consent Form and Informational Materials for abortion must also be in English and in Spanish. The TDH must provide these materials at no cost on request. The forms and materials are also available on the TDH web site, [www.tdh.state.tx.us](http://www.tdh.state.tx.us). As of January 1, 2004, every patient contemplating an abortion must be provided the Informational Materials and Informed Consent. Although these are the only two procedures that statutorily require bilingual consent, the law requires you to obtain informed consent in accordance with the Medical Disclosure Panel specifications. How you get there is up to you. A bilingual form is one tool. A translator is another tool. Because of the cumbersome nature and expense of having a translator for each patient, many hospitals are turning to bilingual forms. It is frequently a one-time only expense. Already, many hospitals and physician offices in south Texas routinely use such forms. The translator option is viable provided there is a written certification signed by the translator establishing that the form was accurately and verbally translated and read

in the language of the patient who expressed their comprehension of the translation.

### **Illiteracy**

What if the patient does not read, regardless of the language in which the form was printed? More than one suit has been filed in which this has occurred. Again, it is difficult to convince the jury that the patient was adequately informed of the risks as evidenced by the signed permit when the patient and his entire family come into court and establish the patient has never learned how to read.

The best solution is to have the permit read to the patient in the appropriate language. The person who read the permit should also sign the permit certifying that he accurately and completely read the form to the patient who then expressed his comprehension.

Overcoming this barrier is not difficult. The true risk management hurdle lies in identifying the barrier in the first instance. Unless the patient tells you, how do you know he does not read? You probably presume to the contrary with almost all of your patients. That presumption could prove wrong. You and your staff need to be on the alert for the signs of illiteracy. It may be more subtle than a simple “X” instead of the patient’s signature. Did the patient complete the forms himself? Do the answers to a new patient questionnaire appear to be in the handwriting of a female when the patient is male? Does the patient sign the form without even looking at its contents?

### **Disability**

How do you get consent from a hearing impaired patient? Since physicians commonly deal with elderly individuals, many of whom will have hearing problems, this question is not necessarily academic. It also implicates the application of the Americans with Disabilities Act (ADA), which prohibits discrimination against disabled individuals.

By the same token, vision impaired individuals may contend that it was too difficult for them to read the small print on the consent permit. Since most juries understand the concept of “fine print,” they may be receptive to the notion that the patient really was not informed because the print was too small and not easily seen.

### **Overly complex forms**

Consent forms have been challenged on the basis that the contents were too technical and beyond the scope of the patient’s understanding. A patient may understand the consequences of “infection,” but not the significance of an “electrolyte” imbalance. A patient might understand that a cardiac medicine may “cause more arrhythmias” but not understand that the medicine might be “proarrhythmic.” Trying to evade a consent form on this basis requires that the patient be somewhat unsophisticated and without a high level education, which may describe a portion of your patients.



## Techniques to overcome barriers

By now you should understand that having a signed consent permit does not mean the patient cannot claim he never consented. You probably would not have believed that proposition at the beginning of this publication. Now, perhaps you can see how a hearing impaired person, a Spanish speaking patient, a drug impaired individual, could all come forward and rationally explain to the jury why their signature on the permit does not necessarily mean they were informed as to the consequences of the decision. We are now into the third generation of informed consent. In other words, how do you go beyond the traditional consent form to protect yourself in these situations. The guidelines below are relatively simple and perhaps represent the heart of this handbook. Give serious consideration to implementing some, if not all, of the suggestions referenced below.

*Use bilingual consent forms.* It is a no-risk proposition. It cannot hurt you and can only help.

*Use large print forms.* The print does not have to be huge, but at least use the typeface found in your average paperback book. It is desirable to keep your form to one page. If the size of the print expands the length of the form, see if it can be included on double-sided paper. If necessary, go to two or more pieces of paper.

*Take your form and give it to a couple of sixth graders.* Have them read it. Then see if they really understood what it was about. Ask them if they understood what the proposed treatment or procedure was. Ask them if they understood, that by signing the document, the person would be consenting to that procedure. Then ask what they thought might happen to them because of the procedure. If your form is not understood by a sixth grader, the plaintiff's attorney has an issue by which he can exploit the level of the patient's comprehension.

*Get the right witness.* Any form worth having printed and signed is worth having witnessed, whether required by law or not. Any witness will not do. That person may potentially have to testify at trial years from now. Is the person articulate or would he or she be easily intimidated in the courtroom or while being questioned by the patient's attorney at a deposition. You will not always be 100 percent successful

in this regard, but make the effort to have a reliable, professional and intelligent person to serve as your witness.

*Be aware of the timing of the patient's signature.* If in the hospital, verify the patient had not recently received any medication that might adversely affect the patient's cognitive abilities. An argument could be made that permits should be signed in the office prior to inpatient admission for a procedure. **In any event, your office note or hospital chart progress note should document the patient's mental status at the time the permit is signed.** The note should reflect the patient's full acuity and comprehension of the risks. If your situation is such that the permit is signed many hours subsequent to your personal discussion with the patient (as when a nurse later brings the permit to be signed upon your order), then consider having hospital administration require nurses to document the patient's acuity in the nursing notes at the time the permit is signed.

*Interpreters for deaf or hearing impaired patients may be appropriate.* In fact, it may be legally required under the ADA. The fact that the expense of an interpreter may not be cost effective for you or a health care facility is legally irrelevant. Generally, the law requires that an interpreter be provided. Additionally, the responsibility for providing an interpreter for hospitalized patients most likely belongs to the hospital. In any event, if you have decided upon an alternate form of communication apart from an interpreter (such as handwritten notes), save those notes as part of your chart. Also document that the patient was satisfied with that mode of communication, did not request an alternate form of communication, and expressed comprehension of your written communications.

*In some cases, physicians videotape their discussions with the patient.* This practice is certainly ill-advised for those physicians who may be tempted to understate the risks referenced in a consent permit. The videotape would only confirm the patient's claim that the physician discounted the significance of any risks and, therefore, the patient was unfairly persuaded into consenting. However, for those physicians who routinely give a very thorough, detailed and unvarnished explanation of the risks, this procedure may be worth considering.



## Brochures and videotapes

It is not uncommon for cardiothoracic surgeons to have an office brochure to hand out to a prospective bypass patient. The general surgeon has a brochure on cholecystectomies. The ophthalmologist has one on cataracts. The more high tech physicians will actually have videotapes for the patient to view in the doctor's office. In some hospitals, closed circuit television lets patients access information on the very procedure for which they have been admitted.

As a general rule, you can never go wrong by providing too much information to the patient. Remember, the essence of these claims relates to whether or not the patient's decision was "informed." The more information, the better.

The trouble with this supplemental information (videotapes, brochures, hospital television) is the type of information given. It is important that you be on the alert for any such materials that tend to down play or otherwise understate the significance of the risks to which the patient is exposing himself. Some risks may be characterized as too remote or more of an annoyance as opposed to a potentially life threatening development. Understandably, this information is not supposed to leave a patient with a sense of "doom and gloom." On the other hand, an overly optimistic brochure gives the patient ample room to argue that he would not have signed the consent if he had known the risks were more likely or more serious than what had been portrayed to him. Therefore, make sure you know what brochures and videos your patients are seeing. You should personally review each one since you are going to be held accountable for each one in a court of law.

To the extent you have cleared a brochure or videotape for distribution to a patient, then presumably you are satisfied that it fairly conveys the likelihood and severity of all inherent risks. In that case, take advantage of that information to bolster your defense that you had properly informed the patient. **Specifically, good risk management strategies suggest that you or your staff document the receipt of a brochure by the patient or the viewing of a videotape in the office or hospital.** It is not enough to say that you typically give the brochure to your patients. That leaves room for the plaintiff to argue he slipped through the crack just this once. By documenting the receipt of such information by each individual patient, you will protect yourself against that argument.



## Other means of consent

So far, we have confined this information to consent as evidenced by the two traditional approaches: a signed consent form, or a physician note that a risk/benefit discussion has taken place and the patient consented. **It cannot be overemphasized that the consent permit and the note documenting the discussion are essential.** But you can still fortify your position even further. In fact, the following comments may even survive a consent challenge when the patient really never did sign a permit and you really did forget to consult with him. Once in a while, somebody will slip through the crack.

Texas law still requires proof of causation, see *Barclay v. Campbell*, supra. The jury will be asked whether the absence of informed consent in this particular case made any difference. For example, the complication the patient developed may have occurred even if the procedure or treatment had never been administered. Therefore, in the event a post-treatment or post-surgical complication does develop, it is important to verify its etiology. If it is unrelated to the procedure/treatment, consent is no longer an issue in most cases.

In other situations, it will be obvious there is a direct relationship between the procedure and the resulting complication. You need not bother to look for other etiologies. However, you can still protect yourself against a challenge to consent if your pre-procedure records document the true necessity of the procedure. For example, let us assume an appendectomy carries a 1 percent risk of infection. Assume you see a patient with clear appendicitis on the verge of perforation. Assume further that you remove the appendix but, postoperatively, the patient develops an infection resulting in a stormy postoperative course. He sues, claiming he really did not quite understand that bit about a 1 percent risk of infection. Maybe he was on drugs at the time.

The jury will still be asked to determine whether or not the patient would have refused the procedure if he had been informed of that 1 percent risk. What do you think the answer to that question is? Would a reasonable person rather take the near 100 percent certainty of a ruptured appendix, peritonitis and an agonizing death over a 1 percent chance that he might get a postoperative infection? The answer is obvious. Any reasonable patient would have willingly agreed to the appendectomy. Therefore, the jury should find in favor of the physician

even if the patient convinced them that he was not informed or not adequately informed about the risk of the appendectomy. The jury would conclude that, had the patient been informed, most likely he would have consented. The actual legal test is not whether this particular patient would have consented, but would a “reasonable patient” have consented. Therefore, the patient cannot get out of this simply by saying he would not have consented. That is not the standard.

**It is important that your office or hospital notes document the necessity of any treatment or procedure prior to its administration or performance.** It is essential that the records, taken as a whole, establish there are no reasonable or viable alternatives. Otherwise, the patient has room to argue that he would have opted for one of those instead. This approach has its limits especially with regard to any elective or cosmetic treatment. It is most effective in emergent surgical situations. It can also be effective in those situations in which it can be shown the patient has exhausted other options.



## Scope of consent

If you refer back to article 4590i, you will see that the Informed Consent Statute refers to medical treatment, too. It is not confined to surgical procedures only.

What this means is that doctors who think consent permits need to be signed only for invasive procedures are wrong. That may be the traditional thinking, but it is not legally accurate. The statute clearly includes medical treatment. Since List A seems focused upon surgical procedures, most medical treatments will fall into the hypothetical “List C.” Once again, this means you must disclose to your patient all inherent risks of the treatment that could influence a reasonable person in making a decision to accept or refuse that treatment.

What does this mean? It means that cardiologists who prescribe anti-arrhythmic drugs probably need to warn their patients that the medication may actually make their arrhythmia worse, for example. To some degree, doctors have already been doing this. Patients given beta blockers are warned about their side effects. Allergists counsel their patients about potential adverse reactions to their injections.

This does not mean that every warning contained in the *PDR* necessarily has to be disclosed to each patient for each prescription. I might add, however, that some doctors actually do this by giving the patient a copy of the *PDR* statement of each prescription. There is probably no reason not to. At the very least, however, you need to be honest with yourself as to the side effects of any medical treatment. You could get in trouble by blindly assuming that, since it is not surgery, informed consent is not required. Indeed, it could very well be required. If you are aware of any material risk associated with the medical treatment, that should be disclosed to the patient.



## Informed refusal

Each of you has had patients who declined an offer of treatment or surgery. The extreme example is that patient whose refusal seems so illogical that it prompts the preparation of an Against Medical Advice (AMA) form. Unfortunately, too often that is used only in the context of the patient who leaves the emergency room or discharges himself from the hospital. Virtually all health care providers feel compelled to document the patient's treatment refusal under those circumstances. If that is your understanding of the only time to make such a record, it is respectfully suggested your perspective is too narrow. **Patients who decline medication, routinely miss office visits, defer or refuse diagnostic testing are all examples where documentation of that fact would be appropriate.** This is not a situation in which we are restricted to non-compliant patients or that contemplates a patient who is refusing to follow his doctor's advice. We are contemplating that situation in which the physician is not necessarily recommending, but instead, offering a treatment or procedure. In most cases, if the patient declines, he is not viewed as non-compliant. Instead, the doctor just views that patient as somebody who exercised his right not to have an angiogram, or an endoscopic examination or take a certain medication.

The trouble is that these patients may later argue that their decision to decline the offered treatment was not an "informed" decision. Sound familiar? This is the flip side to informed consent. In both situations, the patient is essentially complaining that his decision was flawed due to lack of information. The same rationale exists with respect to declining treatment with as much force as it does when the patient accepts (consents) to treatment.

Accordingly, the doctor needs to be in the position of showing that the patient's decision to decline treatment was one based upon a full understanding of all the facts necessary to make that decision. Instead of focusing on risks, the doctor must focus on benefits. The angiogram may show a blocked vessel and reveal hidden vascular disease. The endoscopic procedure may reveal a perforation or tear which otherwise may go unnoticed. The list goes on and on.

Just how far do you have to go in documenting a patient's decision to decline treatment or evaluation? It is suggested that "informed refusal"

should be obtained with respect to any treatment or procedure which could have either diagnostic or therapeutic consequences.

Should it be in writing? Probably. At the very least, a handwritten notation in your chart should be made. As the likelihood of positive diagnostic or therapeutic benefit increases, so should the need to have an actual “informed refusal” form or permit signed by the patient.

What should your notation or form contain? There are six basic components to consider:

- Describe the treatment or procedure offered.
- Identify the reasons the treatment has been offered to the patient.
- Identify the potential benefits.
- Note the patient has been told of the risks in not accepting the treatment.
- Clearly document the patient has unequivocally and without condition, declined the treatment.
- Identify why the patient refused, particularly if the patient’s decision was rational and one which could not be overcome, e.g., a young female patient with no risk factors or symptoms of cardiac disease may refuse a trip to the cardiac catheterization lab in favor of taking a thallium stress test instead because there is a much lower risk of morbidity or mortality in the latter. There is no way to get around this. However, if that same patient refused a catheterization because she was afraid she would be rendered sterile, then a jury might think you did not do your job in explaining to her that the basis for her decision was nonsensical.

Should informed refusal be witnessed? Probably. Again, if it is important enough to have a paper formally signed by the patient, it is probably worth getting a witness. This is not required by Texas law; just a suggestion.

In closing, remember that the same “barriers” to informed consent discussed earlier in this handbook apply with equal force here. Follow the same practices to avoid challenges to consent by individuals claiming the form was too complex, print too small, written in a language they did not understand, etc.



## Package inserts

Texas follows the “Learned Intermediary Doctrine.” What this means is, manufacturers of prescription drugs and equipment (pacemakers, orthopedic hardware, etc.) do not sell their products directly to the patient. Those products go through you, the intermediary between the manufacturer and the patient. And, because you are considered schooled and intelligent in this area, you are the “learned” intermediary.

When you buy cigarettes from the grocery store, the manufacturer sells directly to you. The manufacturer communicates the warning or risk of cigarette smoking directly to the purchaser by way of a label on every packet. Just about every product you buy directly from the manufacturer contains warnings direct from the manufacturer to you. This includes everything from lawn mowers to automobiles to electric knives.

However, what about the person who needs a pacemaker? He does not go to the grocery store and pick one up. He does not have an opportunity to see the warning label that comes with the pacemaker. But you do. Hence, the Learned Intermediary Doctrine. In a nutshell, it provides that the manufacturer can be relieved of liability in failing to disclose risks to the patient if the product came to the consumer by way of a learned intermediary. So, if the pacemaker may injure the heart or a breast implant is alleged to have caused auto-immune disease, the manufacturer may lay the blame on the doctor. Specifically, if the plaintiffs complain they did not know of the risks of the implant, the pacemaker, the orthopedic hardware, etc., the manufacturer can say that was the responsibility of the physician (learned intermediary) to explain it to the patient. In *Coleman v. Cintas Sales Corporation*, 100 S.W. 3d 384 (Tex. App. – San Antonio, 2002, no pet.) the court held that a manufacturer must prove that the warning given by a third party (the doctor) provides the user with “actual, adequate, and specific knowledge” of a hazard. If the warning to the intermediary is inadequate or misleading, the manufacturer may remain liable.

This is where the package insert comes in. The manufacturer lists every risk in the world in that package insert. When something goes wrong, and the plaintiff states, “if only I had known that . . .” the manufacturer will say that the physician should have provided that information to the patient. The manufacturer will contend that they gave that information to the doctor in the form of a package insert.

In an effort to cover themselves, some manufacturers even include very specific instructions on the package insert directing the physician to explain various risks to the patient. It looks pretty bad when the physician has not done that. Never mind the fact that the package inserts are in microprint and sometimes are sealed with the product such that the physician does not even access the insert until he is gowned, gloved and sterilized in the operating room. It is a little too late then.

What is a physician to do? How do you avoid being caught in between the manufacturer and the patient on the issue of consent regarding the risks of the product? The following guidelines are offered which you might want to consider as prophylactic measures in this regard:

- Some doctors make it a point to get the package insert, make a copy of it, and give that copy to each and every patient. Some attorneys recommend that the physician document that the patient has received the package insert and the specific date of receipt.
- Take the time to actually obtain and read the package insert for any medical device you use on your patients. Good practice suggests that you include on your consent permit each and every risk the manufacturer has referenced.
- Document the necessity of the device in the record. The consent issue then becomes academic for the reasons referenced earlier. A patient who will die without a pacemaker cannot logically claim he would have refused it because it carries a 1 percent risk of such and such.

The package insert is the manufacturer's way of transferring the risks arising out of informed consent lawsuits to you. If they show they gave you a list of risks, they have now placed the monkey on your back. In order to shake the monkey loose, physicians have to show that they operated as a conduit between the manufacturer and the patient by transmitting that information from the manufacturer to the patient.

Be aware that manufacturers may update their package inserts without necessarily informing you of that fact. They will not always highlight those updates in the form of a "Dear Doctor" letter. Therefore, good risk management skills suggest that you periodically reacquaint yourself with the current package insert with regard to devices you regularly utilize. An annual review is not too often.



## The Physicians' Desk Reference

This is the same song, second verse of the same principle concerning package inserts, except now we are dealing with medicines rather than medical devices. The players are the same and the Learned Intermediary Doctrine works the same way, too. There is no difference and your approach to this should be the same. Since most doctors do not get consent permits signed when they prescribe a medication, you might be more comfortable using the *PDR* warnings by giving the patient a copy of it.



## Whose duty is it anyway?

Informed consent can be very complex. Most doctors focus on the concept of what information was made available to the patient. Plaintiff attorneys go a step further and ask “Who made that information available?” That is another trap. Can a nurse do as good a job in providing answers to complex medical questions regarding offered treatment as a doctor? For that matter, can the doctor even delegate to the hospital the obligation to obtain consent from the patient? How about the assistant surgeon? What is his responsibility? If an internist clears a patient for surgery, does he have any responsibility to become involved in explaining the risks of that surgery to the patient when determining if the patient is a candidate for the surgery?

The case of *Edwards v. Dr. Garcia Gregory* was decided by the Houston Court of Appeals. In that case, the patient suffered from both diabetes and scleroderma. It took her forever to heal from even the smallest cut. Since 1982, the patient was known to suffer from chest pain caused by two partially occluded coronary arteries. However, in light of her condition, she was treated medically rather than surgically. Six years later, her occlusions had deteriorated to the point that she was considered at high risk for a heart attack. Her attending physician (a cardiologist) decided that surgery could no longer be postponed. The patient died from post-operative complications and the surgeon was sued for failing to advise the patient about the risks of non-healing. The cardiologist was also sued for failing to inform the patient of that same risk. The court concluded that, as a matter of law, the cardiologist had absolutely no duty to have an informed consent discussion with the patient. The court announced the rule that “a referring physician has no duty to obtain informed consent regarding a procedure to be performed by another physician.”

The same decision was recently announced by the San Antonio Court of Appeals in *Ritter v. Delaney*. In that case, Dr. Delaney referred a patient for a carotid endarterectomy. Dr. Delaney was the referring physician and did not perform the procedure. When a complication developed, Dr. Delaney was sued for lack of consent. The court recognized that he had no obligation to inform the patient of the risks since he did not perform the procedure.

This does not mean a referring physician can escape liability for surgical complications. It simply means the referring physician has no obligation to secure informed consent. The patient cannot complain that the referring physician failed to tell him or her of certain risks which, had the patient known, would have caused the patient to reject the procedure. However, the referring physician might be sued for failing to adequately clear the patient for surgery. For example, the internist may be negligent for failing to diagnose hypertension or diabetes. If one of those conditions results in an intraoperative or postoperative-related problem, then the referring physician might have independent liability for not properly checking the patient. Of course, this is an entirely different theory than informed consent although it is easy to confuse the two.

Therefore, the rule to go by is that the physician performing the procedure must secure the informed consent. It is important to note that this duty to secure proper consent **cannot** be delegated to somebody else. The *Ritter* case also addressed that issue. The court held the duty to inform the patient is non-delegable and belongs to the physician alone.

This does not mean a nurse cannot or should not acquire the patient's signature on the permit. There is no reason why that practice cannot continue so long as the nurse essentially acts in a ministerial capacity in acquiring consent. The burden must still fall upon the physician to make sure, through one mechanism or another, that the patient has been properly informed. A nurse should not be required to explain the various risks and benefits of a procedure to a patient, especially given the nature of the nurse's education as compared to a physician. Accordingly, **good practice requires the physician include a progress note indicating he has personally conferred with the patient, explained the risks and benefits to the patient, as well as alternatives to the procedure or consequences in failing to authorize the procedure.** The nurse can then go ahead and have the permit signed later.



## Blood transfusions and consent

This has become a particularly “hot” topic especially given the AIDS controversy. The following Texas case specifically addresses an AIDS/blood transfusion instance in which the claim of lack of informed consent was raised.

In the 1984 case of *Knight v. Department of Army*, 757 F.Supp. 790 (W.D. Tex. 1991), the plaintiff, undergoing cardiac bypass surgery, received a transfusion with blood contaminated with the HIV virus. However, the court refused to find liability for failing to disclose this possible risk since the plaintiff had no choice but to proceed with the bypass surgery. Remember, this deals with the necessity of the procedure. If it can be shown the patient had no other choice, the lack of consent is essentially meaningless.

Few patients will be so bold as to deny their consent to the transfusion, except in cases of religious refusal. What they may claim, however, is that their consent was invalid, having been the product of ignorance. The physician is expected to assume the role of instructor in educating the patient about the risks inherent in transfusions.

Many surgical consent forms contain language purporting to obtain patient consent for a transfusion. The wording is typically broad and phrased in very general terms. The better practice is to use the form incorporating a detailed explanation of transfusion risks, even if this means using a form separate and apart from that provided by the hospital. Both the patient’s medical interests and the physician’s legal interests are well served by a comprehensive consent form.

A good form might contain the four subjects referenced below:

- Blood testing has not evolved to the point that all contaminants or infectious agents can be detected in every instance. Each transfusion of each unit of blood carries with it a risk that the patient will be introduced to a potentially lethal agent.
- A transfusion can provoke hemolytic or other bodily reactions potentially resulting in injury or death.
- On rare occasions, laboratory or other errors have resulted in patient’s receiving incompatible blood, which can result in severe injury or death.

- The actual process of transfusing the blood can result in nerve damage, infection or other injury to the body.

To complement the patient's consent for the transfusion, remember to document the necessity of the procedure. Although this task typically falls to the anesthesiologist, such as in the case of operative blood loss, the responsibility may shift to the surgeon in other situations (such as a transfusion used to correct the patient's low hemoglobin or to correct DIC).



## Husbands and wives

Historically, a spouse with no previously designated legal authority to consent to medical treatment for an unconscious patient in a non-emergency situation did not have the power to extend consent to the physician. A physician who relied upon the spouse's decision could be liable for failure to obtain legal consent. Remember, we are talking about non-emergent situations. In *Gravis v. Physicians and Surgeons Hospital*, 427 S.W.2d 310 (Tex. 1968), the court held that the mere relationship of husband and wife does not in itself make one spouse the agent of the other. In that case, Mr. Gravis had authorized the surgeon to perform exploratory surgery on his wife who was heavily sedated and incapable of providing consent prior to surgery.

The new Consent To Medical Treatment Act changes this. It allows Texas physicians to provide non-emergency medical treatment to adult patients who are comatose, incapacitated or otherwise mentally or physically incapable of communication without having to obtain court approval. The statute provides a list of adult surrogates who may consent to medical treatment on behalf of an incapacitated adult patient in the following order of priority:

- the patient's spouse;
- an adult child of the patient acting as the sole decision maker with the permission of all other qualified adult children;
- a majority of the patient's reasonably available adult children;
- the patient's parents; or
- someone whom the patient has clearly previously designated to act on his behalf, the patient's nearest living relative or a clergy member.

To obtain consent under this Act, **the physician must describe the patient's incapacitated state and the proposed treatment. This should be done in the record.** The physician must then make a reasonable effort to contact possible surrogates in the order of priority listed above. The physician should document what efforts he made. Once the surrogate is located, the physician should record the date and time of the consent and sign the record. The surrogate decision maker should countersign the record and then sign the consent form.

**A surrogate may not consent to certain treatments.** These include voluntary in-patient mental health services, electroconvulsive treatment or the appointment of another surrogate decision maker. Also, this law

does not apply to situations controlled by the Natural Death Act, any decision made under a Durable Power of Attorney for Health Care, treatment for minors, treatment for emergency care, hospital patient transfers or any patient who already has a legal guardian with authority to make decisions regarding the patient's medical care. This law does not authorize a decision to withhold or withdraw life-sustaining treatment.

The point to be made is this. Under old law, physicians would, but should not have been comfortable, with one spouse giving consent for non-emergent treatment for the incapacitated spouse. Under current law, this is now acceptable.



## Emergencies

Texas law implies consent in bona fide emergencies. This means treatment that is not desirable but essential. Essential means it is necessary for the patient to live, or avoid loss of life or limb. For it to apply, the patient must be unconscious or somehow incapacitated to the point where he could not make the decision. It also requires that no other persons authorized to give consent are available and there is no time for a search for such individuals. In other words, we are talking about a life-threatening emergency. In those situations, it is essential that the records, taken as a whole, clearly reflect the emergent nature of the situation. Similarly, the patient's inability to communicate his decision must be carefully noted.

In the case of a minor, the Texas Supreme Court held in *Miller v. HCA*, 2003, WL 22232090 (Tex. 2003) that a physician "who is confronted with emergent circumstances and provides life sustaining treatment to a minor child is not liable for not first obtaining consent from the parents." The court narrowly limits "emergent circumstances" to occasions when there is no time to consult the parents before death is likely to result to the child or seek court intervention if the parents withhold consent.



## General risk management

The following checklist is one that physicians should review in assessing exposure to informed consent lawsuits. It is not all-inclusive, but does represent a fairly good starting point to protect against consent claims. **If you cannot answer “yes” to each of these questions, then a vulnerable point has been exposed which requires corrective action.**

Is your form simple to understand so that a person with less than a high school education could easily read through it and comprehend its contents?

Do you personally counsel each patient regarding the risks of a procedure as opposed to a nurse, physician’s assistant, etc.?

Do you know, really know, the contents of the forms used at the hospital to which you admit your patients? Have you read them within the past year?

Do you utilize the consent forms mandated by the state of Texas?

Do you have bilingual forms for non-English speaking patients? If not, do you always have a translator certify in writing that the form was accurately translated for the patient?

Do your office notes or hospital progress notes portray a picture which collectively suggests that a reasonable person would, in all likelihood, consent to the offered treatment?

Does your informed consent process go beyond merely surgical or invasive treatment but also extend to any medical treatment which has inherent risks?

Do you have written documentation establishing the mental competency of the patient at the time consent is given?

Does all auxiliary information made available to your patients (brochures, videotapes, etc.) fairly and accurately portray the risks of the procedure rather than down play or understate such risks?

Do you have a process by which a patient's refusal to accept treatment is not only documented but demonstrated to be based upon an informed refusal to accept treatment? Does this include diagnostic tests?

Do you regularly review the Texas Medical Disclosure Panel List A to verify that your forms comply with the Panel's most recent requirements?

Do you regularly review package inserts for medical products and verify that the warnings identified by the manufacturer are clearly communicated to the patient?

Do you always have your consent forms witnessed by a competent individual?

Do you treat the informed consent process seriously and dedicate sufficient time to discuss the matter with the patient instead of viewing this as a necessary legal formality?



## Conclusion

The right of self-determination has become increasingly prevalent in the law. The concept of “disclosure” goes beyond medicine. You can see it in everything from new labeling requirements for food products to financial statements issued by Fortune 500 companies. The concept pre-supposes that people should make decisions based upon a full understanding of all material information. Whether it is buying a box of cereal or paying for a cholecystectomy, the law wants to make sure the person knows what he is getting into beforehand. Therefore, it is essential that you understand that any treatment or procedure offered to a patient must also carry with it a detailed explanation of the risks and benefits. Texas law and Texas juries will go hard on those physicians who do not satisfy the expectations of full disclosure.

In February 1991, a study was published about the recollection of 38 patients who were admitted to a hospital for total joint replacement. The purpose of the study was to determine the extent to which they remembered the informed consent discussion. Each patient was extensively counseled prior to the operation. They were even given a little quiz to verify they understood everything. Six months later, however, virtually all of the patients were unable to recollect each of the risks that had been extensively discussed and disclosed to them. More of them remembered the promised benefits but few of them could remember the risks. (See Patients Recall of Preoperative Instruction Form Consent For An Operation. *The Journal of Bone and Joint Surgery*. February 1991. )

From a lawyer’s perspective, the point to be gleaned from this study is that the role of good documentation cannot be overemphasized. You cannot count on the patient to recollect the informed consent discussion. They will testify that certain risks were not disclosed or at least that they do not recollect those disclosures. You need to be in a position to rebut that negative inference. For that reason, it is hoped you will consider and implement the guidelines referenced in this publication.

