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SOAP MISSION STATEMENT

The Society For Obstetric Anesthesia And Perinatology was founded in 1968 to provide a forum for discussion of problems unique to the peripartum period. SOAP is comprised of anesthesiologists, obstetricians, pediatricians, and basic scientists who share an interest in the care of the pregnant patient and the newborn.

The mission of the Society is to promote excellence in research and practice of obstetric anesthesiology and perinatology. Through the newsletter, Internet site, and annual meetings, this Society allows practitioners of several specialties to meet and discuss clinical practice, basic and clinical research, and practical professional concerns.

A membership in SOAP is an opportunity to meet people who share your interests, and to stimulate improvements in health care for pregnant patients.
Edited for the Internet By--
Gerald Burger, M.D.
E-mail-- webmaster@soap.org

For a complete issue of the SOAP Newsletter please contact:

SOAP
P.O. Box 11086
Richmond, VA 23230-1086
(804) 282-5051 / FAX (804) 282-0090
SOAP E-Mail

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President's Message

Official recognition and celebration of the sesquicentennial of the first obstetric anesthetic are now memories. For those of us who provide anesthesia care to women during childbirth, however, it frequently seems that the difficulties that beset the pioneers of obstetric anesthesia 150 years ago are still with us today and the battles fought and thought to be won long ago are still problems seeking solutions. We can only hope that the bicentennial in 2047 celebrates a vastly different landscape for women bearing children.

Arguments against providing effective analgesia for women during childbirth tend to reflect the tenor of the times. One hundred fifty years ago, in a less secular era than now, religious opinion was influential and was frequently employed in social comment. Thus, literal interpretations of various biblical descriptions of parturition and apparent proscriptions against alleviating labor pain figured prominently in the campaign against effective analgesia as it became available. Antagonists often railed from pulpits. These days, religious arguments are unfashionable and, therefore, often ineffective, so the same misogynists who sought to prevent women from having control over this important aspect of their life 150 years ago use updated arguments more in concert with current thinking. "Loss of control" is one such thesis. Paradoxically, to those who spend their professional lives in labor suites, this theory contends that women suffering through a painful labor somehow have control over their life, and this control is forever lost when effective relief of pain is provided. As we all know, nothing could be further from the truth. Yet this argument continues to be promulgated and people continue to subscribe to it. Why? In my opinion the answer lies in the fact that preparation for childbirth classes are often conducted by the same misogynists who advance this and other equally specious theories. Options for analgesia in labor are frequently presented in those classes by the same people whose aim it is to reduce access to effective pain relief. Thus, we hear almost as a routine that the portion of the class devoted to a discussion of regional block consisted of an epidural needle being passed around to the collective "ooohs" and "aahs" of the captivated (and captive!) audience. This is a well known, but only temporarily effective, scare tactic. The effectiveness of such a dishonest approach can be reduced markedly by the honest, reasoned, accurate approach of an anesthesiologist explaining options for analgesia during labor. How many of us play a role in childbirth education programs?

A more insidious but increasingly more common method of analgesic option restriction is the pseudoscience tactic. Here, opinions that portray labor analgesia as (choose one or more): more dangerous than anesthesiologists are willing to admit; being responsible for a vastly increased cesarean section rate; the cause of unnecessary forceps deliveries or episiotomies; the reason so many children have learning disabilities or attention-deficit disorder; interfering with the mother-infant bonding process; and the latest, disrupting normal breast-feeding. To support their claims, superselected literature, frequently from suspect, non-peer reviewed sources, is often misinterpreted and used as "evidence." As with all pseudoscience, any criticism by a scientist (anesthesiologist) is deflected by claiming that it is suspect because anesthesiologists have a financial incentive to provide pain relief. Thus, anesthesiologists' motives must be base. Have you priced a doula lately?
Yet, otherwise thinking people are often swayed by these and other arguments. How can this be? I believe the answer lies in the ability of many of these misogynists to cloak themselves in an aura of women's advocacy. In short, they do a very good job of "snowing" their clientele. When they use the "bully pulpit" of a childbirth education class, they portray themselves as ombudspersons for pregnant women, as the bulwark against avaricious anesthesiologists and scheming obstetricians. The implication is that anesthesiologists don't really care about the women for whom they provide obstetric anesthesia services, they just push their product for financial gain. Once a family embarks upon the labor process and they are able to assess our attitudes for themselves, their opinion changes. They are confronted by our honesty. We explain the pros and cons of all we do in concise and understandable terms. We support their decision making without engendering guilt if they choose one option over another. They recognize that we are committed to their well being, safety and enjoyment. It becomes obvious that we really do care.

I doubt that misogyny will be eradicated by the year 2047. My fervent desire is that at least it will have been eradicated from locations where women will be *enjoying* childbirth.

Gerard M. Bassell, M.D.
Informed Consent: Get it in Writing!

No one debates the necessity to discuss with a patient the process of a requested procedure, its risks and benefits, and to give adequate time for questions before proceeding. But does this process need to be put in writing? A written form becomes an educational document, provides medico-legal evidence of the conversation, and there is evidence that verbal and written consent together improves the patient’s recall of the information given. Recall scores are commonly used as indicators of understanding and comprehension, and informed consent is not really informed if the patient does not understand the information given. So, if adding a written form to the consent process improves the patient’s understanding of events to take place, then we are one step closer to reaching the goal of truly informed consent for all patients. All these reasons provide compelling arguments to say that consent should include putting it in writing.

What constitutes adequate consent? Basically, the courts look for four elements to be present. These include explanation of the procedure, and explanation of the risks and benefits, time for inquiries to be answered, and patient cooperation during the procedure. Most practitioners understand that the first two items, explanation of the procedure and risks and benefits, are part of the consent process. What may not be as obvious is that an invitation for inquiry and patient cooperation are just as important. Courts look for more than one way in which a patient may give or deny consent, and providing an opportunity to object to the proposed procedure or clarify issues is one of those ways. Although not often documented, patient cooperation for the procedure is another way in which consent is implied.

Putting the first three elements of consent on a form for the patient to review while discussing the anesthetic plan may aid in retention of the information, as stated earlier. However, it also provides a written record of the discussion and an area for the patient’s signature. Finally, an addendum can be placed on the form that the patient cooperated for the procedure, or conversely, she did not which is why it was abandoned.

A common question is what should be included in the risks and benefits portion of the discussion. Courts look for evidence that reasonable information was given leaving the question of what is reasonable. There is no absolute answer here as any attempt to list absolutely every benefit and risk can be time consuming and confusing to the patient. An examination of this question suggests that dealing the most
obvious benefits and only the most common and serious risks are enough. The inquiry period allows for further discussion on risks and benefits if the patient wishes to pursue them. A preprinted form can include what the practitioner finds is usually discussed and satisfactory to the patients, and any further information requested and discussed can be documented on the form.

Concern that a laboring woman cannot give adequate consent has not been upheld by the courts. Obviously it is preferable to get consent before the active phase of labor starts. However, the reality is that this is not always possible and the courts understand this. Their interest is to know that a consent process was followed. Including a written form as part of the process which may include the patient’s signature solidifies the practitioner’s position that the process was followed, even if the patient cannot recall it afterward. A form also allows for documentation of a patient’s refusal to discuss risks which may happen when labor is far advanced and she is seeking rapid pain relief.

What about the minor who presents in labor? Many states consider a pregnant minor to be emancipated, and so she may be treated like any other patient. However, this is not true in all states and it is up to the individual practitioner to know what their state’s statutes are. If the state requires that the patient’s legal guardian must give consent, use of a written form can document who the legal guardian is, that they were included in the consent process, and that they consented.

Informed consent is not a complex process and there is little excuse for not obtaining it. Although three are some how would argue that it does not protect the practitioner from law suits, the courts look for it nonetheless. Written documentation is not required to show informed consent but certainly it establishes that the first three elements which constitute consent were present. It may also help the patient better understand and retain the information given her. Getting her signature may also help further establish your discussion with the patient, and a written form given a place for you to document her cooperation during the procedure. Finally, when more than the routine occurs such as a discussion with a legal guardian or an in-depth discussion of ways in which nerve damage can occur, a form lets you get it down in writing.

McCallum R. Hoyt, M.D.
University Hospitals of Cleveland
Cleveland, OH

REFERENCES

CON

Should consent for epidural labor analgesia be written as opposed to verbal?

Let us begin by clarifying terminology. For the purpose of this debate, I am defining "written consent" as a patient signature on a preprinted consent form. A handwritten note describing verbal consent is defined as documentation of verbal consent and not "written consent". If the patient has difficulty with speech and/or hearing, "verbal" consent implies a similar discussion utilizing alternative means of communication.

Informed consent is a concept in two realms, ethical and legal (1-4). The ethical concept is based on comprehension and free consent by the patient. In ethical terms, informed consent is a process of communication between patient and physician based on respect for the patient’s autonomy. The legal definition and requirements for informed consent may vary between jurisdictions. In the absence of any consent by the patient, an elective medical procedure constitutes battery. Basic consent becomes informed consent through the disclosure to the patient of risks, benefits, and alternative treatments. Legal requirements for disclosure have evolved from a professional (medical) standard to a lay standard. In the latter case, current legal interpretation suggests that physicians should disclose to patients the information that a "reasonable" person would need to make a decision about medical treatment. In deciding what risks should be disclosed as part of informed consent, physicians may be guided by the legal concept of materiality which is estimated by multiplying the severity of a risk by its incidence. Combined with a procedural injury, failure to adequately disclose risks during the consent process may lead to a charge of negligence even if the injury itself was not negligent.

With this background it is obvious that the essence of informed consent is the process of communication between physician and patient, not the type of documentation. Numerous authors support the position that verbal consent stands alone both ethically and legally (1,2,9-11), and that a printed consent form may not be substituted for verbal consent (1,2,5-8). Some authorities believe that preprinted written consent forms are counterproductive by distracting efforts away from verbal consent and discouraging individualized risk discussions (5,6). A summary of different informed consent options in OB anesthesia is presented in the Table.

Two recent clinical practice surveys provide information about the current utilization of written consent for epidural labor analgesia. In the first study, 52% of U.S. and 15% of U.K. anesthetists surveyed obtained written consent for epidural labor analgesia from patients not impaired by pain or medications (11). These percentages decreased to 33% and 11% respectively in the presence of labor pain or impairing medications. In the second survey of 86 obstetric units in the U.K., only 45% obtained written consent for epidural labor analgesia (12). I would have expected a much higher utilization of written consent for epidural labor analgesia, if it were a "necessary" part of the informed consent process.

Six cases in the legal literature are concerned with informed consent for epidural/spinal labor analgesia, as described below*. In Hall v. United States (13), the patient was paralyzed following a spinal
anesthetic for vaginal delivery administered by her obstetrician. In the case summary, the consent process is unclear. The obstetrician testified to his "usual" consent process, which implies a lack of documentation. The patient claimed that she had not given consent for the anesthetic. The court found in favor of the obstetrician based on "implied" consent by the patient and no duty for the obstetrician to inform the patient of risks. The outcome of this case, brought in 1955, likely would be different if 1998 legal standards were applied.

In Gasiorowski v. Hose (14), the patient experienced a chronic lower extremity pain syndrome following a vaginal delivery that included a lumbar epidural placed by an anesthesiologist. The facts of the case revolve around the technique of epidural catheter placement routinely used by this anesthesiologist. Informed consent apparently was verbal and undocumented, since the anesthesiologist testified about his "routine practices" concerning consent. Otherwise, the consent process was not a significant issue in this 1994 case. The original court decision in favor of the defendants was reversed on appeal and remanded for a new trial, based on legal procedural issues.

In Ratcliffe v. University Hospitals (15), the patient described chronic lower back pain that began 14 months after a vaginal delivery in 1985. Several attempts had been made by an anesthesiologist to place a lumbar epidural for labor analgesia. These attempts were stopped at the patient’s request just prior to delivery. In the original lawsuit, the patient charged battery because of an alleged "failure to apprise (the plaintiff) of the reason for selecting the epidural and the risks associated with it." The consent process is not described in the available documents, because of a summary judgment for the defendant based on expiration of the statute of limitations for malpractice. This judgment was affirmed on appeal based on the legal procedural issue. In Dunlap v. Marine (16), the patient had a cardiorespiratory arrest during an obstetric spinal anesthetic. The facts of the case are as follows. This obese patient was admitted in labor in April 1959. After arrest of descent, the obstetrician requested a cesarean section. Following hospital policy, written consent for the surgery was not obtained from the patient because she had received sedation (demerol and phenergan for labor analgesia) within 24 hours of consent. Instead, the obstetrician obtained written consent for the surgery from the patient’s husband. Later, the obstetrician introduced the anesthesiologist to the patient. The anesthesiologist advised the patient that he planned to administer a spinal for the cesarean section, and the patient cooperated with the subsequent placement of a hyperbaric tetracaine spinal. Shortly after injection of the spinal anesthetic, the fetal head was crowning and the patient was placed in the lithotomy position for vaginal delivery. The patient had a cardiorespiratory arrest at approximately the time of delivery. Subsequent maternal management was successful with endotracheal intubation, epinephrine administration, and open cardiac massage. The issue of consent for spinal anesthesia was raised in the lawsuit by the patient. The trial court found that "such permission and consent was in fact obtained." As discussed in an earlier section, this legal issue was decided on the basis of the "professional standard" of disclosure for informed consent in use at the time of this case. The trial court found in favor of the defendants, in part because the anesthesiologist convinced the court that the cardiorespiratory arrest was not necessarily a result of the spinal anesthetic. The appeal court affirmed the original verdict, and specifically refused to overturn the trial court’s ruling on informed consent.

A written consent form for labor analgesia played an interesting role in the two following cases. In Patterson v. Van Wiel, the patient had a cardiorespiratory arrest following placement of a lumbar
epidural for labor analgesia. The facts of the case are as follows. The patient was admitted in 1973 for induction of labor. Apparently without the knowledge of the obstetrician or the anesthesiologist, a hospital employee approached the patient at the time of admission with a written consent form for anesthesia. The patient refused to sign the form. On the second day of induction, the obstetrician requested epidural labor analgesia for this patient. According to the trial court summary, the anesthesiologist had a full discussion of the procedure with the patient including risks and the patient gave her informed consent verbally. The documentation of the consent process is unclear. However, the trial court stated that "(the plaintiff) expressly consented to the anesthetic. Consent may be oral or written. Van Wiel gave a full and frank disclosure to (the plaintiff) of all pertinent facts relative to the anesthetic." The patient had a cardiorespiratory arrest shortly after initiation of the epidural analgesic. Excellent emergency care by the anesthesiologist and the obstetrician resulted in excellent neonatal and maternal outcomes. The patient had no recall of a conversation with the anesthesiologist or the placement of the epidural, but she did remember refusing the written consent form two days earlier. The trial court awarded a summary judgment in favor of the defendants. This was affirmed on appeal in part because of a lack of expert testimony for the plaintiff on key nonconsent issues. In my opinion, the written consent form significantly contributed to the patient’s dissatisfaction with her medical care.

In Denton v. LaCroix (18), the patient suffered a significant permanent hypoxic brain injury after a cardiorespiratory arrest during a cesarean section in 1991. A labor epidural had been placed and subsequently converted to a cesarean section anesthetic by an unsupervised CRNA. The hospital had contracted with a group of anesthesiologists and CRNAs to provide anesthesia services in its "Women’s Pavilion." The provisions for CRNA supervision in this contract did not meet the standards and policies of the hospital’s anesthesia department (a separate group of anesthesiologists). The trial court determined that the CRNAs and anesthesiologists were not negligent. However, a $10 million judgment was made against the hospital and its parent corporation that was affirmed on appeal. During the lawsuit process, the anesthesiologists were surprised to learn that the hospital was routinely presenting written anesthesia consent forms to patients for signature on admission. The anesthesiologists names were preprinted on the consent form without their knowledge. Consent for anesthesia was not an issue in this case. Although the patient had signed the written consent form on admission, it is unlikely that this consent process would have survived a challenge in court.

Unfortunately, these six legal cases provide little guidance for current informed consent issues in OB anesthesia. For example, two cases (13,16) were litigated in the 1950’s and the courts applied the now obsolete "professional standard" for risk disclosure. Ratcliffe v. University Hospitals (15) illustrates that procedural issues may conclude a legal case prior to the substantive examination of a consent question. Overall, two cases imply that the courts will grant considerable latitude to anesthesiologists concerning the format of informed consent. In Gasiorowski v. Hose (14) from 1994, the court accepted the anesthesiologists testimony about his "routine" practices of obtaining consent for epidural analgesia (presumably verbal and undocumented). In Patterson v. Van Wiel (17) from 1973, the court ruled that consent "may be oral or written." Written consent forms may be counter productive, since two of the legal cases describe misuse of the forms by hospitals without the anesthesiologist’s permission (17,18). The impact of active labor pain on the validity of informed consent for labor analgesia is a continuing
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controversy. This issue is not directly addressed by any of the six legal cases described above. However, several courts have accepted informed consent from patients during active labor (13,14,16,17), implying that consent is valid during labor pain. One anesthesiologist, writing in reference to inflexible prenatal "birth plans", has stated that informed consent for labor analgesia is not truly valid until the patient has experienced labor pain (19). No discussion of informed consent in women’s health care can ignore the historical perspective of limited autonomy for women in medical care and society as a whole. "The gender of patients makes a difference where ethical questions of informed consent are concerned, because gender in our society has been a relevant factor in interpreting the meaning of autonomy and relationality" (2). Therefore, the issue of labor pain and mental competence for consent remains difficult from an ethical perspective. This issue should not affect the format of consent (verbal vs. written). However, it seems appropriate that anesthesia consent formats within an institution should be consistent across clinical locations (including OB).

Two clinical studies in OB anesthesia have measured the postpartum recall of risk disclosures made prior to labor epidural placement. Swan and Borshoff (20) found that 33 percent of patients had no recall of verbal risk disclosures made just prior to initiation of labor epidural analgesia, when surveyed at 36-48 hours postpartum. Grice et al. (21) randomized obstetric patients to verbal consent or verbal plus written consent groups during an admission preanesthetic evaluation. Patients were surveyed by telephone at 5 to 7 months postpartum. The patients in the verbal plus written consent group had higher scores on an arbitrary recall scale than patients in the verbal consent group (90 vs. 80 mean scores). Although the recall scores were statistically different between groups, the clinical significance is questionable based on the small magnitude of the difference between groups. Grice et al (21) apparently is only available in abstract form, and this limits its analysis and applicability. Postoperative recall has been used in other clinical settings to examine consent issues (22-24), but the exact relationship between informed consent and postoperative/postpartum recall remains obscure.

Recent surveys have documented the variability of current practice styles in OB anesthesia, particularly during on-call hours (25-27). For example, some institutions have the staffing to perform a preanesthetic evaluation on each patient as she is admitted to the OB service. In other institutions, the anesthesiologist is called in from home when each patient is "ready" for a labor epidural analgesic. Recommendations about informed consent in OB anesthesia must accommodate these differences in practice style. For this reason, I recommend that each practice view informed consent as part of the overall patient education system in their locality. A number of authors share this opinion (8,11,28,29). Each practice could design a locally viable prenatal education system for OB anesthesia from the following components; brochures, videotapes, visits/lectures at childbirth education classes, and scheduled appointments in a preanesthesia clinic (29,31,32). If anesthesiologists are unwilling to help develop a prenatal education system for OB anesthesia, nurse midwives appear willing to accept this role and apply their own agenda (33). Surveys conducted at the 1993 and 1997 SOAP Annual Meetings show that 38-40 percent of anesthesia departments do not participate in an organized prenatal education program (26-27). Other surveys suggest that patients and anesthesiologists are dissatisfied with current prenatal education concerning OB anesthesia (29,30). When patients have adequate prenatal education about OB anesthesia, the immediate preanesthetic interview can focus on rapport and informed consent instead of basic explanations of regional anesthesia. This seems to be an efficient use of professional resources at the anesthetizing
location.

A written consent form may seem like a reasonable solution when the verbal consent process for labor analgesia in your institution experiences difficulties. A common example would be a letter to the anesthesiology chair from an unhappy patient. Patient dissatisfaction with the consent process suggests existing patient-physician communication deficits. Adding a written consent form to a flawed verbal consent process will not repair the underlying problem. Poor patient rapport is high-risk medicolegal behavior for physicians (28,34,35). In contrast, the presence or absence of a written consent form is largely irrelevant from a medicolegal perspective. Improving the verbal consent process in your department requires an ongoing informed consent education program for the physicians utilizing components such as CME, grand rounds, medicolegal conferences, or departmental QA audits. One goal of this education program should be to develop and improve interpersonal skills. Junior and senior members of the department should be reminded that patient rapport is one of the great professional satisfactions of medical practice available in OB anesthesia.

In summary, informed consent is a process of communication between patient and physician. Written consent is only one of several documentation options following verbal consent (See Table). Preprinted written consent forms may detract from the verbal consent process, and occasionally they are misused by institutions. A preprinted checklist of specific anesthesia risks on the preanesthetic evaluation form might act as a cue for the verbal consent process and assist in its documentation.

Richard N. Wissler, M.D., Ph.D.
University of Rochester
Rochester, NY

References


*In preparation for this debate, I used a computerized legal database (Lexis-Nexis). Subject searches in this database produce both annotations (legal review articles) and case summaries. Lexis-Nexis is a commercial enterprise and access to the system may be gained through individual law offices, regional law libraries, or the internet. If you are faced with medicolegal questions, I recommend a review of the relevant material on Lexis-Nexis so that you may better assist your attorneys. Knowledge can be power.
GETTING STARTED IN RESEARCH

Research is an academic exercise that takes time, effort and commitment, and is an activity that should be conducted in an environment that will contribute to its success. This can best be accomplished in an academic institution where research is considered an important pursuit, and where the resources needed, including time and money, are available to support its progress.

As with any new endeavor you should find a mentor. That person should be someone who is already well established and who can help you during all phases of your career. Your mentor will be able to provide you with advice and help as you embark upon your research project. A good mentor will also go beyond making himself available to you, but will also motivate you as you develop as a researcher.

Another important resource is your statistician. You must have a basic understanding of statistics, but most journals want details about the study design, the number of patients enrolled, and the statistics utilized, that are beyond the knowledge of most anesthesiologists - you will find your statistician indispensable.

Selecting the correct research topic is critical if you are to succeed. By reviewing the literature and by attending national anesthesia meetings, such as the annual meetings organized by the ASA, the IARS and SOAP, one will get a sense of what other researchers are studying and what areas need further study. Most importantly, choose a topic that you find interesting. If you find it interesting, you will be more likely to see the project through to completion as you encounter the usual setbacks that occur during the execution of any study. When you design the study, make every effort to keep it simple yet interesting rather than complex and uninteresting, and do not allow it to be long and drawn out. Set a goal towards completing your first study as expeditiously as possible. Remember, your first publication will not only open avenues for further research, but it will also be a tremendous boost to your drive to begin other research projects.

Shiv K. Sharma, M.D., F.R.C.A.
Assistant Professor
Obstetric Division
Department of Anesthesiology and Pain Management
University of Texas, Southwestern Medical center Dallas Texas

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For Your Information

Labor analgesia, c-section rate, and ambulation are hot topics in both the lay and professional literature. These controversial topics have even made their way into the *New England Journal of Medicine* in December 1997. The paper by Nageotte, et al\(^1\) is an important one to be aware of since it is likely to be frequently quoted by general medical practitioners and primary care providers when discussing labor analgesia. I encourage you to read the article and the response by Dr. David Birnbach\(^2\) cited below and form your own conclusions.

The Editor


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