Reporter
May/June,1998
TMLT
Texas Medical Liability Trust

Informed Consent

How it Works in Texas

The Medical Liability and Insurance Improvement Act (article 4590i) became Texas law in 1977. It states:

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.

The statute also states that consent is effective if:

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

Article 4590i also created the Texas Medical Disclosure Panel, an administrative adjunct to the Texas Department of Health. The Panel is tasked with reviewing treatments and procedures to determine which procedures require disclosure. Those requiring disclosure are identified in List A. List A also indicates the specific risks that must be disclosed. Those for which no disclosure is required are identified in List B. Of course not all possible treatments and procedures are included in these lists. If the physician is aware of any material risk associated with a medical treatment, those risks should also be disclosed to the patient.

The duty to inform the patient is not delegable and belongs to the physician alone. This does not mean that a nurse cannot acquire the patient's signature on the consent form. Nevertheless, a nurse must not be required to explain the various risks and benefits of a procedure to a patient. The physician should personally confer with the patient, explaining the risks/benefits/alternatives of the treatment or procedure, as well as the consequences of failing to consent. This discussion should be documented in the medical record, preferably as part of the progress note in the office chart. Once this is done, a nurse can obtain the patient's signature at a later time.

If possible, a stable, presentable and intelligent person should serve as the witness. That person may potentially have to testify at trial years from now, so it would be wise to select an articulate individual who would not be easily intimidated at a deposition or in a courtroom. Physicians may wish to consider including an addendum above the witness signature by which the witness certifies not only the fact the patient signed the document, but also that the patient was alert, understood the discussion and voluntarily signed the permit.

List A and List B are revised from time to time by the Panel, most recently in February of 1998. For a copy of the 1988 revision of List A and List B, please contact Shanna Homann in the TMLT Risk Management Department at 1-800-580-8658 X5910.

What Could Go Wrong?

Obtaining the patient's written consent may not be enough to prevent a claim related to informed consent issues. A patient could come into court and allege that he or she was not properly informed even though the patient's signature appears on the form in question. To support this allegation the patient might show that he or she could not read, was intoxicated or was otherwise unable to comprehend what was signed.

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 or brain injury), 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). All too often, patients may sign an operative permit while under the influence of narcotics or other mind altering drugs administered during their inpatient stay. Patients seen in the office may be on medication known to cause cognitive impairment.

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Our special issue on informed consent continues on page 2. Page 3 covers Roche Laboratories' withdrawal of Posicor from the market and we provide a list of drugs that may interact with mibefradil.

It is recommended that informed consent documents be signed by the patient in the office prior to inpatient admission for a procedure. Include in the note the patient's comprehension of the risks and his mental status, e.g., that the patient was awake, alert, participated in the discussion and asked appropriate questions. Consider incorporating into your forms a brief statement to the effect that the patient fully comprehends the risks of the procedure and is not subject to any medication, illness, or other impairment which might affect his ability to comprehend or understand.

Language. If a patient presents evidence in court that he cannot speak English whatsoever and the permit is entirely in English, the jury is likely to believe that the patient just signed whatever was placed in front of him. There is no case or statute in Texas which specifically requires the use of a bilingual consent form, but it may be a very helpful tool, particularly in areas where there are many individuals who do not speak English. Already, many hospitals and physicians' offices in south Texas routinely use bilingual consent forms. Use of a translator is another tool to help overcome the language barrier. If a translator is used, the translator should sign a written certification establishing that the form was accurately and verbally translated and read in the language of the patient who expressed comprehension of the translation.

Illiteracy. If it is established that a patient does not read any language, it could be difficult to convince a jury that the patient was adequately informed of risks. Obviously, the solution is to have the permit read aloud to the patient in the appropriate language. The person who reads the permit should also sign a written certification that he accurately and completely read the form to the patient who then expressed comprehension. Although the solution to this barrier is a simple one, the real difficulty lies in identifying illiteracy. It is important to keep alert for possible clues that a patient might not be able to read. Did the patient complete the new patient registration form himself? Did the patient sign the consent form without even looking at its contents?

Handicap. The Americans with Disabilities Act (ADA) prohibits discrimination against individuals who are handicapped. Interpreters for individuals who are deaf or hearing impaired may be legally required under the ADA. If the patient is willing to use an alternate form of communication, such as handwritten notes passed back and forth, save those notes as part of your chart. Document that the patient was satisfied with that mode of communication, did not request another form of communication, and expressed comprehension of your written communications.

Aperson with visual impairment may contend that it was too difficult to read the small print on a consent form. The print on consent forms should be at least the size print found in most paperback books. For ophthalmologic treatments and procedures, consider using much larger print.

Overly Complex Forms. Consent forms have also been challenged on the basis that the contents were too technical and beyond the scope of the patient's understanding. For example, a patient might understand the consequences of infection, but not the significance of an electrolyte imbalance. Consider asking several sixth graders to review your consent form. Ask them if they understood what the treatment or procedure was. Ask them if they understood that by signing the document they would be consenting to that procedure. Then ask what they thought might happen to them because of the procedure. If the form is beyond their understanding, consider how you might simplify the form.

Patient Education: Teaching More in Less Time

Documented patient education can be very helpful in the defense of a case involving an allegation that consent was not informed. TMLT Risk Management Representatives have noted that although a great deal of excellent and thoughtful patient education is being done by TMLTphysicians, much of that patient education is not documented. Mentioning in a progress note the explanations given to a patient is one way to document this. Also consider the use of patient education checklists, for example, a checklist of anticipatory guidance given to parents at pediatric well-child visits.

If brochures or videotapes are used to help inform the patient regarding a procedure or treatment, make sure these do not downplay potentially serious or significant risk. Document the receipt of a brochure by the patient or the viewing of a videotape in the office or hospital. By keeping on file a copy of each brochure or information sheet you distribute, you can refer to it in your notes with a short name given to the filed document. If new material has been substituted for old, set up a new file with a new start date. In that way it becomes clear that after a specific date, new material was distributed.

Although physicians have primary responsibility for educating patients about their conditions and treatments, registered nurses may also provide some patient education. Other members of the health care team may also reinforce previously done teaching if they have the appropriate specific training and have demonstrated their competency to educate patients.

Reference: *Informed Consent: The Third Generation.* G. E. Evans, Jr., TMLT, 1995.

Posicor Withdrawn By Manufacturer

Drugs that may interact with mibefradil

Generic Name	Trade Name
amiodarone	Cordarone
astemizole	Hisminal
bepridil	Vascor
cisapride	Propulsid
cyclosporine	Neoral, Sandimmune
cyclophosphamide	Cytoxan
desipramine	Norpramin
erythromycin	Erythrocin, Ilosone,others
etoposide	VePesid
flecainide	Tambocor
flutamide	Eulexin
halofantrine	Halfan
ifosfamide	Ifex
imipramine	Tofranil
lovastatin	Mevacor
mexiletine	Mexitil
pimozide	Orap
propafenone	Rythmol
quinidine	Cardioquin, Quinaglute, Quinidex, others
simvastatin	Zocor
tacrolimus	Prograf
tamoxifen	Nolvadex
terfenadine	Seldane
thioridazine	Mellaril
vinblastine	Velban
vincristine	Oncovin

Roche Laboratories, the manufacturer of Posicor (mibefradil), a calcium channel blocker for patients with chronic stable angina and hypertension, has withdrawn the medication from the market due to its potential for drug interactions. There have been indications that some patients have experienced drug interactions upon substituting certain alternate therapy for Posicor. The manufacturer has shared the following information with physicians who have patients formerly receiving Posicor. The TMLTRisk Management Department wishes to make our insured physicians aware of the withdrawal of Posicor from the market and to relay the following information submitted by the manufacturer.

> "We wish to immediately share the following information with you and suggest it be taken into consideration if you choose to prescribe either calcium channel blockers or beta blockers as alternate therapy:
>
> 1. If you choose to substitute amlodipine or atenolol, they should preferably be started two to three days after Posicor discontinuation.
> 2. If you choose to substitute other calcium channel blockers (except felodipine) or other beta blockers (except timolol), they should preferably be started seven days after Posicor discontinuation.
> 3. If you choose to substitute felodipine or timolol, they should preferably be started fourteen days after Posicor discontinuation.
> 4. No special precaution regarding the timing for switching is necessary for other antihypertensive or anti-anginal medications (e.g., ACE inhibitors, angiotensin II antagonists, diuretics, nitrates).
>
> Any drugs metabolized by the cytochrome P450 3A4 or 2D6 isoenzymes may interact with Posicor. Therefore, as a reminder, the co-administration of mibefradil with drugs metabolized by the 3A4 or 2D6 isoenzymes of the cytochrome P450 system may result in increased plasma levels of those drugs, so dose adjustments may be necessary as mibefradil is withdrawn.
>
> The consequences of clinically relevant interactions depend on the side effect profile of the individual drug to be used. Posicor's inhibition of the CYP450 3A4 and 2D6 isoenzymes may increase the side effects of the drugs metabolized by these enzymes or prevent the formation of active metabolites. It takes an average of 7 days, but can take up to 14 days, for sufficient elimination of the metabolites of Posicor to minimize the inhibition of CYP 450 system. You should consider this pharmacokinetic information along with the patient's medical history and current status when initiating drugs metabolized by the CYP450 system, including those identified on the attached table. If you have any questions, please call Roche Laboratories at 1-800-205-4611."

TMLT offers this information to physicians in our continuing effort to provide timely and relevant risk management information to our policyholders.

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