

Informed Consent: Whys, Wherefores, What Ifs

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ABSTRACT

This article discusses standards of informed consent for interventional radiology procedures. I bring to the reader specific examples of court cases. The article also discusses the similarities and differences among malpractice conditions in the United States, Great Britain, and Japan

KEYWORDS: Conscious sedation, consent, lawyer, interventional radiology

One of the primary concerns in modern health care is the relationship between the physician and patient. The authors of this article become involved when that relationship goes awry. This article will discuss current issues involving informed consent in interventional radiology and provide some guidelines and forms to help the practitioner. The authors have more than 30 years combined experience in the defense of medical malpractice cases. In our experience, informed consent cases although relatively rare, can still be quite challenging to defend.

The informed consent doctrine relates to the right of every competent adult to decide what will happen to his or her body. The scope of the informed consent doctrine is vast. It applies from an act as routine as prescribing antibiotics to the most delicate and experimental of procedures. Virtually every patient-physician interaction involves the informed consent doctrine to one extent or another. For example, a young mother takes her three year old to the pediatrician for a suspected ear infection. The pediatrician prescribes antibiotics and after a very brief evaluation, mother and child are on the way to the pharmacy. Rarely does the pediatrician discuss the risks and benefits of the particular antibiotic prescribed versus another antibiotic or the prescribed antibiotic versus no antibiotic at all. Yet, under the broad sense of the informed consent doctrine these issues should be discussed. In another example, it would be difficult to imagine a physician treating an intra cerebral arteriovenous malformation with Braun NBCA liquid adhesive without a long and involved

discussion regarding the risks and benefits of the proposed procedure.

The cases we typically see are at neither end of this spectrum. They typically do not involve something as routine as the prescribing of antibiotics, nor do they involve something as advanced as the NCBA adhesive used in arteriovenous malformation. The cases that we generally see involve interactions between physicians and patients on moderate to complex issues and moderate to complex procedures. Most physicians in academic centers who are involved with new technology are very conscious of the need for adequate informed consent. However, there continues to be laxity with regard to informed consent within the general radiology community on those more routine procedures.

It is also necessary to have an understanding of the differences in the informed consent doctrine in different parts of the world. The United States is certainly the "leader" in advancing the legal theory of informed consent. Prior to the early 1900s, a physician had the ability to decide what treatment was necessary for a patient's condition and what, if any, information needed to be conveyed to a patient. In the landmark case of *Schloendorff v. Society of New York Hospital* (211 N.Y. 125 [1914]), a physician removed a fibroid tumor from a patient after the patient had agreed to an abdominal exam but specifically refused to undergo an operation. Judge Cardozo writing for the majority stated that: "Every human being of adult years and sound mind has the right to determine what can be done with his own body, and a surgeon who continues to operate

without his patient's consent commits an assault for which he is liable for damages" (*Schloendorff v. Society of New York Hospital*, 211 N.Y. 125 [1941]). This decision became the foundation of the modern doctrine of informed consent. For several decades after the *Schloendorff* case, the informed consent doctrine was construed to require merely that the patient consent to the treatment. The doctrine was broadened in 1957 when the term "informed" was added to the consent doctrine requiring that the physician disclose any pertinent risks which would be necessary for a patient to make an informed decision as to whether to undergo that particular procedure (*Salgo v. Leland Stanford Jr. University Board of Trustees*, 317 P2d 170 [1957]). In that case, the Plaintiff was permanently paralyzed as a result of a translumbar aortogram.

The doctrine of informed consent has changed irrevocably the doctor patient relationship. Prior to the doctrine of informed consent, the doctor patient relationship was paternalistic. The physician determined what would be good for the patient and at best, obtained the patient's consent. Under the informed consent doctrine, the patient makes the ultimate decision as to what is done to his or her body and has the right to demand enough information from the physician to make that decision an informed one. In the United States, the critical issue is how much information regarding the risks of a particular procedure is necessary. Physicians must also be aware that the benefits of the procedure as well as the alternatives to the procedure need to be discussed. These latter two issues are not nearly so troublesome as determining what risks should be communicated to a patient. Most physicians have no difficulty explaining the benefit of a procedure or test to the patient. The alternatives are typically not to undergo the procedure, take the medicine, etc. Therefore, in this article we will focus primarily on determining what material risks should be communicated to a patient.

Two standards are used in the United States to determine whether consent is informed. One standard requires the disclosure of what a reasonable health-care provider would disclose under the same or similar circumstances. This "expert" standard requires expert testimony on the required standard for informing the patient about a particular risk in the community. Therefore, if physicians in Baltimore tell patients that one of the risks associated with a CT Scan with intravenous contrast enhancement is death but in Dallas the physicians do not, the standard in the community where the case is pending prevails.

This standard has been rejected in many jurisdictions in favor of the "reasonable man" standard. Under the reasonable man standard a jury must determine what a reasonable person in the same or similar circumstances would want to know regarding a particular procedure, etc. This doctrine does not require expert testimony from the plaintiff. However, it is fraught with difficulties.

In virtually every informed consent case with which we have been involved, the patient testifies that if they had been informed of the risk of what happened to them actually happening, they would never have undergone the surgery or procedure. For example, in a recent case a physician used pedicle screws to fuse a patient's lumbar spine following a failed non-instrumented fusion. Excessive scarring and inflammation developed around the pedicle screws. The plaintiff was willing to undergo the procedure after she had been informed that the pedicle screws could break or shift and that the operation could result in paralysis or death yet she testified at trial that she would not have undergone the procedure if she had been aware of the possibility of scarring and inflammation. Given that the patient's pain from the failed fusion prior to surgery was so severe that she had contemplated suicide, one would think that a reasonable person would have undergone the surgery even knowing the risks of inflammation and scarring. Nonetheless, a jury returned a verdict in that case in favor of the Plaintiff holding that the risk of scarring and inflammation was material and that a reasonable person knowing of those risks would not have undergone the surgery.

It is interesting to contrast the informed consent doctrine in the United States with the doctrine as it exists in Great Britain and Japan. Only in the last decade has there been an emphasis on consent in the United Kingdom. In fact, as late as 1985, a trial court ruled that a physician has no obligation to disclose the one to two percent chance of paralysis to patients undergoing laminectomy. The surgery left a woman paralyzed. This decision was affirmed on appeal. As a result of that decision in 1990, the government issued a document entitled *Patient Consent to Examination or Treatment*. Physicians were instructed to inform patients of substantial risks. The United Kingdom still gives the doctor tremendous discretionary powers to disclose only the material he or she considers necessary for the patient (*Sidaway v. Board of Governors Bethlehem Hospital*, 2 W.L.R. 480 [1985]).

Similarly, the Courts in Japan have left it to the doctor's discretion to determine how much

information a patient should receive. In a 1992 case (*Makino v. The Red Cross Hospital*, 1325 Hanji 103 31 Wahbrun 445 [1992]), a patient went to a doctor complaining of stomach pain. The physician believed after several tests that the patient had gall bladder cancer but it could not be confirmed until a biopsy was performed. The physician did not tell the patient of the probable diagnosis and the patient canceled the biopsy and collapsed several months later and died shortly thereafter. The Japanese Court stated that as the doctors were not certain if it was cancer, they did not have an obligation to tell the patient of this probable diagnosis. Even if the diagnosis had been confirmed, the Court held that a physician did not need to disclose to a patient the diagnosis of an incurable disease. However, the physicians were found to have a duty to inform the patient's family of the diagnosis.

Thus, Japan and Great Britain have not embraced the doctrine of informed consent to the same extent as the United States. Similar to what occurred in the United States in the early part of the twentieth century, one can predict that informed consent will become more of an issue in these countries in the future.

Lawyers are taught, and hopefully medical students also, that whether the risk of a procedure needs to be disclosed is dependent upon the materiality of the risk. In theory, a one percent chance of paralysis and/or death should always be disclosed whereas a five percent chance of excessive scarring may not need to be disclosed. However, in actual practice, all risks of a serious nature such as death, paralysis, loss of a limb, loss of vision, etc., should be communicated to a patient regardless of the remoteness of the risk. Therefore, the first rule of informed consent: if death is even remotely possible (and it most always is), it must be contained in the informed consent discussion and written on the form.

Several years ago one of the authors represented a radiologist who was sued for the death of a patient who suffered a respiratory arrest 30 minutes following a CT Scan with iodinated intravenous contrast enhancement. Prior to the procedure, the patient, according to the nurse, had denied any allergies to seafood, iodine, etc. The CT Scan was completed. After the patient was dressed and in the waiting room with her husband, she became short of breath, went into respiratory arrest and ultimately died. Unfortunately, although the consent form had been signed, a second form that was used to note allergies or the absence of allergies was blank. Therefore, Rule No. 2, if your department

has a form to be used for a particular procedure, it must be used and completed. Any item if not applicable for some reason, should be crossed out and initialed. In this case, the Plaintiff's family, not surprisingly, testified to her significant seafood allergies. The physician prevailed, but if the form had been filled out correctly and signed by the nurse and the patient, the case may never have been brought, thereby avoiding tremendous expense and emotional distress on the part of the physician and the hospital.

We have attached a number of consent forms to this article which were obtained from major academic centers as well as several community hospitals. Figure 1 entitled Hospital A Department of Imaging shows a similar allergy disclosure form for intravenous iodinated contrast material to the one in the case just mentioned. Whenever possible if contrast material is going to be used, a form such as this can be helpful in reducing (nothing in law is truly eliminated) disputes regarding what information was told to the radiologist regarding any allergies. However, as indicated above, all forms must be consistently used and completed. If forms such as that in Figure 1 are not used in every instance by all practitioners, then testimony that the department uses these forms but the form was not used in the case being litigated can be devastating. Since jurors are often suspicious and conspiracy-minded, the failure to use a form for a particular patient, raises inferences of destroyed and/or altered records. We like the format of Figure 1 because it requires a definitive yes or no.

The second consent form (Fig. 2), is an example of an open ended informed consent form. The physician or nurse to fill in the procedure indications, probability of success, allergies, and so on. In the busy practice of medicine, however, forms such as these are not adequately filled out thereby raising the issue of what was in fact discussed between the physician and the patient. Too often we hear the adage "if it isn't written down it didn't happen." Therefore, Rule No. 3: All risks discussed by the physician must be written on the consent form. The benefit to this type of a form is that it highlights the three requirements for informed consent, namely, (1) benefit or probability of success; (2) possible complications or risks; and (3) alternative procedures.

Figure 3 is a similar open ended form used for interventional procedures. Again, these forms are too often left blank and/or the risks are generally and very vaguely described. However, the same hospital does have a separate consent form for intravenous injection of gadolinium for magnetic resonance

imaging (MRI) in which the more common reactions are listed. The most serious reaction, death, although it is described in the manufacturer's insert, is not included (Fig. 4). Because most radiologists will have to deal with the death of a patient at some point their careers, death should be included in this form.

Many articles have been written on the subject of what patients remember regarding discussions about procedures, risks, etc. The majority of patients recall very little of their conversations with the physician. We believe that it is important to identify in the informed consent document the risks that were discussed. We prefer an informed consent form that has the common, but less serious, risks pre-printed as well as the serious risks.

Figure 5 shows a consent form for intravascular injection from a hospital department of radiology. This consent form discusses common, less serious, risks and complications such as nausea and hives as well as the serious but rare risks of choking and death. However, even with this consent form, we would recommend that there always be a line left blank for other risks which may be pertinent for the particular individual so that the doctor has a place to write in if the patient has a risk which is material and yet does not appear on the consent form.

Figure 6 represents a two page consent form which is currently used by Veterans' Administration hospitals. From a lawyer's perspective it has some benefits. First, it details who is present at the discussion. This can be critically important when a spouse claims to have been involved in an informed consent discussion and the physician has no recollection whatsoever of the discussion. In addition, documenting the patient's mental status can be critical. Informed consent documents should never be signed after a patient has been administered any sedation or any type of anesthesia. An effort should be made where possible not to have informed consent documents signed after the administration of narcotics. This prevents the

potential plaintiff from claiming that he was unable to consent due to the effects of pain medication. In this form, the procedure and the physician are designated and there is a closed consent form, *i.e.* with risks and alternatives pre-printed.

There can be various preprinted forms for common procedures as illustrated in Figures 7 and 8. These forms do a good job of reducing the amount of writing a busy practitioner needs to do and yet ensure that the specific risks are identified. The drawbacks, however, are that the descriptions of the risks are too general. For example, a patient could claim that the physician never told them that he or she could possibly have respiratory arrest as a result of the reaction to X-ray dye (listed as number 4 in Figure 8). Most typically a physician would testify that he didn't recall this particular informed consent discussion, however, he would routinely tell all of his patients that among the usual reactions to x-ray dye are anaphylactic reaction and death. However, since it is not on the form, the plaintiff could argue and a jury could believe that on this particular occasion, the physician had forgotten to mention the more serious reactions to X-ray dye.

In conclusion, the authors recommend informed consent forms such as those identified in Figures 5, 6, 7 and 8 be used either with the physician writing in the specific risks, alternatives and benefits or having those typical risks, alternatives and benefits pre-printed in a form with blank space after each for room to include anything particularly pertinent to that patient. Although viewed by many physicians as burdensome and time consuming, an informed consent discussion does not need to be long. The vast majority of these discussions can be held in five minutes or less. These five minutes, however, are well spent if the discussion and the documentation related to the discussion prevent a lawsuit when a poor outcome or serious adverse reaction occurs as surely it will to every interventional radiologist at some point in their careers.