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Informed Consent in Anesthesia

Use of Model Consent Forms can Help Protect Providers from Liability

Issues involving “informed consent” are of continuing concern to nurse anesthetists. In response, the Practice Committee of the American Association of Nurse Anesthetists (AANA), in collaboration with a risk management consultant, developed this document.

Before discussing the substantive issues the model forms were designed to address, it is important to understand the concept of informed consent and the legal theories upon which the law is based. It is equally important to remember that while this paper discusses the general rules applicable in most states, the law may differ from state to state. Consequently, the law of informed consent in your state may be different than what is stated herein. The model consent forms are sufficiently generic to be acceptable in most jurisdictions. Readers are cautioned to thoroughly investigate their respective state laws that pertain to informed consent or consult with legal counsel before attempting to implement the forms or draft policies and procedures dealing with consent issues.

Importance of Documenting Evidence of Communication

It is important to distinguish between informed consent as it pertains to the communication of relevant information to the patient or his/her substitute and the methods used to acquire evidence that such communication took place. Often health professionals assume that if they possess some evidence indicating that the patient has given consent, such as a signed form, they have met the requirements of the law. This assumption is incorrect and is frequently the basis of many disputes. In order to prevent future problems, it is recommended that consent issues be addressed on the basis of the substance of the communication and the quality of the evidence.

Subjective Nature of Communication Creates Barriers to Understanding

By definition, the concept of informed consent implies that the patient has elected to have or forgo a medical or surgical procedure after having been provided with sufficient information to make an informed decision. An informed decision cannot be made unless the provider has communicated the necessary information in a clear, concise and comprehensive manner so that the patient understands it. Because communication is subjective, it is prone to problems. The provider cannot always be certain that the patient really understands the reason why informed consent is being sought. Differences in education, language, culture and health status can create barriers to communication that must be considered and overcome in order to obtain meaningful informed consent.

Model Forms Help Establish Strong Presumption of Consent

When informed consent is an element in a legal dispute, the question of whether the patient was adequately informed and consented to the procedure often shifts to the quality of the evidence. If the evidence is weak or insubstantial, then the debate can focus on communication, which is always subject to the interpretation of the patient. Predictably, the patient will testify that he/she did not understand what

was said, even if the evidence indicates that a meeting between provider and patient took place. The fact that a meeting took place does not necessarily mean there was a meeting of the minds.

As a result, some providers argue that consent forms have no value because there is no way to adequately prove that informed consent was obtained. This position should be resisted because it is incorrect and legally problematic. Healthcare professionals must merge the concepts of communication and evidence of consent so that when a challenge arises about an individual case the consent form itself will create a strong presumption that informed consent was obtained.

The model consent forms incorporate substantial details of anesthesia techniques, risks and other elements of informed consent so a strong presumption is established on its face. This does not mean they cannot or will not go unchallenged. However, if the provider follows the guidelines in this document, it should help in the event a dispute arises.

Importance of Merging Communication and Evidence

For informed consent to be sustained certain elements must be communicated. This requirement has arisen from two separate theories of liability. The first is common law battery, which is the performance of a procedure (unauthorized touching) without valid consent, even though it may have been performed without negligence. The second is negligent failure to warn and arises where the healthcare professional fails to warn the patient of risks or to instruct him/her of alternative methods of treatment that are available. The rules of informed consent are well founded in American common law. The bases of the law were articulated in 1914 by Justice Cardozo in the landmark case of *Scholendorff v. Society of New York Hospitals*.¹ Cardozo stated the principle of the right of self-determination when he wrote: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained."

Court decisions have generally determined what needs to be discussed with the patient to effectively satisfy the patient's right of self-determination and the informed consent doctrine. Generally, a well-designed consent form will merge most of the communication and evidence factors. Consequently, standardized forms should contain the following elements needed for a patient to make an intelligent decision regarding recommended procedures: 1) diagnosis, 2) nature and purpose of the treatment, 3) risks and consequences of the particular procedure, 4) probability of success, 5) alternative treatment, and 6) prognosis if the proposed treatment is not given.

Regulatory agencies or state statutes may require additional information or more details. For example, the Joint Commission on Accreditation of Healthcare Organizations calls for the above information, as well as the date, patient's identity, names of the individuals who will perform the procedure, specific authorization for anesthesia, and disposition of any tissues removed.²

The model consent forms in this document contain most of the required information discussed above including specifics about the risks, expected results, and techniques used in each anesthesia procedure. Anesthesia consent forms differ from surgical consent forms in that they do not contain the diagnosis, or the surgical or diagnostic procedures. However, in the first paragraph on the model consent form the patient acknowledges that the surgical consent process occurred and that he/she understands the reason for anesthesia. This acknowledgment by the patient is included to protect all parties and assure that appropriate informed consent took place.

Obtaining Informed Consent from Impaired Patients

For the consent to be valid the patient must be able to understand the nature and risk of the proposed treatment, as well as alternatives to it. Among the circumstances that can diminish or impair a patient's capacity to understand are: 1) the inability to speak or understand English, 2) the patient's physical condition adversely affects his/her capacity to decide, 3) senility or another mental or emotional condition adversely affects the patient's capacity to comprehend, and 4) medication, alcohol or drugs prevent comprehension. The patient must also have reached legal majority, which usually is 18 years old.

Substitute can Provide Consent when Patient is Unable

If the patient is a minor, difficult consent issues can arise since a minor cannot consent to procedures except in limited circumstances. It is imperative that local counsel be consulted since exceptions to the general rule exist, such as performance of some abortions, treatment of sexually transmitted diseases, access to contraceptives, and procedures on emancipated minors and others.

Anesthesia professionals who realize that the patient is either a minor or lacks capacity to consent should obtain consent from a substitute who can legally provide it on behalf of the patient. Many states have statutes that list in order of priority those who may consent for another. The following are commonly accepted substitutes.

- A parent (usually only one is necessary) for a minor child.
- A husband or wife for a spouse.
- A guardian for a ward.
- Any adult standing in *loco parentis* (place of the parent) for a minor. (Often defined in state statutes or case law; example, the principal of a boarding school.)

These are common rules as defined by law; however, there are other parties who also may provide substitute consent in limited circumstances.

Implied Consent Rule Enables Provider to Act in an Emergency

A common exception to the law of informed consent prevails in an emergency situation. The general rule is that if a true emergency exists, consent is not required since it is implied. The problems providers face are in recognizing and understanding a true emergency. In *Canterbury v. Spence*,³ the federal court said, "An emergency exists when the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent and outweighs any harm threatened by the proposed treatment." There is a general presumption in the law that a person will opt to approve acts necessary to save his/her life or limbs. Consequently, in an emergency, if a provider follows a course of action that is in the best interest of the patient, the provider usually will not incur liability.

The doctrine of therapeutic privilege is an exception to the law of informed consent that grants *physicians* the privilege of withholding information in instances where disclosure would likely harm the patient either emotionally or physically. No legal authority has been found that extends the privilege to nonphysicians. Therapeutic privilege should rarely be used and should only be exercised very judiciously. It is recommended that the provider consult legal counsel in situations where he/she feels the privilege might need to be exercised. There are many cases where the privilege is abused, usually by withholding information because of fear that the patient might choose to forego the procedure if the risks were known. In the event a provider should elect to use the privilege, a detailed note should be placed in the patient's medical record outlining all the relevant facts and circumstances regarding why the provider reached the decision.^{4 (P. 71)}

Preanesthetic Evaluation Integral to Informed Consent Process

The process of informed consent is becoming more problematic because of the increase of same-day surgery and the use of other nontraditional locations such as ambulatory surgical centers, physicians' offices and clinics. As a result of this phenomenon, patients often arrive for surgery a short time before the procedure is scheduled to begin. Consequently, providers frequently do not have enough time to spend with their patients. When patients are medicated prior to obtaining consent, there is a risk that they will lack the capacity to make an informed decision. These administrative barriers must be overcome so that anesthesia professionals can satisfactorily fulfill their responsibilities. Adequate preanesthetic evaluation is not only the quality standard of care, but the legal standard as well. The court, in *LeBeuf v. Atkins*,⁵ said that, "*The preanesthetic evaluation is integral to the informed consent process and the provision of quality anesthetic care. The information elicited from such an evaluation concerning the patient's history might influence the requisite disclosure.*"

In order to adequately meet the requirements of informed consent, anesthesia professionals should arrange for a patient to arrive in ample time to conduct a preanesthetic visit with the patient or their substitute. Regardless of the detail of the anesthesia consent form, the anesthesia professional should explain the form and procedure to the patient or the substitute. The patient should not simply be given the form and asked to read and sign it. In *Brown v. Dahl*,⁶ the court addressed this issue and reinforced the accepted procedure when it said, "*The requirement of obtaining an informed consent is not fulfilled by having the patient sign a consent form unless the proper information has been provided to the patient. The health care provider must supply the information, not just respond to questions.*"

The degree of specificity regarding risks has always been an issue. In *Lindquist v. Ayerst Laboratories, Inc.*,⁷ the court said, "The anesthesia provider is not required to inform the patient of every conceivable risk, but only significant risks." The model consent forms include all significant risks; however, space constraints preclude adding all information that might be desirable in order to answer most questions a patient might ask. A frequently asked question is, "What are the chances of dying or sustaining a serious anesthesia complication?" In order to relieve anxiety and maintain good patient rapport, it is generally wise to attempt to answer such a question by quoting statistics and emphasizing the improved safety of anesthesia due to newer technology and monitoring techniques. Estimates of anesthesia mortality rates vary according to which study is quoted. According to E. C. Pierce⁸ and Richard Keenan⁹, reports published between 1954 and 1985 established mortality rates at somewhere between 1 per 1,560¹⁰ to about 1 per 10,000 anesthetics administered. Recent studies^{11, 8, 12} have shown a dramatic reduction in anesthesia mortality rates, with ranges between 1 per 185,000 and 1 per 280,000.

Besides the risks, the provider must mention the details listed in the above section on "Merging Communication and Evidence." In *Sauro v. Shea*,¹³ the court said, "*The health care provider must disclose the alternatives to and relative merits of proposed procedures or anesthetics. The comparative risks between types of anesthetics must be disclosed as part of an informed consent. The health care provider's belief that a patient already knows the risks of a proposed procedure is inadequate; valid disclosure must be tailored to the immediate case.*"

Once the consent process has been completed, an additional precaution can be taken by writing a brief progress report or other note in the patient's record stating that the provider met with the patient and/or substitute, and informed consent was obtained. The note should include the time, date, and name of persons present. This note, plus the signed and witnessed form, will create a strong legal presumption that valid informed consent was obtained.

Provider, not Hospital, must Obtain Informed Consent

The responsibility for obtaining a patient's consent rests with the person who provides the actual diagnostic, medical or surgical care. The specialist or consultant, not the referring physician, has the obligation to obtain the patient's consent to treatment.^{4 (P. 646)} Case law generally holds that in the area of consent it is not the hospital's duty, and therefore hospitals (or other, institutions) cannot be held responsible for obtaining a patient's authorization for treatment.¹⁴ The only exception is when the hospital knows that a physician has not obtained a patient's consent.¹⁵ This general rule is based on the fact that the surgeon or specialist carrying out the procedure is usually the person who has the most knowledge of what is to be done and the risks and other details associated with the selected procedure. The individual who obtains informed consent is responsible for informing the patient about other individuals who will have access to the information about the patient. The hospital is responsible for ensuring that the patient's healthcare information is protected.¹⁶

Although this rule appears clear on its face, the use of the team concept can cause confusion. In the anesthesia setting, it is recommended that the person who will be commencing and carrying out most elements of the procedure, such as decisions about routes, agents, etc., should obtain the consent. Since both nurse anesthetists and anesthesiologists are viewed as being specialists and qualified anesthesia professionals, either can conduct the consent process. Institutions should avoid a situation where one team member conducts the consent process, and it is that member's last contact with the patient. This is a risky practice that could raise allegations of misrepresentation as well as negligence in the event of an adverse outcome. The patient may not understand that multiple parties will be providing anesthesia care, or the patient might decide to go through with the procedure based on the confidence he/she has in the person who conducted the consent process.

Model Consent Forms Available for Anesthesia Professional's Use

The two model consent forms on the pages that follow are exactly the same, except that one contains a field dealing with blood and blood transfusions and the other does not. Some institutions elect to use an individual form for blood and blood products. The AIDS crisis focused attention on issues of informed consent related to the use of blood and blood products. As a result, many legal theorists recommend that providers obtain informed consent from patients who will or might have to receive blood or blood products during a procedure. This recommendation can be carried out either by using a special blood consent form or incorporating the necessary language in the anesthesia or surgery consent form. Since anesthesia professionals often administer blood and blood products, the relevant language has been incorporated into one of the model forms.

These model forms have not been copyrighted and healthcare professionals and institutions are welcome to use all or parts of them in their own settings at no cost. We advise potential users to consult local legal counsel before adapting the forms and to seek permission from the appropriate "forms" committee or administrator of the hospital or institution in which you plan to use them. The AANA does not warrant the forms as being free of legal defects, and providers who elect to use them do so at their own risk.

Model Form without Transfusion Language

CONSENT FOR ANESTHESIA SERVICES

I, _____, acknowledge that my doctor has explained to me that I will have an operation, diagnostic, or treatment procedure. My doctor has explained the risks of the procedure, advised me of alternative treatments, and told me about the expected outcome and what could happen if my condition remains untreated. I also understand that anesthesia services are needed so that my doctor can perform the procedure.

It has been explained to me that **all** forms of anesthesia involve some **risks** and no guarantees or promises can be made concerning the results of my procedure or treatment. Although rare, unexpected *severe complications* with anesthesia can occur and include the remote possibility of *infection, bleeding, drug reactions, blood clots, loss of sensation, loss of limb function, paralysis, stroke, brain damage, heart attack or death*. I understand that these risks apply to all forms of anesthesia and that additional or specific risks have been identified below as they may apply to a specific type of anesthesia. I understand that the type(s) of anesthesia service checked below will be used for my procedure and that the anesthetic technique to be used is determined by many factors including my physical condition, the type of procedure my doctor is to do, my doctor's preference, and my own preference. It has been explained to me that sometimes an anesthesia technique which involves the use of local anesthetics, with or without sedation, may not succeed completely and therefore another technique may have to be used including general anesthesia.

<input type="checkbox"/> General Anesthesia	Expected Result	Total unconscious state, possible placement of a tube into the windpipe
	Technique	Drug injected into the bloodstream, breathed into the lungs, or administered by other routes
	Risks	Mouth or throat pain, hoarseness, injury to mouth or teeth, awareness under anesthesia, injury to blood vessels, aspiration, pneumonia
<input type="checkbox"/> Spinal or Epidural Analgesia/ <input type="checkbox"/> With sedation <input type="checkbox"/> Without sedation	Expected Result	Temporary decrease or loss of feeling and/or movement to lower part of body
	Technique	Drug injected through a needle/catheter placed either directly into the spinal canal immediately outside the spinal canal
	Risks	Headache, backache, buzzing in the ears, convulsions, infection, persistent weakness, numbness, residual pain, injury to blood vessels, "total spinal"
<input type="checkbox"/> Major / Minor Nerve Block <input type="checkbox"/> With sedation <input type="checkbox"/> Without sedation	Expected Result	Temporary loss of feeling and/or movement of a specific limb or area of the body
	Technique	Drug injected near nerves providing loss of sensation to the area of the operation
	Risks	Infection, convulsions, weakness, persistent numbness, residual pain, injury to blood vessels
<input type="checkbox"/> Intravenous Regional Anesthesia <input type="checkbox"/> With sedation <input type="checkbox"/> Without sedation	Expected Result	Temporary loss of feeling and/or movement of a limb
	Technique	Drug injected into veins of arm or leg while using a tourniquet
	Risks	Infection, convulsions, persistent numbness, residual pain, injury to blood vessels

<input type="checkbox"/> Monitored Anesthesia Care (with sedation)	Expected Result	Reduced anxiety and pain, partial or total amnesia
	Technique	Drug injected into the bloodstream, breathed into the lungs, or by other routes producing a semi-conscious state
	Risks	An unconscious state, depressed breathing, injury to blood vessels
<input type="checkbox"/> Monitored Anesthesia Care (without sedation)	Expected Result	Measurement of vital signs, availability of anesthesia provider for further intervention
	Technique	None
	Risks	Increased awareness, anxiety and/or discomfort

I hereby consent to the anesthesia service checked above and authorize that it be administered by _____ or his/her associates, all of whom are credentialed to provide anesthesia services at this healthcare facility. I also consent to an alternative type of anesthesia, if necessary, as deemed appropriate by them. I expressly desire the following considerations be observed (or write "none"):

I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the anesthesia service; and that I had ample time to ask questions and to consider my decision.

PATIENT IDENTIFICATION

Patient's Signature

Date and Time

Substitute's Signature

Relationship to Patient

Witness

 Developed by the
 American Association of
 Nurse Anesthetists -
 1991

Model Form with Transfusion Language

CONSENT FOR ANESTHESIA SERVICES

I, _____, acknowledge that my doctor has explained to me that I will have an operation, diagnostic, or treatment procedure. My doctor has explained the risks of the procedure, advised me of alternative treatments, and told me about the expected outcome and what could happen if my condition remains untreated. I also understand that anesthesia services are needed so that my doctor can perform the procedure.

It has been explained to me that **all** forms of anesthesia involve some **risks** and no guarantees or promises can be made concerning the results of my procedure or treatment. Although rare, unexpected *severe complications* with anesthesia can occur and include the remote possibility of *infection, bleeding, drug reactions, blood clots, loss of sensation, loss of limb function, paralysis, stroke, brain damage, heart attack or death*. I understand that these risks apply to all forms of anesthesia and that additional or specific risks have been identified below as they may apply to a specific type of anesthesia. I understand that the type(s) of anesthesia service checked below will be used for my procedure and that the anesthetic technique to be used is determined by many factors including my physical condition, the type of procedure my doctor is to do, my doctor's preference, and my own preference. It has been explained to me that sometimes an anesthesia technique which involves the use of local anesthetics, with or without sedation, may not succeed completely and therefore another technique may have to be used including general anesthesia.

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	Technique	Drug injected into the bloodstream, breathed into the lungs, or administered by other routes
	Risks	Mouth or throat pain, hoarseness, injury to mouth or teeth, awareness under anesthesia, injury to blood vessels, aspiration, pneumonia
<input type="checkbox"/> Spinal or Epidural Analgesia/ Anesthesia <input type="checkbox"/> With sedation <input type="checkbox"/> Without sedation	Expected Result	Temporary decrease or loss of feeling and/or movement to lower part of body
	Technique	Drug injected through a needle/catheter placed either directly into the spinal canal immediately outside the spinal canal
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<input type="checkbox"/> Major / Minor Nerve Block <input type="checkbox"/> With sedation <input type="checkbox"/> Without sedation	Expected Result	Temporary loss of feeling and/or movement of a specific limb or area of the body
	Technique	Drug injected near nerves providing loss of sensation to the area of the operation
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<input type="checkbox"/> Intravenous Regional Anesthesia <input type="checkbox"/> With sedation <input type="checkbox"/> Without sedation	Expected Result	Temporary loss of feeling and/or movement of a limb
	Technique	Drug injected into veins of arm or leg while using a tourniquet
	Risks	Infection, convulsions, persistent numbness, residual pain, injury to blood vessels

<input type="checkbox"/> Monitored Anesthesia Care (with sedation)	Expected Result	Reduced anxiety and pain, partial or total amnesia
	Technique	Drug injected into the bloodstream, breathed into the lungs, or administered by other routes producing a semi-conscious state
	Risks	An unconscious state, depressed breathing, injury to blood vessels
<input type="checkbox"/> Monitored Anesthesia Care (without sedation)	Expected Result	Measurement of vital signs, availability of anesthesia provider for further intervention
	Technique	None
	Risks	Increased awareness, anxiety and/or discomfort

I hereby consent to the anesthesia service checked above and authorize that it be administered by _____ or his/her associates, all of whom are credentialed to provide anesthesia services at this healthcare facility. I also consent to an alternative type of anesthesia, if necessary, as deemed appropriate by them. I expressly desire the following considerations be observed (or write "none"):

BLOOD TRANSFUSIONS

The likelihood of needing a blood transfusion for this procedure is: Highly unlikely Possible Probable
 I understand that there are potential risks from blood transfusions, though rare, and that some of these include transfusion reaction, hepatitis, and AIDS (Acquired Immune Deficiency Syndrome). *Initial in appropriate box:*

I give consent to receive blood or blood products as determined by my anesthetist and doctor to be necessary for my well-being.
 I give consent to receive blood or blood products only as an emergency life-saving measure.
 I do not want to receive blood or blood products under any circumstance.

I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the anesthesia service; and that I had ample time to ask questions and to consider my decision.

PATIENT IDENTIFICATION

Patient's Signature

Date and Time

Substitute's Signature

Relationship to Patient

Witness

 Developed by the
 American Association of
 Nurse Anesthetists -
 1991

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