

INFORMED CONSENT IN OBSTETRIC ANESTHESIA: THE EFFECT OF  
THE AMOUNT, TIMING AND MODALITY OF INFORMATION  
ON PATIENT SATISFACTION

Michelle B. Hicks, B.A., M.S.I.R.

Dissertation Prepared for the Degree of  
DOCTOR OF PHILOSOPHY

UNIVERSITY OF NORTH TEXAS

December 2008

APPROVED:

Maurice Wheeler, Major Professor  
Brian O'Connor, Committee Member  
Miguel Ruiz, Committee Member  
Herman L. Totten, Dean of the College of  
Information, Library Science and  
Technologies  
Sandra L. Terrell, Dean of the Robert B.  
Toulouse School of Graduate  
Studies

Hicks, Michelle, B. Informed Consent in Obstetric Anesthesia: The Effect of the Amount, Timing and Modality of Information on Patient Satisfaction. Doctor of Philosophy (Information Science), December 2008, 113 pp., 81 tables, references, 72 titles.

Using mainly quantitative methods of evaluation, as well as patient comment assessment, this study evaluated whether changing the current informed consent process for labor epidural analgesia to a longer, more informational process resulted in a more satisfied patient. Satisfaction with the labor epidural informed consent process was evaluated using a questionnaire that was mailed and also available online. Half of the patient population was given a written labor epidural risk/benefit document at their 36-week obstetric check up. All patients received the standard informed consent. Survey responses were evaluated based on three independent variables dealing with the modality, timing, amount of informed consent information and one dependent variable, whether the patient's expectations of the epidural were met, which is equated with satisfaction. Patients in this study clearly indicated that they want detailed risk/benefit information on epidural analgesia earlier in their pregnancy. A meaningfully larger percentage of patients who received the written risk/benefit document were satisfied with the epidural process as compared to those who did not receive the document.

Copyright 2008

By

Michelle B. Hicks

## ACKNOWLEDGMENTS

I would like to thank my committee, who helped me bring this project to completion. Thank you Katie, Rachel and Rebecca, my lovely daughters, for putting up with the frustration and work along with me. Thank you, Michael, for your love and faith. This is for you.

## TABLE OF CONTENTS

	Page
ACKNOWLEDGMENTS.....	iii
LIST OF TABLES.....	vi
Chapter	
1. INTRODUCTION .....	1
Statement of the Problem	
Purpose of the Study	
Significance of the Study	
2. REVIEW OF THE LITERATURE .....	5
History of Anesthesia	
Epidural Analgesia in Modern Practice	
Communication and the Physician-Patient Relationship	
Communication of Information in the Medical Encounter	
Communication Models Used in Health Care	
Communication and Sense-making	
Power, Authority and Accuracy of Information	
Physician Gender and Communication	
Ethics in Medicine/Anesthesia	
Informed Consent and its Purpose	
Patient Information Seeking Behavior	
Information Relevance for the Patient	
Patient Information Needs	
Patient Satisfaction	
Patient Satisfaction as Customer Satisfaction	
Satisfaction and Quality of Care	
3. METHODOLOGY .....	39
The Patient Questionnaire	

	Measures	
	Independent Variables	
	Dependent Variable	
	Research Questions	
	Data Analysis	
4.	RESULTS .....	46
	Problems with the Use of Multinomial Logistic Regression	
	Research Question 1	
	Research Question 2	
	Research Question 3	
	Relationship between Education and Satisfaction	
	Relationship between Education and Amount of Information	
	Relationship between Education and Timing of Information	
	Patient Comments on Epidural Process	
5.	DISCUSSION .....	67
	Modality of Information	
	Amount of Information	
	Timing of the Delivery of Informed Consent Information	
	An Optimal Process of Information Dissemination	
	Practical Applications	
	Future Research	
	Conclusion	
	APPENDICES .....	79
	REFERENCES.....	108

## LIST OF TABLES

	Page
1. Responder Age and Delivery of Most Recent Baby .....	46
2. Education Level.....	47
3. OB Gender .....	47
4. Number of Children .....	48
5. First Labor Epidural .....	48
6. Type of Delivery .....	49
7. Outcome of the Delivery.....	49
8. Expectations of Effectiveness of Epidural .....	50
9. How Well Did the Epidural Work .....	51
10. Were Expectations of the Epidural Met .....	51
11. Attended Childbirth Education Classes .....	52
12. Amount of Information from Education Classes .....	52
13. Type of Informed Consent.....	53
14. Warnings .....	55
15. Parameter Estimates.....	55
16. Type of Informed Consent - Were Your Expectations of the Epidural Met / Crosstabulation .....	56
17. Type of Informed Consent - Were Your Expectations of the Epidural Met / Crosstabulation .....	57
18. Fisher's Exact Test for Type of Informed Consent .....	57
19. Amount of Information during Informed Consent – Enough Information - Were Your Expectations of the Epidural Met / Crosstabulation .....	59

20.	Fisher’s Exact Test for Amount of Information .....	59
21.	Best Time to Receive Epidural Information – OB Visit Last Month of Pregnancy – Were Your Expectations of the Epidural Met / Crosstabulation .....	60
22.	Fisher’s Exact Test for Best Time to Receive Information .....	61
23.	The Best Time to Receive Epidural Information .....	61
24.	Patient Expectations and First Labor Epidural .....	61
25.	Education – Were Your Expectations of the Epidural Met / Crosstabulation .....	62
26.	Fisher’s Exact Test for Education and Expectations .....	63
27.	Education – Amount of Information during Informed Consent – Enough Information / Crosstabulation .....	63
28.	Fisher’s Exact Test for Education and Amount of Information .....	64
29.	Education – Best Time to Receive Epidural Information – O Visit Last Month of Pregnancy / Crosstabulation .....	64
30.	Fisher’s Exact Test for Education and Timing of Information .....	65
31.	Positive Comments on the Epidural Process – Could Anything Have Been Done Better? .....	65
32.	Negative Comments on the Epidural Process – Could Anything Have Been Done Better? .....	66
C.1	Education Level .....	88
C.2	Primary Language .....	88
C.3	OB Gender .....	88
C.4	First Baby .....	89
C.5	How Many Children .....	89
C.6	Type of Delivery .....	89
C.7	Outcome of the Delivery .....	90
C.8	Expectations of Effectiveness of Epidural .....	90



C.9	How Well Did Epidural Work.....	91
C.10	First Labor Epidural .....	91
C.11	Were Your Expectations of the Epidural Met.....	91
C.12	Attend Childbirth Education Classes.....	92
C.13	Amount of Information from Education Classes.....	92
C.14	Type of Informed Consent .....	93
C.15	Informed Consent Document-Read Completely .....	93
C.16	Informed Consent-Skimmed Over It .....	94
C.17	Informed Consent-Understood Document .....	94
C.18	Informed Consent-Did Not Understand Document .....	94
C.19	Informed Consent-Looked for More Information after Reading Document .....	95
C.20	Informed Consent-Document Contained Enough Information to Make a Decision .....	95
C.21	Other Sources-Magazines .....	95
C.22	Other Sources-Friends .....	96
C.23	Other Sources-Family Members .....	96
C.24	Other Sources-Current or Past OB/GYN .....	96
C.25	Other Sources-Literature from the OB/GYN .....	97
C.26	Other Sources-Internet Websites.....	97
C.27	Other Sources-Library .....	97
C.28	Most Information.....	98
C.29	Understand Information from Anesthesiologist .....	99
C.30	Did Not Understand Language .....	99
C.31	Did Not Understand Terms .....	99

C.32	Did Not Understand Because of Pain .....	100
C.33	Did Not Understand Because of Other Distractions.....	100
C.34	Asking Doctor Questions .....	100
C.35	Any Questions After Verbal Informed Consent .....	101
C.36	Amount of Information Informed Consent-Not Satisfied.....	101
C.37	Amount of Information during Informed Consent-Satisfied .....	102
C.38	Amount of Information during Informed Consent-Very Satisfied .....	102
C.39	Amount of Information during Informed Consent-Not Enough Information .....	102
C.40	Amount of Information during Informed Consent-Enough Information.....	103
C.41	Amount of Information During Informed Consent-More Information Than I Wanted.....	103
C.42	Amount of Information during Informed Consent-Information Given at the Right Time.....	103
C.43	Amount of Information during Informed Consent-Information Not Given at the Right Time .....	104
C.44	Best Time to Receive Epidural Information-Prenatal Class .....	104
C.45	Best time to Receive Epidural Information-OB Visit Beginning of Pregnancy .....	104
C.46	Best Time to Receive Epidural Information-OB Visit Last Month of Pregnancy .....	105
C.47	Best Time to Receive Epidural Information-Admission to Hospital for Delivery .....	105
C.48	Best Time to Receive Epidural Information-Immediately Prior to Receiving Epidural .....	105
D.1	Descriptive Statistics.....	107

## CHAPTER 1

### INTRODUCTION

Informed consent for medical procedures, which consists of the treating physician discussing the risks and benefits of a procedure with a patient, has been a practice standard for many years. This process involves communication between the physician and patient, information seeking and needs of the patient, as well as relevance of information in order to reduce uncertainty of the medical procedure. Informed consent has changed radically over the past 40 years by becoming patient-centered instead of practitioner-centered (West & Palmer, 2007). In spite of this change, many patients do not get enough information about their procedure or treatment plan and do not have adequate knowledge of its risks and benefits (White, Gorton, Wee & Mandal, 2003). In a 2002 study of satisfaction levels for inpatient care, patients indicated that physical needs, emotional support and respect for their preferences were tied most closely to satisfaction (Jenkinson, Coulter, Bruster, Richards & Chandola, 2002). Patients have also indicated that they want to be more involved in the decision-making process of their care (Adams, 2007). A driving force behind this desire is the amount of health care information available and the ease of access to it, not only on the Internet, but through increased media coverage as well. Patients' increased awareness and use of this easily available information is referred to as *consumerism* by experts in the field of health information; this is more than just a trend in medicine, it is now standard in most doctor-patient interactions (Neuberger, 2000). One response to the patient as informed consumer has been to ensure that the information the patient has is accurate and adequate. An example of this type of response is a new inpatient

anesthesia consent form that has been developed by researchers at Wake Forest University Baptist Medical Center. This written consent form provides additional information on various types of anesthesia and documents the patient's consent process (Vlessides, 2007). The purpose of this new type of consent document is to give accurate and physician-approved information allowing the patient to be a participant in the management of his / her care. There is no available information on how satisfied patients are with a written document as part of informed consent but there is evidence that patients have not been happy with just a verbal explanation of the risks and benefits of anesthesia (Pattee, Ballantyne & Milne, 1997). For the health care industry, patient satisfaction is the key to a positive patient encounter. This dissertation examined the effect of a two-part informed consent process on patient satisfaction for obstetric patients who want epidural analgesia during labor and delivery. Informed consent and how it is given was evaluated to determine its influence on the patient's satisfaction with the epidural procedure. This evaluation pertains to Information Science in general and biomedical informatics, specifically because of the extraordinary amount of communication necessary between physician and patient, in order to facilitate a meaningful and useful relationship in which the patient understands fully the options available for treatment and has the opportunity to participate in the decisions about that treatment.

### Statement of the Problem

Obstetric patients who have elected to receive an epidural analgesic during labor and delivery are often surprised about the process of the insertion of the epidural and do not feel well informed about the risks and benefits (Pattee et al., 1997). The current

practice of obtaining consent from the patient usually involves a legal form for the patient to sign, which may be completed at the time of their admission to the hospital accompanied by a verbal explanation immediately prior to the procedure. Research conducted in the area of informed consent shows that receiving a written, as well as an oral explanation of risks and benefits is well received by patients and helps to increase their recall of these factors after the delivery of the baby. Clearly, more information given in several formats (verbal and written) is optimal for the patient. There is no research on the timing of that information delivery and whether the timing of that information is important enough to patients to have an impact on their satisfaction with the epidural process. Anesthesiologists are left to guess at what is the most appropriate and effective method to inform their patients and at what point in the prenatal timeline. Generally, the result is to remain with the current model of verbally informing the patient immediately prior to the epidural procedure.

### Purpose of the Study

This study evaluated whether changing the informed consent delivery for epidural analgesia to a longer, more informational process resulted in a more satisfied patient. Specifically, will adding a written risk/benefit document given to the patient during the last month of her pregnancy have an effect on her satisfaction with the informed consent process for the epidural? Many anesthesiologists in Pinnacle Anesthesia Consultants (the participant medical group) who administer obstetric anesthesia and analgesia note that patients who have requested epidural analgesia have preconceived ideas about the actual procedure and the amount of pain relief they will have. Patients also do not appear to be well informed about the risks to themselves and their babies.

Meeting a patient's information needs and encouraging her to communicate questions after reading and thinking about the risks and benefits of epidural analgesia prior to entering the hospital for delivery of her baby is one of the ultimate goals of the anesthesia group who participated in this study. They hope that by changing the process of their informed consent they will achieve this goal and, as a result, have a patient who is satisfied with the epidural process.

### Significance of the Study

There is little specific research on the informed consent process for labor epidural analgesia. Researchers recommended further study on the timing of the delivery of the informed consent and whether this information should be in written form. Some study participants felt that women would benefit from receiving the informed consent information earlier than immediately prior to the epidural insertion. This study takes the current research to the next logical level: testing whether the timing of this information and how it is delivered to the patient has an effect on patient satisfaction with the anesthetic process and on a patient's expectations of that process. Initially, if there is a positive connection between the timing and amount of risk/benefit information and patient satisfaction, adding a detailed written document to the informed consent process could be expanded to include all procedures that involve any type of analgesia or anesthesia. Positive results could also potentially affect the way informed consent is delivered in other healthcare delivery settings such as non-emergency surgery, outpatient and inpatient cardiac procedures, cancer treatment, etc., and would represent and solidify a migration to patient-centered care that has already progressively been occurring.

## CHAPTER 2

### REVIEW OF THE LITERATURE

Pain relief during labor and delivery is an important treatment consideration for pregnant women. Studies have shown that epidural analgesia for relief of labor pain is superior to most other types (Gilbert, 1997). In the past, epidural analgesia was thought to slow labor contractions, increasing the rate of caesarean deliveries. Recent research has shown that the rate of caesarean births is not related to epidural analgesia; therefore, more women are opting for this type of pain relief (Gilbert, 1997). According to estimates by the American Society of Anesthesiologists, one million pregnant women a year choose an epidural for pain relief during labor and delivery. This type of pain relief is not without risks and it is the job of the anesthesia provider to communicate these risks in the most ethical and efficient manner to the patient. Determining the best method to inform patients of these risks involves not only the informed consent process but patient information needs and satisfaction as well.

#### History of Anesthesia

In order to understand and appreciate the current practice of pain management in the medical specialty of anesthesia, the developments that have led to acknowledging and treating pain must be discussed. The fact that human beings have sought relief from physical pain is well documented. The word pain is derived from the Greek word *poine*, or to punish (Larson, 2005). Early medical literature often referred to easing the pain and suffering of those afflicted with wounds (frequently received in wars). The mandrake root, known for its pain relieving properties, was used by the ancient Babylonians, Egyptians, Hindus and Chinese as early as 2000 B.C. (Frost,

1985). Frost (1985) states, the “oldest record of medical practice that clearly dealt with pain relief was of the Chinese procedure of acupuncture” (p. 39). Other than this type of procedure, most pain relief was achieved by using plant derivatives in an oral or topical manner until scientists began experimenting with the inhalation of gasses to cause sleep for surgical procedures. During the 13<sup>th</sup> century, the Italian author Theodoric described such a procedure where the patient inhaled the vapors of a mixture of substances that were boiled together (Frost, 1985). Though little was done to alleviate it, pain during surgery continued to be a major concern for physicians.

The next serious attempt to deal with pain during surgery occurred with experimentation with nitrous oxide gas by Sir Humphrey Davy in England in 1798 (Frost, 1985). His research focused mainly on the relief of pain associated with dental inflammation. Nitrous oxide gas was initially tested in the United States (U.S.) in the mid-1800s. Dentists experimented with its use to relieve the pain of dental extractions. Of note, the dentists Gardner Colton, Horace Wells and J. H. Smith all used this gas to provide pain-free dental extractions with varying results. Although Colton had the most success (25,000 cases without a fatality, which was the most common medical risk at that time) he gave full credit for the discovery of the use of nitrous oxide gas to Horace Wells in his (Colton’s) 1886 account of the facts entitled “Anaesthesia: Who made and developed this Great Discovery? A statement *delivered upon the mellowing of the occasion!*” (Frost, 1985, p. 25).

At the same time that nitrous oxide gas was being used for dental extractions, a public demonstration of the use of ether anesthesia by William T. G. Morton was given at the Massachusetts General Hospital. This occurred in October of 1846 and is



considered to be the beginning of anesthesia as a specialty (Larson, 2005). The use of ether was noted in medical literature as early as the 13<sup>th</sup> century (Frost, 1985). In 1818, Michael Faraday published a report on its effects, likening them to nitrous oxide gas (Frost, 1985; Larson, 2005). After Morton's demonstration, ether's use during surgery quickly grew in acceptance and popularity. A name was not given for the drug or its effect until November of 1846 when, in a letter to Morton, Oliver Wendell Holmes wrote: "Everybody wants to have a hand in a great discovery. All I do is to give you a hint or two as to names or the name to be applied to the state produced and the agent. The state should, I think, be called *anaesthesia*, the adjective would be *anaesthetic*" (Frost, 1985, p. 28). Thus, a medical specialty was born.

The groundwork that paved the way for advances in anesthesia between 1925 and 1960, which represent the greatest progress in the specialty, occurred years earlier in the areas of cardiopulmonary physiology, the autonomic nervous system, and the historical development pain theories (Larson, 2005). Scientific research on the cardiopulmonary system and respiration in the late 19<sup>th</sup> and early 20<sup>th</sup> centuries has led to discoveries in the areas of blood gas and total respiration measurements as well as pulse oximetry, all used in modern anesthesia delivery (Larson, 2005). Research in the area of the autonomic nervous system was essential in order for modern day anesthesiologists to fully understand the nervous system and neurotransmitters. The most important research in this area occurred in 1889 when John Langley was able to block synaptic transmission in the autonomic ganglia. With this research he was able to map the distribution of presynaptic and postsynaptic autonomic nerves (Larson, 2005). Ten years later, John Able discovered the hormone epinephrine, which is a commonly

used lifesaving agent in anesthesia today (Larson, 2005). Further discoveries were made by various researchers in the area of the sympathetic nervous system, which led to their ability to block nerves and achieve regional anesthesia.

Theories of pain and discovery of the distribution of nerves in the body have also contributed to the modern anesthesiologist's ability to control a patient's pain. This began with Albrecht von Haller's conclusion in 1752 that "only those parts of the body that are supplied with nerves possess sensibility, whereas irritability is a property of the muscular fibers" (Larson, 2005, p. 9). The existence of specific neural pathways that transmitted painful sensations was demonstrated by both Charles Bell and Francois Magendie in the early 1800s (Larson, 2005). According to Larson (2005), "By the end of the 19<sup>th</sup> century the idea was firmly established that acute pain was a distinct sensory modality that was susceptible to interruption through conduction block initiated with local anesthetics" (p. 10). Ultimately, research and developments in the area of pain theory has led to the Gate Control Theory of pain (Larson, 2005). Proposed by Ronald Melzack and Patrick Wall in 1965, this theory of pain essentially states, "that the transmission of pain from the peripheral nerve through the spinal cord was subject to modulation by both intrinsic neurons and controls emanating from the brain" (Dickenson, 2002, p. 755). In other words, the peripheral nervous system has both small and large nerve fibers that carry information to the spinal cord. The small nerve fibers carry nociceptor (or pain stimulation) information and the large fibers carry non-nociceptor (or non-pain stimulation) information. Both types of fibers activate projection neurons to the brain, which signal pain, but the large nerve fibers also activate interneurons, which block the projection neurons. Therefore, it is the small nerve fibers that are responsible for pain.

According to the theory, the large nerve fibers can also have a dampening effect on the signals sent from the small nerve fibers. An example of this is stimulating a bumped elbow by rubbing it, which (a non-nociceptor stimulation) often lessens the initial pain. The Gate Control Theory has changed the way anesthesiologists look at pain control and has led to better methods to control pain with the use of intrathecal and epidural injections (Larson, 2005).

There are several important discoveries and inventions that opened the door for regional anesthesia and analgesia (Fink, 1998). The first is the invention of the syringe and hypodermic hollow needle in the 1850s. The first was invented by Charles-Gabriel Pravaz in Lyon (although there is some evidence that this was invented centuries before) and the second by Alexander Wood in Edinburgh (Fink, 1998). With this invention Wood originated and developed the “practice of percutaneous subcutaneous injection to medicate locally a peripheral nerve” (Fink, 1998, p. 3). This means that the injection goes through and under the skin to cause a loss of sensation at the injection site. Wood’s technique was adopted by C. Hunter. He renamed it the *hypodermic injection* and used it to achieve systemic absorption of the injected drug (Fink, 1998). Leonard Corning, in 1885, was the first to attempt to use an analgesic (or pain-controlling) drug directly on the spinal cord, but was unsuccessful due to poor technique and lack of a complete understanding of the mechanisms of pain in the human body (Fink, 1998). It is important to make the distinction between an anesthetic and an analgesic at this point. An anesthetic causes the loss of all sensation, while an analgesic causes the loss of pain.

Another important discovery and application was the use of cocaine as a local

ocular anesthetic by Carl Koller in 1884 (Fink, 1998). This discovery was reported to the New York Medical Record by ophthalmologist H. D. Noyes, which led to the testing of the procedure and use of this drug in other areas of medicine (Fink, 1998). Leonard Corning, in 1885, is credited with finding a way to prolong the local anesthetic effects of cocaine so that it could be used for longer surgical procedures of the extremities. He did this by blocking the circulation of the site proximal to the point of injection, which allowed for almost indefinite anesthesia (Fink, 1998). This ultimately led to the development of a block still commonly used today, known as the Bier block. Developed by August Bier in 1908 it was called direct vein anesthesia and brought about complete anesthesia and paralysis of a limb in 5-15 minutes (Fink, 1998).

Spinal anesthesia, as earlier noted, was investigated initially by Leonard Corning in 1885. Because the lumbar puncture had not been developed at the time of his early work, Corning was not successful in achieving true spinal anesthesia, only analgesia. The lumbar puncture was developed by Heinrich Quincke around 1891 and was originally used to treat hydrocephalus (Fink, 1998). Eight years later, Quincke's technique was used for (what is now known as) spinal anesthesia by August Bier. He used the Quincke technique and noted that an intrathecal (directly into the thecal sac or spinal fluid) injection of cocaine produced anesthesia of the lower body (Fink, 1998). This technique was adopted very quickly by S. Marx for obstetric patients and by many surgeons for general surgery patients (Fink, 1998). Fink (1998), reports that Marx praised this technique's ability to quiet "the agonizing and maniacal shrieks of these poor women" for up to five hours without interfering with labor (p. 11). A refinement of this procedure and the development of better acting agents and anesthetic drugs

followed over the next 30 years. Adriani and Roman-Vega developed and reported on the saddle-block, which allowed the anesthesia to be confined to the perineal area of the body (Fink, 1998). Continuous spinal anesthesia was developed by Lemmon in 1940 and adopted for obstetric anesthesia by Edwards and Hingson in 1942 (Fink, 1998). This process allowed the doctor to begin the anesthetic earlier and continue it for as long as five to six hours until labor and the repair of any tearing or episiotomy were complete. Anesthesia and analgesia administered by anesthesiologists for labor did not become popular until the 1970s. This came about because of increased knowledge of the mechanisms of available drugs and the desire on the part of physicians and patients for effective and reliable pain relief. While spinal anesthesia was initially used for the end of labor and the delivery of the baby, the introduction of the use of opioids for epidural analgesia in the late 1970s helped to shift physician and patient relief preferences from spinals to epidurals (Larson, 2005).

### Epidural Analgesia in Modern Practice

The pain of childbirth can be very severe and it is in the best interest of the mother and newborn to control that pain in some manner. The benefit of some type of pain control also helps to control maternal anxiety, which can cause an abnormal fetal heartbeat and can also prolong labor (Eberle & Norris, 1996). Some women control pain by using methods that do not require medical intervention such as massage, breathing techniques, meditation, warm baths, etc. Other women choose some type of medical intervention, and a great many are opting for a procedure called a labor epidural (Leighton & Halpern, 2002). This procedure is accomplished by placing an epidural catheter into the epidural space during labor that allows the anesthetist to continue to

supply a local analgesic to the patient. The benefit of a labor epidural is primarily maternal pain relief. It also allows the laboring patient to continue to move her legs and use all of the muscles necessary for the delivery of the baby. Risks include the potential for a moderate drop in blood pressure, a post-dural puncture headache (frequently called a spinal headache), short-term backache and urinary incontinence immediately postpartum (Vincent & Chestnut, 1998; Leighton & Halpern, 2002). Leighton and Halpern (2002), in their systematic review of randomized controlled trials and high-quality prospective cohort studies on epidural analgesia, reviewed two other possible risks associated with this type of pain relief: the increase of the incidence of cesarean section delivery and the slowing of labor. They found that the rate of cesarean births was unaffected by epidural analgesia, even in studies that were performed before and after significant increases in the utilization of epidural analgesia for labor. This type of analgesia is associated with a 15-minute increase in the second stage of labor, but the authors were not sure if this was independent of labor induction and suggested that further research was needed to determine the exact cause. In general, this is an effective method of pain control for laboring women, with little or no effect on the baby and minimal maternal risk.

## Communication and the Physician-Patient Relationship

### *Communication of Information in the Medical Encounter*

Appropriate communication between doctor and patient allows for many things to occur in the exchange, as well as the relationship. The patient's symptoms are communicated to the doctor and from these, a dialog can begin in order for the doctor to

assess, evaluate and suggest a treatment plan. For this dialog to be sufficient for both the doctor and patient the correct channels of communication must be available and open in both directions, from the patient to the doctor and then back to the patient. The patient then, in turn, gives feedback to the doctor and this type of communication continues until a mutually agreed-upon treatment plan occurs. This is the current manner of communication between the doctor and patient, but it was not always so. In the past, treatment communication was one directional from doctor to patient. Important to this discussion is not only the manner of the communication between doctor and patient, but the communication theory used for it as well.

The main type of communication in health care is the medical interview. When a healthcare provider, or more specifically a doctor, interviews a patient, there are three clear goals that should be achieved. They are to gather information that will aid in a diagnosis, to develop and foster a treatment relationship and to disseminate information (Goold & Lipkin, 1999). In the past, the communication between doctor and patient was paternalistic and mostly one directional in nature (American College of Obstetricians and Gynecologists [ACOG], 2004). Doctors would ask the patient for their symptoms and come up with a diagnosis and treatment plan. The patient was not part of the decision process for this plan. The doctor was the authority and the possessor of the knowledge, and made the decision for the patient. Patients accepted this process and some older patients still accept and prefer this method today (Branch, 2000). Branch (2000), in the description of his therapeutic model of patient-physician relationships gives a very accurate portrayal of the current practice of communication within the context of this relationship. He asserts that mutual decision-making between the doctor

and patient is best for both participants. It allows the doctor to address more than just the patient's disease process, but the patient as a whole person. The patient, in return, as a partner in the decision process, may be more compliant with the therapies that were mutually decided upon. Branch calls this a therapeutic model and not a theory because he sees this reflected in the actual practice of medicine. It can be applied to the informed consent process that the physician (anesthesiologist) goes through with the laboring patient. Usually, risk / benefit information is discussed with the patient and through this dialog, the patient maintains her autonomy in the decision-making process and doctor and patient go through a question and answer period to make sure the patient understands the procedure and accepts the potential risks. Ultimately, the patient makes the decision as to whether the benefits outweigh the risks. This model has its roots in several communication theories such as the Shannon-Weaver and the Osgood-Schramm models of communication.

### *Communication Models Used in Health Care*

The Shannon and Weaver model of communication is based upon the seminal journal article by Claude Shannon, written when he worked for Bell Labs in 1947 (Shannon, 1948). He proposed a linear model of communication that primarily focused on noise in the interaction between sender and receiver. Weaver wrote an introduction to this article, which was used as a chapter in the book *The Mathematical Theory of Communication* authored by Warren Weaver and Claude Shannon. While this book and Shannon's original theory focused on converting communicated messages to electronic signals, the theory was ultimately applied quite successfully to the study of communications, in general. According to the model, there are six components that are



required in order for communication to occur (Underwood, 2003).

The first component is the source of the information. In a typical medical encounter between a doctor and patient, the source can be either party: the patient is the source of information about the presenting problem and the doctor is the source of treatment information. However, in the doctor patient relationship that surrounds the informed consent process, the source of the information is the doctor, who transmits information about the benefits and the potential risks of the treatment to the patient. The second component of the Shannon and Weaver model is the encoder. Simply put, this encompasses the verbal and motor skills of the source of the information. At play here is whether the source (physician) is a good communicator. The third component is the message, or what the communication is about. An important part of the message is whether what was sent was the message received (Underwood, 2003). The channel, which is the fourth component of the model, is what the message travels through. A very important issue that affects the channel is called *noise*, which can interfere with the message and how it is received. The informed consent process can be considered noise according to Shannon and Weaver's model of communication depending on when and how the patient receives that informed consent. The fifth component is the decoder or translator of the information. The decoder works to put the message in a form that the receiver, the sixth component of the model, can receive and understand. Finally, the receiver can send feedback to the sender or source of the information. This theoretical model is applicable to the doctor-patient communication processes of the past and present. In the past, the doctor did not seek feedback from the patient, but in the current manner that doctors and patients communicate with each other, feedback is essential to

the process.

There are several major drawbacks to this model as it is applied to the doctor-patient communication process. Shannon viewed noise as more physical or mechanical. Physical noise in the informed consent process between the anesthesiologist and laboring patient might include pain, the presence of others in the room as part of the interaction (husband, children, parents, etc.), the TV or radio, the fetal monitor, or the patient's hunger, to name but a few. Noise can also be semantic in nature, which might deal with the patient's knowledge level, their personal experience, and their biases (Underwood, 2003). Some examples of semantic noise in the informed consent process might be physical distractions behind or around the doctor when they are speaking to the patient, the doctor is emphasizing the wrong part of the message for the patient and the patient does not pay attention to what is really important, the patient thinks that the doctor looks too young to know what he or she is doing or the patient is so afraid of the procedure that she can not focus on the information the doctor is giving her. Another drawback to the application of this theory to the doctor-patient communication process is the meaning of the message. The Shannon and Weaver model deals with transmission of information, but does not deal with meaning (Underwood, 2003). Meaning can be derived from the context of the situation, the intention of the sender or source and the relationship between the sender and the receiver (doctor and patient, respectively). Ultimately, the communication between a doctor and patient, whether it is for a treatment plan or informed consent, is all about meaning and understanding. This leads to a reduction in anxiety in the patient when she knows the doctor's intentions are for her welfare, the doctor works to inform her by using words that she understands and

allows her to make the decision about what is best for her and her baby.

Another model that is relevant to doctor patient communication is the Osgood-Schramm circular model of communication (Underwood, 2003). Although similar to Shannon's model in that there is a sender and receiver of messages, Schramm placed a greater emphasis on what the message means – there is an encoder and decoder response that occurs on each side when receiving and sending messages (Underwood, 2003). The encoder and decoder devices are particularly helpful in noting if the doctor is not a good communicator or the patient does not have the ability to understand the message. Semantic noise would be a serious impediment to the understanding of the message. Schramm also felt that the communication process was circular in the sense that it was a continuum. This is a model that is appropriate for the doctor-patient communication process in general as it occurs today. Doctors can create understanding with patients by being the authority figure (context) and the provider of information (intention) to a patient who expects both of those things from the doctor but should try to maintain their autonomy and ask questions (feedback) in order to be a partner in the treatment decision. This allows the focus to be on the dialog between doctor and patient as a two-way process (Geist & Dreyer, 1993).

### *Communication and Sense-making*

When a doctor and patient have a dialog, the doctor must understand what the patient is trying to communicate and the patient must make sense of the information that is communicated by the doctor. If both parties cannot accomplish these things, then the dialog is useless and the patient will not receive the care that is needed. Cegala (1997), in his 1997 research study on doctor patient communication during primary care

visits, notes that two processes are at work in the medical interview: the exchange of information from patient to doctor and back again, and establishing rapport and communicating care and concern.

Information that is exchanged in the interview may consist of medical history, patient's symptoms, diagnosis, and a treatment plan. In the informed consent process this exchange consists of risk and benefit information and questions and answers about that information. According to Cegala (1997), information exchange also requires information-seeking behavior on the part of both the doctor and patient. This behavior allows both parties to acquire pertinent information needed to achieve the goal of treatment.

The relationship established between the doctor and patient during the medical interview is a determinant of patient satisfaction (Cegala, 1997; Brown, Boles, Mulloony & Levinson, 1999). When patients are dissatisfied with the communication it is because of a lack of responsive feedback, disregard for their needs in the doctor patient relationship and nonrecognition of the patients' desire to be a part of the decision process in their own care (Cegala, 1997; Jenkinson, Coulter, Bruster, Richards & Chandola, 2002). Although this component of the communication process between doctor and patient is very important, according to Cegala (1997), information exchange is of primary importance for both parties. That is where sense-making of information in the communication exchange between doctors and their patients comes into play.

In 1986, they summarized their approach as a method to assess the ways individuals use various types of information in the process of making sense of the things that affect their lives (Dervin & Nilan, 1986).

Their model specifically looks at the situation the information seeker finds him / her in, a gap that constrains the seeker in attaining the needed information and the manner in which they broke from those constraints to acquire the needed information. The model goes one step further and looks at how the information actually helped the information seeker (Dervin & Nilan, 1986). Kuhlthau (1993) explains further that sense-making is done within a personal frame of reference; she states “The person seeks meaning, rather than a right answer, and views information as a way of learning and finding meaning or as a process of construction” (p. 3). The patient involved in a medical dialog with a doctor not only desires to be understood, but must also find meaning in the information from the doctor. The doctor has given the best answer to the patient and the patient must apply that information to his/her own frame of reference and find the relevance. In the informed consent process, when an anesthesiologist is giving risk and benefit information to a patient, that patient must internalize that information and find the relevance or meaning as it applies to her situation, that of pain relief during labor and delivery. The anesthesiologist must deliver that information in an ethical manner, respecting the patient’s ability to make choices and act as an equal partner with the patient in her health care plan.

### *Power, Authority and Accuracy of Information*

An important consideration for patients is whether the information that is given to them by a healthcare worker is accurate and useful. Accuracy is tied to quality of information in the sense that it is a prerequisite of quality of information (Fallis, 2004). Fallis (2004) comments that people have a need for information in order to make practical and important decisions that can have a life-changing impact. This is true of

the decisions that patients make based on the information given to them by healthcare workers in general and physicians specifically. When a physician is giving information to a patient that leads to a decision on the course of treatment, it should be incumbent on the physician to give accurate, quality information to the patient. The physician is in a position of authority and has power over the patient based on his or her medical expertise. This medical expertise is earned by the years of study, practical experience and continuing education that the physician has and continues to engage in. This type of power is detailed in the seven types of social power identified by French and Raven (as cited in Andrews & Baird, 2005). The seven types of power French and Raven identify include: reward, coercive, referent, legitimate, expert, informational and connective power. Patients usually apply legitimate, expert and informational power to their physicians.

Prior to the emergence of readily available information on medical websites that have been developed for consumer use, individuals in need of medical treatment got their information from the treating physician. That physician held informational power over the patient because he or she was the primary source of valid and accurate information of the patient's disease and treatment. Although informational power has been somewhat diminished because of the proliferation of medical information available on the Internet, expert power is still exerted over patients by physicians. Patients will take the advice of a physician because they recognize that their physician has a depth of knowledge and expertise in the medical field that they do not possess (Andrews & Baird, 2005). Thus, patients ultimately believe that, because of their physicians' medical training and knowledge acquisition, they will be a reliable source of accurate

information.

Another type of power that physicians have with patients is legitimate power. This type of power is accorded an individual when he or she is considered to be in a position of authority (Andrews & Baird, 2005). Legitimate power is closely tied to expert power in that both are tied to position in society. When a patient says, “Well, I guess you know best because you’re the doctor” he or she is acknowledging both legitimate and expert power.

It is extremely important for a treating physician to communicate information to the patient in a manner that allows that patient the freedom to trust the information and the physician, and participate in the decisions pertaining to medical treatment and care. Patients can participate better in their care process when physicians and patients have exchanges in the medical interview that are patient-centered. Encouraging the expressions of ideas and options creates a transfer of power and some control to the patient (Roter, Hall & Katz, 1987; Thiedke, 2007). This will increase the patient’s satisfaction and compliance to physician treatment advice (Thiedke, 2007).

### *Physician Gender and Communication*

The gender of the physician has a significant influence on communication with children. A female pediatrician will communicate to establish rapport during a longer clinical visit as compared to her male counterparts (Bernzweig, Takayama, Phibbs, Lewis & Pantell, 1997). This has also been seen in physicians that treat adult populations. In primary care, female physicians are seen as better communicators, spend more time with the patient during the clinical visit and engage in communication that can be interpreted as patient-centered (Roter, Hall & Aoki, 2002). Although there

are an increasing number of female physicians (according to the AMA, in 2003, 49% of the entering medical school classes were females), patients consider gender as one of many factors when choosing a physician. In a survey on the importance of gender when a woman chooses an obstetrician or gynecologist, 52.8% preferred a female physician, while 37.6% of the women surveyed had no gender preference (Plunkett, Kohli & Milad, 2002). All of the women surveyed considered a variety of factors before making their choice. Factors such as hospital affiliation, recommendations from friends and family, and physician bedside manner are more important than physician gender (Plunkett, et al., 2002). Therefore, the communication abilities of the physician may not be as important as their behavior and treatment of their patients. In agreement with Plunkett, et al.'s findings, a study by Howell, Gardiner and Concato (2002) also found that of the 67 study participants, only one third of them preferred a female obstetrician. 90 percent of the patients surveyed did not think that the gender of their physician had any impact on their care. What was most important to the patients included in this study was the *connection* or relationship they had with their obstetrician, whether that doctor was male or female (Howell, Gardiner & Concato, 2002). Howell et al. (2002) found that "patient satisfaction in obstetrics is related to specific physician traits, such as communication style, participatory decision making, or interpersonal style, rather than gender" (p. 1034).

### Ethics in Medicine/Anesthesia

Medical ethics have their origins in one of the most widely known medical texts, the Hippocratic Corpus (which, incidentally, was probably not written by Hippocrates) (National Library of Medicine [NLM], 2002). Although not a required standard, a modern



version of the Hippocratic Oath is frequently recited upon the graduation of a new class of physicians. The phrase in the oath that underscores ethical behavior in medicine is *I will do no harm or injustice to them* (translation by Michael North, NLM History of Medicine). The United Kingdom's General Medical Council updated this oath by publishing a core piece of guidance for doctors called Good Medical Practice (General Medical Council, 2006). In the section of the document titled Duties of a Doctor, the Council emphasizes that *patients must be able to trust doctors with their lives and health*. Doctor's, therefore must make patient care their first concern, respect patients' dignity and treat them as individuals, *work in partnership with patients and be honest and open and act with integrity*.

The reasons for this new interest and emphasis on ethics are a result of changes in both society and medical practice (Nandi, 2000). There has been a tremendous growth in scientific knowledge, the availability of new technologies, and a change in the relationship between a patient and healthcare provider and the acute interest on the part of the payor (insurance companies, governments, etc.) to contain costs. According to Nandi (2000), "Ethical codes are the major characteristic that differentiates profession from occupation" (p. 22). Clinical ethics combines science and morality with the goal of improving the quality of patient care; this care is a moral undertaking (Nandi, 2000). In the U.S., the American Medical Association (AMA) first developed a code of ethics in 1847, with its latest revision published in 1998. Over the course of those 150 years, changes have been made specifically to benefit the patient.

The principles that are involved in medical ethics, according to Nandi (2000) are autonomy, beneficence, fidelity, justice and utility. Hoehner (2003) agrees with Nandi,

with the exception of utility, which means that a physician's actions should provide good results (Nandi, 2000). Autonomy refers to the self-determination of the patient and the doctor's respect thereof; beneficence deals with the beneficial acts for the welfare of the patient; fidelity and justice deal with the physicians obligations to the patient and society as a whole (Nandi, 2000; Hoehner, 2003). Although the doctor patient relationship may be seen as one, where the doctor has the power of information, knowledge and skill that can be used to make a patient well - because of the ethical requirement that doctors treat patients as equals and are able to make personal choices, that power is eliminated or, at least muted in the favor of the patient (Delany, 2005). Ultimately, ethics in modern medical practice deal with the competence of the physician practitioner, respect for a patient's autonomy and their healthcare choices and meeting that need in spite of social and political pressures (Nandi, 2000). Medical ethics is the cornerstone of informed consent and the doctor-patient relationship, and is the ultimate way to respect a patient's autonomy (Waisel & Truog, 2005).

### Informed Consent and its Purpose

Informed consent is the legal and ethical obligation by a healthcare professional to communicate the diagnosed condition, treatment options (including no treatment) and the risks and benefits of those options to a patient. The patient can then make a decision as to which procedure is the right course of action for them. Informed consent is frequently obtained by the healthcare provider (usually the one performing the procedure) or by an agent of the facility where the procedure will be carried out. Many healthcare providers consider obtaining informed consent prior to a procedure not only a necessity ethically but also because of legal implications. If informed consent is not

obtained from a patient prior to that patient undergoing a course of treatment or procedure, it can be considered a criminal act (battery) and / or medical negligence (Pape, 1997; Bernat, 2001). Bernat (2001) asserts that many physicians do an inadequate job of obtaining informed consent from their patients. A patient can only give informed consent with adequate information, and the full capacity to decide whether to have the procedure and the absence of coercion by the healthcare provider. Physicians must also be fully aware that a patient has the right to informed refusal of care (Pace & Hendry, 2006). This is a fundamental aspect of a patient's autonomy and has become vitally important as the focus in healthcare shifts more to patients and their rights. Patient autonomy is a core principal of informed consent; autonomy referring to an individual's freedom to act within legal and societal constraints (Pape, 1997). Because healthcare has become more focused on the desires of the patient, patients and their physicians should work together to decide upon a treatment plan and informed consent is a natural outcome of that process.

Historically, informed consent for anesthesia has been part of the informed consent for the surgical procedure itself. As anesthesiology has evolved as a specialty, its informed consent process has changed as well. In 2003, anesthesiologists in the United Kingdom began calling for a written informed consent document, separate from that of the surgical procedure (White & Baldwin, 2003). They justified this change in the informed consent process by using the following reasoning, that anesthesia is associated with a large number of risks that are usually unknown to most surgeons. Tying the anesthesia informed consent to the surgical informed consent does not satisfy the necessity to fully inform the patient of all of the risks of undergoing anesthesia. The

legal environment in the United Kingdom has been moving toward “a reasonable patient standard of information disclosure” (White & Baldwin, 2003, p. 771). A standardized consent form would also protect the physician from claims of negligence, as they would have a documented record of risk and benefit disclosure to the patient (White & Baldwin, 2003). The American Society of Anesthesiologists (ASA) has entered this debate very recently with several medical and legal articles on the necessity of a separate informed consent document. O’Leary (2006) makes a case for a separate anesthesia consent form based on better-informed patients who expect to discuss the anesthetic process with their doctors along with the current legal implications, mainly that of negligence (also found in Neuberger, 2000). O’Leary (2006) also states “Anesthesiologists have long been engaged in the battle to be recognized as skilled professionals whose scope of practice is far different from that of our surgical colleagues; Delivery of safe anesthesia care is a challenging process that requires engaging our patients as partners in their care to ensure the best outcome” (p. 12).

In a legal opinion given by Bierstein (2006) ASA staff counsel, she notes that the main reason for a separate anesthesia consent form is to manage legal risk. It is important for the anesthesiologist to make a concerted effort to inform the patient directly of the risks of the anesthetic. In a dissenting article, Cheney (2006) asserts that a two-part consent consisting of the section in the surgical informed consent form and a separate form that documents that a member of the anesthetic team discussed risks immediately prior to induction (delivery of the anesthetic agent) has worked adequately for his department. He goes on to ask how a separate anesthesia informed consent would improve any aspect of clinical practice, “Will it improve patient care, operating

room efficiency, cost of delivering care, patient satisfaction or provide legal protection?” (p. 18).

Informed consent for laboring women who want pain intervention in the form of epidural analgesia involves issues that are not present with surgical anesthesia. The first issue is the question of whether a laboring woman who is in pain has the ability to make an informed decision about her own care. This problem has been addressed in several studies; a recent one shows that labor pain does not interfere with higher brain functions and therefore allows laboring patients to make reasonable decisions for their own healthcare (Siddiqui, Siddiqui, Ranasinghe, Steadman & Shera, 2005). An earlier study by Pattee, Ballantyne and Milne (1997) also found that the discomfort and pain that laboring women experience prior to receiving epidural analgesia did not interfere with their ability to hear and comprehend the informed consent process.

Another issue that anesthesiologists face in obtaining informed consent from laboring women is that the women have frequently been medicated with pain-relieving drugs prior to the epidural. This is a problem that is faced by anesthesiologists when giving other types of anesthesia, as well. According to West and Palmer (2007), generally, the anesthesiologist must assess four areas of abilities of a patient:

1. The ability to understand the proposed treatment and options
2. The ability to appreciate how that information applies to the patient's own situation
3. The ability to reason in a manner that is supported by the facts and the patient's own values
4. The ability to communicate and express a choice clearly (p. 16)

A study of this problem by Gerancher, Grice, Dewan, & Eisenach (2000) showed that

there was no difference in the informed consent satisfaction rates of patients who were administered opioids prior to receiving epidural analgesia and those who did not receive them prior to the epidural. Therefore, patients are able to not only consent to the pain-relieving procedure of the epidural under the effects of other pain medication, but they are also able to determine whether they are satisfied with the informed consent process.

### Patient Information Seeking Behavior

Patients usually engage in information seeking behavior to meet a specific need. That need is most frequently to address an immediate health concern that the patient is facing. Generally speaking, a patient's information seeking behavior is motivated by the same need as any individual in a situation of information need - the reduction of uncertainty (Wilson, Ford, Ellis, Foster, & Spink, 2002). According to Harris (1998), decision-making is tied to the reduction of uncertainty, and for the patient who is faced with some type of medical decision, "Decision-making is the process of sufficiently reducing uncertainty and doubt about alternatives to allow a reasonable choice to be made from among them" (¶ 3). Information seeking behavior is important to review in the context of this study because it is now an imperative of the health care industry and society as a whole to have educated patients who can participate in the care decisions that are made for and with them.

Information seeking behavior is defined in various ways that all have the same central theme. An early definition by Krikelas in 1983 (as cited in Mahapatra & Panda, 2001), refers to "any activity of an individual that is undertaken to identify a message that satisfies a perceived need" (p. 125). In 1999, Wilson proposed a problem-solving model as a way to define information seeking behavior (as cited in Wilson, et al, 2002).

He suggests that information seekers are, in fact, behaving in a manner that would suggest that they have an informational goal in mind and that they seek information to fulfill that goal and thus resolve their information need. Determining why information is being sought is part of creating the informational goal.

Individuals seek information for varying reasons. Their motivations may be a result of an ongoing situation or a one-time, immediate need. These are referred to as continuous or discrete (Mahapatra & Panda, 2001). When a patient is dealing with a systemic disease such as diabetes, that can be present for a long time, the information need is considered continuous because information is necessary on an ongoing basis to manage and be informed about the disease. If a patient is facing a one-time procedure such as the removal of the gall bladder, the information need is discrete because an individual only has one gall bladder. This procedure can only be performed once. It is also instructive to identify the information that is necessary and know the situation that would cause an individual to seek it in the first place.

Information seekers go about looking for information because they find themselves in a situation that calls for knowledge or information that they lack. There is a need present that cannot be filled from the individual's store of personal knowledge. This lack of information creates dissonance within the individual, something social psychologist Leon Festinger called cognitive dissonance (as cited in Griffin, 2006). According to Festinger, this is a feeling that people have when they "find themselves doing things that don't fit with what they know, or having opinions that do not fit with other opinions they hold" (as cited in Griffin, 2006, p. 228). In the case of patients with long-term or short term medical conditions, the lack of knowledge or information about

the condition they are facing creates a need to discover and add that information so they can move forward and make appropriate decisions about the necessary treatment. The essential parts of the information seeking equation are the recognition of the need for information that the seeker is lacking and that the information is relevant and meets the needs of the seeker.

### Information Relevance for the Patient

According to Saracevic (2007), relevance is one of the most important areas of study in the field of Information Science. He states, "All Information Relevance (IR) and information seeking models have relevance at their base either explicitly or as an invisible hand – in effect they are relevance models" (Saracevic, 2007, p. 1928). Saracevic (2007) goes on to say that "relevance does not have to be explained; it is universally understood" (p. 1918). Most people understand that if they get the information that meets their need, that information is considered to be relevant. Although there are many manifestations of relevance, according to authors such as Borland, Wilson, Cosijn and Ingwersen, to name a few, the main manifestations can be distilled down to the following five: system, topical, cognitive, situational and affective (as cited in Saracevic, 2007). The medical patient would find him or herself concerned with all five.

Wilson's concept of situational relevance is particularly applicable in the world of patient information seeking as a means to finding relevant information. Wilson describes situational relevance as the information seekers' ability to use their own store of personal knowledge and their immediate informational need to evaluate the relevance of information they find (Wilson, 1973).



The most important activity for this type of information seeker is to interface with an information system in such a way that the information found is pertinent to the need or task at hand and makes sense to the seeker in keeping with his or her sphere of knowledge. Relevance will allow that individual to use the information to reduce his or her anxiety and uncertainty about the healthcare situation and ultimately make a decision that is in keeping with his or her life and goals. The most difficult part of relevance for the patient is recognizing what information he or she might need before actually seeking that information. If an individual doesn't know what information is needed then recognition of relevant information is impossible.

### Patient Information Needs

For years, patients did not have a choice about the medical information they received from their physician. Most medical students were taught that the doctor knows best, and also knows what information should be given to the patient. This was called the paternalistic model of communicating information (ACOG, 2004). Using this model, an anesthesiologist would suggest that a laboring woman receive a spinal anesthetic for labor pain, without offering any information on other alternatives. Prior to the 20<sup>th</sup> century, this was considered to be an ethical and compassionate choice for delivering information to the patient. Common thinking was that too much of a burden would be placed on the patient if they had to make an important medical decision themselves (Hoehner, 2003). Clearly, in this age of easy access to medical information on the Internet and an emphasis on the autonomous patient, this model of meeting patient information needs is outdated.

An analysis of data from the Health Information National Trends Survey collected

in 2003 (Hesse, Nelson, Kreps, Croyle, Arora, Rimer, & Viswanath, 2005) shows that not only are more people in the US connected to and using the Internet, but that 63.7% of the population looked for health information for themselves or someone else. Those who searched online for this type of information tended to be younger (18-34 and 35-64 years of age), female, better educated with higher incomes and tended to put a great deal of trust in the information they found from Internet sources. Individuals “in the 18-34 age group were also almost 9 times more likely to go to the Internet first before going to providers” (Hesse, et al., 2005, p. 2621). In spite of this fact, 49% of responders would prefer to get information from their health care provider first.

Because of the strong inclination for patients to look for health information online, there has been a proliferation of health care websites, such as WebMD, which offer authoritative information on health issues ranging from the common cold to incurable cancers and have allowed patients to acquire information that was not available to them five or ten years ago. Patients can research their diseases and medical conditions using government, health care institution and insurance web sites and search engines. This information that they gather can be confusing for patients and it is incumbent on the treating physician to discuss and clarify this information with the patient, not dismiss it as irrelevant (Neuberger, 2000). Physicians are clearly still the most trusted interpreter of medical information. This can be seen by the fact that the responders who used online sources the most (young, female, educated) were the ones who rated their physicians most highly in the area of trusted information sources (Hesse, et al., 2005). Physicians must recognize and accept this change in information needs of their patients and be willing to discuss and interpret all outside information brought into the medical

encounter.

Current research in the area of patient information needs regarding informed consent for obstetric anesthesia has revealed that most patients received the majority of their information from the treating anesthesiologist or from a prenatal course (Pattee et al., 1997). Patients wanted to be informed about all complications, no matter how severe; this desire was also independent of a patient's educational level (Pattee et al., 1997). Many authors have noted this desire for as much information as possible, in spite of the fact that patients may not ask for it (Roter, et al., 1987). Other research in the area of disclosure of risks and benefits of epidural analgesia points to the facts that physicians should be willing to be partners with patients in the information discussion and pain management decision, but that the physician can not expect the patient to have the same level of understanding as they do (Hoehner, 2003). In another study on what laboring women want to know about epidural analgesia, results were clear that they wanted all risks disclosed during the informed consent process but did not want to know the specific incidences of those risks (Jackson, Henry, Avery, VanDenKerkhof & Milne, 2000). Finally, research by Bethune, Harper, Lucas, Robinson, Cox, Lilley and Yentis (2004) determined that the informed consent process should be tailored to the type and amount of information that the patient wants; they found that women receiving epidural analgesia in different hospital centers and settings had varying needs from full disclosure of every risk to minimal disclosure. In general, patients would like to be informed to the extent of their subsequent experience therefore giving full disclosure of risks and benefits will satisfy that need (Chapman & Wolff, 2002). It is clear that the obstetrics patient (generally young and in reasonably good health) is highly motivated

and desires as much information about risk as is available and the anesthesiologist should provide that information (Kelly, Blunt, Moore, & Lewis, 2004). According to Roter et al., (1987), there is a strong indication that providing information to patients can have therapeutic effects such as “shortened hospital stays, decreased use of analgesics, and reduced pain and anxiety, among others” (p. 449). They go on to note positive correlations between giving information to patients and their satisfaction with their care. If the patient gets the type of information about her obstetric pain relief that she wants and needs, then satisfaction with the procedure may be the result.

### Patient Satisfaction

There was little research in the area of patient satisfaction prior to the early 1980s. Because of the emergence of the Health Maintenance Organization (HMO) and managed care, as well as a move to a more consumer-oriented focus on healthcare, measuring satisfaction of patients became important (Thiedke, 2007). Patient satisfaction is frequently defined as “the extent of an individual’s experience compared with his or her expectations” (Asadi-Lari, Tamburini, & Gray, 2004, ¶ 11). Satisfied patients are more likely to be active participants in their healthcare, comply with treatment and stay with the same healthcare provider, establishing a consistent and long-term relationship (Thiedke, 2007; Asadi-Lari et al., 2004). According to Theidke (2007), higher rates of patient satisfaction are related to age (older patients are more satisfied), better health status, time spent with the physician during the office visit (more is better) as well as the inclusion of the patient in the decision-making process. Patients are also more satisfied if the diagnosis and treatment are appropriate and result in the patient getting well. Lower rates of satisfaction are related to ethnicity, socioeconomic

status, uncontrolled chronic disease and unmet expectations (Theidke, 2007).

Physicians who ascertain their patients' expectations before the office visit can better meet those expectations, resulting in a more satisfied patient or customer population.

### *Patient Satisfaction as Customer Satisfaction*

Patient satisfaction has its theoretical foundation in consumer or customer satisfaction. Oliver (1980), in his research that proposed a model for the expectation disconfirmation theory, states that researchers in the fields of social and applied psychology (prior to his own) agree "that satisfaction is a function of an initial standard and some perceived discrepancy for the initial reference point" (p. 460). In other words, "expectations ...create a frame of reference about which one makes a comparative judgment" (p. 460). Disconfirmation is the "mental comparison of an actual state of nature with its anticipated probability" (p. 35). The consumer uses expectations and perceptions to make an evaluative judgment and decision about the quality of a product or service. If the perception is greater than expectations, a positive disconfirmation has occurred; if perceptions are below expectations, then a negative disconfirmation is the result. When perceptions equal expectations, a zero disconfirmation (or confirmation) occurs (Weiss, Feinstein, & Dalbor, 2004). Expectations of a product or service can be considered to be what normally would be present or consistent with that product or service. Perceptions focus on the subjective thoughts or judgments that occur while the product or service is actually being used (Weiss, et al., 2004). Satisfaction is achieved when a customer expects a product or service to be a certain thing and, to the customer, it actually is that thing.

Satisfaction can also be evaluated by using the three-factor theory (Matzler &

Sauerwein, 2002). This theory gained acceptance in the early 1980's when it was adapted from job satisfaction theory. This theory states there are three distinct factors that are part of satisfaction. These factors include basic factors (dissatisfiers), excitement factors (satisfiers), and performance factors (hybrids) (Fuller & Matzler, 2008).

According to Fuller and Matzler (2008), basic factors are “minimum requirements that cause dissatisfaction if not fulfilled but do not lead to customer satisfaction if fulfilled or exceeded” (p. 117). These are requirements that are expected by the customer and are taken for granted. In the epidural process, the patient, as the customer would require a clean environment, technical skill proficiency of the anesthesiologist and timely pain intervention and would take these things for granted. If these requirements are not present, the patient will have a high level of dissatisfaction. Their presence will not, however, have an effect on satisfaction.

According to Fuller and Matzler (2008) excitement factors are “the factors that increase customer satisfaction if delivered but do not cause dissatisfaction if they are not delivered” (p. 117). These are things that are not expected by the customer and when they are received, have a positive impact on satisfaction. If a patient receives an extra amount of attention and care from her anesthesiologist during the epidural process and after the epidural is given, the extra care and attention are considered excitement factors and will increase the patient's satisfaction with the process. Not receiving them will not cause her to be dissatisfied.

Fuller and Matzler (2008) say performance factors “are directly connected to customers' explicit needs and desires” (p. 117). Customers make these needs known in

a very explicit manner; therefore, companies know and can meet these needs in order to compete for customers and increase their satisfaction. Patients may not have the ability to voice performance factors in the epidural process if they have never had an epidural. Patients do want and voice their need for pain relief, and this may be considered a performance factor in their satisfaction.

### *Satisfaction and Quality of Care*

The medical industry is no different than any other industry in that it has products and services and offers these to consumers or patients. Physicians must concern themselves with the satisfaction of their patients not only for ethical reasons, but also for repeat business – the maintenance and continuity of their patient population. Therefore, physicians in a specialty such as anesthesiology must know their patients' satisfaction factors and their type in order to provide the best quality of care.

The evaluation of patients' satisfaction with the healthcare they receive is an effective and useful tool in assessing quality of medical services (Jenkinson, et al., 2002). As previously noted, according to (Capuzzo, Gilli, Paparella, Gritti, Gambi, Bianconi, Giunta, Buccoliero and Alvisi (2007) patient satisfaction can be defined as “the balance between expectations and perception of what was received” (p. 435). Quality of care has become a measure used by both the federal government and insurance companies in setting reimbursement rates for healthcare providers (Zhang, 2006). Because this has become a very important issue, the importance of patient satisfaction with the informed consent process in obstetric anesthesia has also become a subject of research. Pattee et al. (1997) surveyed 60 patients who received an epidural for labor pain. The patient sample was randomly chosen over the course of a

year. Among other findings, “36% of patients were not satisfied with the oral informed consent” (p. 921), which was the type of informed consent given for epidural analgesia in the testing facility. Patients place a high value on the communication of health information, more so than physicians. In fact, “a lack of information was a major cause of patient dissatisfaction.” (Durieus, Bissery, Dubois, Gasquet, & Coste, 2004, p. 201). These studies, coupled with the fact that health care is becoming more patient-centric give an indication as to why quality care has become so important to providers and to those who pay for care.

Most studies that researched the informed consent process and associated problems such as risk recall and patient satisfaction came to the conclusion that further research was needed on the modality of the informed consent and the timing of the delivery of informed consent information (Pattee et al., 1997; Gerancher et al., 2000; Swan & Borshoff, 1994; Jackson et al., 2000; White, et. al., 2003; Bethune et al., 2004). The next logical step in the research on informed consent for epidural analgesia is to look at the amount, modality and timing of the information given to patients and to evaluate whether the information received by the patient has an effect on her satisfaction with the analgesic process.



## CHAPTER 3

### METHODOLOGY

This study involved the patient population of , MD, Alan Cowan, MD, and Rebecca Robert, MD, who practice Obstetrics and Gynecology in a partnership at the Baylor Grapevine Hospital and the Grapevine Division of Pinnacle Anesthesia Consultants. The study assessed whether patients are satisfied with the information they are getting from the anesthesiologists in the informed consent process. Communication of risks and benefits, information needs and information seeking behavior are part of this process.

This group of anesthesiologists has noted anecdotally that many obstetric patients who request pain relief in the form of an epidural do not have much prior information about the procedure and are not well-informed as to the specific risks and benefits of epidural analgesia. The current method of delivering informed consent by this group is a verbal informed consent discussion with the patient immediately prior to the insertion of the epidural. These anesthesiologists plan to supplement this method of informed consent with a detailed, written document, given to every patient at least one month prior to her due date, whether they plan on epidural analgesia or not. The document also contains supplemental information that can be found on the Internet, the library or in bookstores. This supplement to the informed consent process is the treatment or intervention in this study and was handed out to patients from December 10, 2007 to April 28, 2008.

This study surveyed two groups of obstetric patients: the first (control) group received their informed consent in its current form, given by the attending

anesthesiologist. The current informed consent consists of a general surgical consent form that does not list any risks or benefits of obstetric anesthesia/analgesia. The patient signs this document when she enters the hospital. The patient also receives a verbal explanation of the main risks of the procedure immediately prior to the insertion of the epidural. The attending anesthesiologist gives this explanation of risks and benefits to the patient. This process is the current practice standard for informed consent for epidural analgesia. The second group (treatment group) received the new additional informed consent document at 36 weeks of gestation (their 8 month obstetric appointment) as well as the verbal informed consent given immediately prior to the epidural. The nurse at the obstetric office handed the informed consent document to the patient. Both groups of patients received the same survey document from one to nine months post-delivery. Study participants also had the option of filling out and submitting the survey online through a secure University of North Texas (UNT) server. This was offered to capture as many types of responders as possible. There were 198 surveys mailed with 75 returned. Collection and analysis took approximately five months. The study, cover letter and survey instrument were initially approved by the UNT Institutional Review Board (IRB) (Appendix A) on October 31, 2007 and modifications were approved on January 29, 2008.

### The Patient Questionnaire

The survey or patient questionnaire (Appendix B) was designed by me and has been reviewed by five anesthesiologists for question clarity and relevance. It was also tested on a group of 10 women who have been through the labor and delivery process to evaluate whether the questions are understandable and make sense in relation to the

labor and delivery experience.

The survey contains three demographic questions pertaining to age, education level and language. Six questions deal with general labor and delivery information. Five questions focus on the subject of the patient's most recent labor epidural, its effectiveness and the patient's expectations of that effectiveness. These questions specifically evaluate patient satisfaction with the labor epidural, because satisfaction is based on how well expectations are met. There are four questions pertaining to how or if the patient gathered information about labor epidurals. Four questions are about how well or if the information given to the patient by the anesthesiologist was understood. Finally, there are two questions on the communication style of the patient, one question on the amount of information provided by the anesthesiologist to the patient and one question on the timing of the delivery of that information.

The printed survey was mailed to participants from the offices of Pinnacle Anesthesia Consultants to ensure patient privacy. Patients were told of the study and its purpose at that time and given assurances that no protected personal information will be used in the study. Participants mailed their completed survey back to Pinnacle to satisfy the privacy requirements mandated by the federal government or completed the survey online in an anonymous manner using a secure server. No identifiable patient information was gathered with the online survey. Health Insurance Portability and Accountability (HIPAA) rules and regulations were properly followed.

## Measures

### *Independent Variables*

Modality of Epidural Information (MEI): This was measured on a categorical

scale with two categories. The type of epidural information provided to the patient was recorded as either *verbal* or *verbal and written*. This measure was obtained from question 18 on the patient questionnaire.

Amount of Epidural Information (AEI): This was measured on a categorical scale with two categories. The patient's feelings about the amount of epidural information they received was recorded as *enough information* or *not enough information*. This measure was obtained from question 26, part e on the patient questionnaire.

Timing of Epidural Information (TEI): This was measured on a categorical scale with two categories. The patient's opinion about the best time to receive information about an epidural was recorded as *regular OB visit during the last month of pregnancy* or *not regular OB visit during the last month of pregnancy*. This measure was obtained from question 27 part c on the patient questionnaire.

### *Dependent Variable*

Fulfillment of Epidural Expectations (FEE): This was measured on a categorical scale with 2 categories. The extent to which the patient's expectations about the epidural process were met was recorded as *my expectations were not completely met* or *my expectations were completely met*. This measure was obtained from question 13 on the patient questionnaire.

The, *my expectations were not met at all* and *my expectations were partially met* responses were combined into one category: *my expectations were not completely met*.

## Research Questions

1. Is there a relationship between the extent to which the patient's expectations about the epidural were fulfilled (FEE) and the modality of the epidural information (MEI)?
2. Is there a relationship between the extent to which the patient's expectations about the epidural were fulfilled (FEE) and the amount of the epidural information (AEI)?
3. Is there a relationship between the extent to which the patient's expectations about the epidural were fulfilled (FEE) and the timing of the epidural information (TEI)?

## Data Analysis

The study's research questions deal with combinations of the survey question topics. Research Question 1 combines patient expectations of the epidural with the type of information provided from the informed consent. The second research question is more specific as to the amount of information given in the informed consent with patient satisfaction with the epidural. The final research question deals with the timing of the information on epidural analgesia with the patient's satisfaction with the epidural. In general, all of the research questions deal with patient satisfaction or expectations with the labor epidural and whether the type, amount and timing of the information had an effect on that satisfaction.

"Data from the laboratory and the field have shown that both expectation and disconfirmations affect post-exposure product reactions; specifically, in investigations where expectations have been manipulated or measured prior to product exposure,

significant expectation effects have been observed consistently” (Oliver, 1980, p. 461). This statement on customer satisfaction is one of the reasons for the conjecture that early information intervention will have an effect on a patient’s expectations of the epidural process.

All statistical analyses were performed using SPSS™<sup>1</sup> for Windows and Mac. The study sample was described using the mean, standard deviation and range for continuous scaled variables and frequency and percent for categorical scaled variables. All of the analyses were two-sided with a 5% alpha level.

Question 13 on the patient questionnaire was used to measure the dependent variable, fulfillment of epidural expectations. Question 13 has three response choices: *my expectations were not met at all*, *my expectations were partially met*, and *my expectations were completely met*, which indicates multinomial logistic regression was indicated for testing research questions 1-3. However, inspection of the data revealed that only one patient stated their expectations were not met at all and only seven patients stated their expectations were only partially met while 67 patients stated their expectations were completely met. As a rule of thumb, Peduzzi, Concato, Kemper, Holford and Feinstein (1996) recommends that the smaller of the categories of the dependent variable (e.g. those whose expectation were not met at all) have at least 10 events per independent variable in the model. Therefore, the sample data were not appropriate for a multinomial logistic regression model.

In considering alternative analyses more suitable to the sample data, binary logistic regression was considered. For example, by combining the one patient that

---

<sup>1</sup> SPSS Inc., <http://www.SPSS.com>

reported their expectations were not met with the seven patients that reported their expectations were partially met, a total of eight patients in the *expectations not completely met* and 67 patients in the *expectations completely met* could be achieved. However, this strategy still falls short of the recommended 10 cases in the smaller of the two groups per independent variable in the model. In addition, logistic regression is a maximum likelihood method of analysis that relies on large sample sizes for asymptotic assumptions to be satisfied. Therefore, binary logistic regression was not appropriate for the sample data.

Fisher's Exact Test is a method that does not rely upon large sample asymptotic assumptions and is ideally suited to small sample sizes. In particular, the Fisher's exact test is indicated for testing cross-classification tables when one or more expected cells counts are less than five. Thus, research questions 1-3 were answered using cross-classification tables with Fisher's Exact Tests. The dependent variable was first converted to a two category variable by combining the one patient that reported their expectations were not met with the seven patients that reported their expectations were partially met to create a total of eight patients in the *expectations not completely met* group and 67 patients in the *expectations completely met* group.

CHAPTER 4  
RESULTS

Surveys for this study were mailed out beginning on February 15, 2008 and continuing through March 15, 2008, for a total mailing of 195. Five surveys were returned unopened, 72 returned through the mail and three were filled out using the online survey form for a total of 75 completed surveys and a response rate of 39%, taking into account the unopened returned surveys. The aggregate responses for each individual question in the survey are found in the frequency tables (Appendix C).

Survey responders were all female English speakers with an average age of 31.6 years, with a range from 19 to 45. All responders had delivered their most recent baby between one and nine months prior to completing the survey (Table 1).

Table 1  
*Responder Age and Delivery of Most Recent Baby*

	N		Mean	Std. Deviation	Minimum	Maximum
	Valid	Missing				
Age	75	0	31.61	4.623	19	45
When did you deliver most recent baby	75	0	3.44	2.068	1	9

Responders were mostly educated beyond the high school level, with 69.3% having an undergraduate degree, coursework beyond their undergraduate degree or a Master's degree or higher (Table 2).



Table 2

*Education Level*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	High School diploma or GED	4	5.3	5.3	5.3
	Some college coursework	19	25.3	25.3	30.7
	College degree (BS, BA or equivalent)	37	49.3	49.3	80.0
	Coursework beyond Undergraduate degree	7	9.3	9.3	89.3
	Masters Degree or higher	8	10.7	10.7	100.0
	Total	75	100.0	100.0	

Approximately one third of the patient responders had most recently delivered their first baby, and were equally likely to be treated by a male or female Obstetrician, and had a range of between one and five children. One third of the responders said this was their first labor epidural (Tables 3, 4 and 5).

Table 3

*OB Gender*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	male	51	68.0	68.0	68.0
	female	24	32.0	32.0	100.0
	Total	75	100.0	100.0	

Table 4

*Number of Children*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	25	33.3	33.3	33.3
	2	34	45.3	45.3	78.7
	3	12	16.0	16.0	94.7
	4	3	4.0	4.0	98.7
	5	1	1.3	1.3	100.0
	Total	75	100.0	100.0	

Table 5

*First Labor Epidural*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	26	34.7	34.7	34.7
	No	49	65.3	65.3	100.0
	Total	75	100.0	100.0	

Patient responders were approximately split between delivering by cesarean section or vaginally with the greatest percentage having an outcome of a healthy baby while staying healthy as well (Tables 6 and 7).

Table 6

*Type of Delivery*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	vaginal delivery	40	53.3	53.3	53.3
	cesarean section	35	46.7	46.7	100.0
	Total	75	100.0	100.0	

Table 7

*Outcome of the Delivery*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	healthy baby and healthy mom	61	81.3	81.3	81.3
	healthy baby and complications with the mom	4	5.3	5.3	86.7
	complications with the baby and healthy mom	8	10.7	10.7	97.3
	complications with the baby and complications with the mom	1	1.3	1.3	98.7
	No response	1	1.3	1.3	100.0
	Total	75	100.0	100.0	

When questioned on their expectations of the epidural prior to receiving it, the greatest percentage of patients expected to be pain free, with some pressure or squeezing

during delivery, with the second highest percentage of patients reporting that they expected some pain with some pressure or squeezing during delivery (Table 8).

Table 8

*Expectations of Effectiveness of Epidural*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	pain free, no sensation	14	18.7	18.7	18.7
	pain free, some sensation such as pressure or squeezing	42	56.0	56.0	74.7
	some pain, some sensation such as pressure or squeezing	18	24.0	24.0	98.7
	very little pain relief, a lot of sensation such as pressure or squeezing	1	1.3	1.3	100.0
	Total	75	100.0	100.0	

Patients overwhelmingly reported that their epidural worked very well, 88 percent being pain free. 89.3 percent said their expectations of the epidural process were completely met and 9.3 percent said their expectations of the epidural process were partially met (Tables 9 and 10).

Table 9

*How Well Did the Epidural Work*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	did not work, minimal pain relief	2	2.7	2.7	2.7
	provided partial pain relief	7	9.3	9.3	12.0
	provided complete pain relief	66	88.0	88.0	100.0
	Total	75	100.0	100.0	

Table 10

*Were Expectations of the Epidural Met*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	my expectations were not met at all	1	1.3	1.3	1.3
	my expectations were partially met	7	9.3	9.3	10.7
	my expectations were completely met	67	89.3	89.3	100.0
	Total	75	100.0	100.0	

Only 18 of 75 responders reported attending childbirth education classes and of them only two indicated that they did not receive enough information during the classes (Tables 11 and 12).

Table 11

*Attended Childbirth Education Classes*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	18	24.0	24.0	24.0
	no	57	76.0	76.0	100.0
	Total	75	100.0	100.0	

Table 12

*Amount of Information from Education Classes*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid					
	a little, but I wanted more	1	5.5	5.5	5.5
	a little, but it was enough	9	50.0	50.0	55.5
	a lot, but I wanted more	1	5.5	5.5	61.0
	a lot, but it was enough	7	39.0	39.0	100.0
	Total	18	100.0	100.0	

Of the 75 survey responders, 24 received a verbal informed consent discussion, while 51 received both the written informed consent document and a verbal informed consent discussion (Table 13).

Table 13

*Type of Informed Consent*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	a verbal explanation at the time of the epidural	24	32.0	32.0	32.0
	a written document given to you before you went into the hospital and a verbal explanation at the time of the epidural	51	68.0	68.0	100.0
	Total	75	100.0	100.0	

Of those responders who received both the written informed consent document and the verbal explanation, 11 said they read the document completely and 28 said they skimmed it for a total of 39 patients, or 76%, who reported looking at the document in some manner. Thirty-three (or 65%) responded that they understood the document and one (or 2%) responded that she did not understand it. Thirty patients responded that the document contained enough information for them to make a decision about whether or not to have an epidural and eight patients reported looking for more information after receiving the informed consent document. The top four sources of information that patients reported using were their current or past OB/GYN (26), friends (25), family members (18) and Internet websites (14). Patients reported that they overwhelmingly understood what the Anesthesiologist told them (92%) and those who did not understand were either distracted (2.7%) or unable to understand because of pain (5.3%). Language and medical terms were no barriers to patients' understanding. Patients reported being very comfortable asking questions of their doctors (89.3% very

comfortable and 9.3% somewhat comfortable – 98.7% cumulative). Most patients did not have questions for the anesthesiologist after the verbal informed consent explanation (62.7%) and most of those that had questions reported that they asked their questions and they were answered by the anesthesiologist (32%).

#### Problems with the use of Multinomial Logistic Regression

The study was originally designed with the intention of using multinomial logistic regression to answer the three research questions. However, as discussed in the revised data analysis plan, the sample data were not suitable for multinomial logistic regression. To further demonstrate this, a multinomial logistic regression analysis of fulfillment of epidural expectations (dependent variable) versus modality of epidural information (independent variable) was performed.

Table 14 shows that SPSS™ produced a warning message indicating the validity of the model is uncertain. Table 15 shows that p-values for the model parameters could not be computed, as indicated by the ‘.’ in the column labeled *Sig.* Table 16 shows why these errors occurred; there is a *0 cell* problem. This means, there were no patients in the *verbal and written* consent group that stated, *my expectations were not met at all.* Multinomial logistic regression requires that all cells be non-zero, and even then, there should be at least 10 patients in each cell. Therefore, this analysis confirms that the sample data were unsuitable for multinomial logistic regression analysis.



Table 14

*Warnings*

Unexpected singularities in the Hessian matrix are encountered. This indicates that either some predictor variables should be excluded or some categories should be merged.

The NOMREG procedure continues despite the above warning(s). Subsequent results shown are based on the last iteration. Validity of the model fit is uncertain.

Table 15

*Parameter Estimates*

		B	Std. Error	Wald	df	Sig.	Exp(B)	95% Confidence Interval for Exp(B)	
								Lower Bound	Upper Bound
Were your expectations of the epidural met <sup>a</sup>									
my expectations were not met at all	Intercept	-23.272	1.026	514.494	1	0.000			
	[Typeofconsent=1]	20.327	0.000		1		6.730E8	6.730E8	6.730E8
	[Typeofconsent=2]	0 <sup>b</sup>			0				
my expectations were partially met	Intercept	-2.773	0.595	21.705	1	0.000			
	[Typeofconsent=1]	1.214	0.810	2.246	1	0.134	3.368	0.688	16.492
	[Typeofconsent=2]	0 <sup>b</sup>			0				
a. The reference category is: my expectations were completely met.									
b. This parameter is set to zero because it is redundant.									

Table 16

*Type of Informed Consent - Were Your Expectations of the Epidural Met / Crosstabulation*

Count		Were your expectations of the epidural met			Total
		my expectations were not met at all	my expectations were partially met	my expectations were completely met	
Type of informed consent	a verbal explanation at the time of the epidural	1	4	19	24
	a written document given to you before you went into the hospital and a verbal explanation at the time of the epidural	0	3	48	51
Total		1	7	67	75

Because of the small sample size that reported a negative response for the dependant variable, Fisher’s Exact test was used to show a relationship between the independent variables and the dependant variable.

#### Research Question 1

Table 17 is a cross-classification table that shows the percentage of study participants that reported their expectations were completely met, separately for those who received only a verbal explanation at the time of the epidural and those who received a written document and verbal explanation. Table 18 shows there is not a statistically significant difference in the percent that reported their expectations were completely met between the two groups,  $p=0.10$ .

Table 17

*Type of Informed Consent - Were Your Expectations of the Epidural Met / Crosstabulation*

			Were your expectations of the epidural met		Total
			My expectations were not completely met	My expectations were completely met	
Type of informed consent	A verbal explanation at the time of the epidural	Count	5	19	24
		% within Type of informed consent	20.8%	79.2%	100.0%
	A written document and verbal explanation	Count	3	48	51
		% within Type of informed consent	5.9%	94.1%	100.0%
Total		Count	8	67	75
		% within Type of informed consent	10.7%	89.3%	100.0%

Table 18

*Fisher's Exact Test for Type of Informed Consent*

	Exact Sig. (2-sided)
Fisher's Exact Test	0.101

Additionally, patients who received the written risk/benefit document along with the verbal informed consent discussion did not have more appropriate expectations of the epidural process than those who only received the verbal informed consent discussion. Of those patients who received both the written document and verbal explanation, 76.5% fell in the two middle categories (pain free, some sensation and some pain, some

sensation), which are the most common pain relief outcomes and are discussed in the written risk/benefit document. The patients who only received the verbal explanation had an 87.5% chance of falling in the same two categories. Patients who received an epidural for the first time had an 81% chance of falling into the two middle categories for expectations prior to receiving the epidural as compared to those who had previously received an epidural. This group had a 79.5% likelihood of falling into the two middle categories regarding their expectations prior to receiving the epidural.

## Research Question 2

Table 19 is a cross-classification table that shows the percentage of study participants that reported their expectations were completely met, separately for those who felt the amount of information during the informed consent was enough versus those who did not feel the information was enough. Table 20 shows there was not a statistically significant difference in the percent that reported their expectations were completely met between the two groups,  $p=0.47$ .

Patient responders did report being either satisfied (38 out of 75) or very satisfied (31 out of 75) with the amount of information in the informed consent. Four responders indicated that they did not receive enough information or too much information in the informed consent while 29 reported that they received enough information.

Table 19

*Amount of Information during Informed Consent - Enough Information - Were Your Expectations of the Epidural Met / Crosstabulation*

			Were your expectations of the epidural met		Total
			My expectations were not completely met	My expectations were completely met	
Amount of info during informed consent - enough information	yes	Count	2	27	29
		% within Amount of info during informed consent - enough information	6.9%	93.1%	100.0%
	Response not chosen	Count	6	40	46
		% within Amount of info during informed consent - enough information	13.0%	87.0%	100.0%
Total	Count		8	67	75
	% within Amount of info during informed consent - enough information		10.7%	89.3%	100.0%

Table 20

*Fisher's Exact Test for Amount of Information*

	Exact Sig. (2-sided)
Fisher's Exact Test	0.473

Research Question 3

Table 21 is a cross-classification table that shows the percentage of study

participants that reported their expectations were completely met, separately for those who felt the best time to receive epidural information was at the obstetric visit the last month of pregnancy versus those who did not feel that was the best time to receive the information. Table 22 shows there was not a statistically significant difference in the percent that reported their expectations were completely met between the two groups,  $p=0.43$ .

Table 23 shows the break down of responses to the question: *When is the best time to receive epidural information?* Responders could select any that apply. The most frequently selected response was the last month of pregnancy, with a total of 50 positive responses.

Table 21

*Best Time to Receive Epidural Information - Ob Visit Last Month of Pregnancy - Were Your Expectations of the Epidural Met / Crosstabulation*

			Were your expectations of the epidural met		Total
			My expectations were not completely met	My expectations were completely met	
Best time to receive epidural information-Ob visit last month of pregnancy	yes	Count	4	46	50
		% within Best time to receive epidural information-Ob visit last month of pregnancy	8.0%	92.0%	100.0%
	no	Count	4	21	25
		% within Best time to receive epidural information-Ob visit last month of pregnancy	16.0%	84.0%	100.0%
Total		Count	8	67	75
		% within Best time to receive epidural information-Ob visit last month of pregnancy	10.7%	89.3%	100.0%

Table 22

*Fisher's Exact Test for Best Time to Receive Information*

	Exact Sig. (2-sided)
Fisher's Exact Test	0.429

Table 23

*The Best Time to Receive Epidural Information*

---

Prenatal class	19
Regular OB visit, beginning of pregnancy	12
Regular OB visit during last month of pregnancy	50
Admission to hospital for delivery	9
Immediately prior to receiving epidural	8

---

Patients who reported receiving a labor epidural for the first time had approximately the same satisfaction and dissatisfaction rates as those who had previously received an epidural for labor and delivery (Table 24).

Table 24

*Patient Expectations and First Labor Epidural*

			Were your expectations of the epidural met		Total
			My expectations were not completely met	My expectations were completely met	
First labor epidural	yes	Count	3	23	26
		% within First labor epidural	11.5%	88.5%	100.0%
	no	Count	5	44	49
		% within First labor epidural	10.2%	89.8%	100.0%
Total		Count	8	67	75
		% within First labor epidural	10.7%	89.3%	100.0%

## Relationship between Education and Satisfaction

Only four study participants reported an education level of high school or GED, therefore, those participants were combined with the 19 study participants who reported that they had some college coursework (Table 2).

Table 24 is a cross-classification table that shows the percentage of study participants that reported their expectations were completely met, separately for the four different education groups. Table 25 shows there was not a statistically significant difference in the percent that reported their expectations were completely met between the four groups,  $p=0.52$ .

Table 25

### *Education - Were Your Expectations of the Epidural Met / Crosstabulation*

		Were your expectations of epidural met		Total	
		My expectations were not completely met	My expectations were completely met		
Education	High school, GED or some college	Count	4	19	23
		% within Education	17.4%	82.6%	100.0%
	College degree (BS, BA, or equivalent)	Count	3	34	37
		% within Education	8.1%	91.9%	100.0%
	Coursework beyond undergraduate degree	Count	1	6	7
		% within Education	14.3%	85.7%	100.0%
	Masters degree or higher	Count	0	8	8
		% within Education	0.0%	100.0%	100.0%
Total		Count	8	67	75
		% within Education	10.7%	89.3%	100.0%



Table 26

*Fisher's Exact Test for Education and Expectations*

	Exact Sig. (2-sided)
Fisher's Exact Test	0.516

Relationship between Education and Amount of Information

Table 27 is a cross-classification table that shows the percentage of study participants that reported the amount of information they received was enough, separately for the four different education groups. Table 28 shows there was not a statistically significant difference in the percent that reported the amount of information they received was enough, between the four groups,  $p=0.56$ .

Table 27

*Education - Amount of Information during Informed Consent - Enough Information / Crosstabulation*

		Amount of info during informed consent - enough information		Total	
		yes	no		
Education	High school, GED or some college	Count	9	14	23
		% within Education	39.1%	60.9%	100.0%
	College degree (BS, BA, or equivalent)	Count	12	25	37
		% within Education	32.4%	67.6%	100.0%
	Coursework beyond undergraduate degree	Count	4	3	7
		% within Education	57.1%	42.9%	100.0%
	Masters degree or higher	Count	4	4	8
		% within Education	50.0%	50.0%	100.0%
Total		Count	29	46	75
		% within Education	38.7%	61.3%	100.0%

Table 28

*Fisher's Exact Test for Education and Amount of Information*

	Exact Sig. (2-sided)
Fisher's Exact Test	0.561

Relationship between Education and Timing of Information

Table 28 is a cross-classification that shows the percentage of study participants reporting that the best time to receive epidural information was at the obstetric visit during the eighth month of pregnancy, separately for the four different education groups.

Table 29

*Education - Best Time to Receive Epidural Information-OB Visit Last Month of Pregnancy Crosstabulation*

			Best time to receive epidural information-Ob visit last month of pregnancy		Total
			yes	no	
Education	High school, GED or some college	Count	12	11	23
		% within Education	52.2%	47.8%	100.0%
	College degree (BS, BA, or equivalent)	Count	28	9	37
		% within Education	75.7%	24.3%	100.0%
	Coursework beyond undergraduate degree	Count	5	2	7
		% within Education	71.4%	28.6%	100.0%
	Masters degree or higher	Count	5	3	8
		% within Education	62.5%	37.5%	100.0%
Total	Count	50	25	75	
	% within Education	66.7%	33.3%	100.0%	

Table 29 shows there was not a statistically significant difference in the percent that reported the best time to receive epidural information was at the obstetric visit the eighth month of pregnancy, between the four groups,  $p=0.30$ .

Table 30

*Fisher's Exact Test for Education and Timing of Information*

	Exact Sig. (2-sided)
Fisher's Exact Test	0.295

Patient Comments on Epidural Process

Patient comments were divided into two sections: Positive and Negative. The negative comments were further divided into two sections: Communication and Technical/Medical. The positive comments are all found in Table 31; the negative comments are found in Table 32. The comments of none or nothing (two responses of this type) were not included as they are neutral comments.

Table 31

*Positive Comments on the Epidural Process – Could Anything Have Been Done Better?*

1. Absolutely nothing!
2. Wonderful!!
3. Anesthesiologist did very well
4. Everything was great
5. He was perfect
6. My anesthesiologist made me feel completely safe. He answered all of my questions and eased my nervousness!
7. None – he did a great job
8. None – it was great
9. Nothing – my doctor was awesome
10. Nothing – they gave me stadol prior to the epidural which calmed me down – I was rather nervous about the epidural
11. Nothing everything went great

Table 32

*Negative Comments on the Epidural Process – Could Anything Have Been Done Better?*

---

Communication:

1. Ask me if I am feeling anything or let me know what to expect – all pain gone or could feel some
2. Could have been more understanding of how painful it was
3. I was so anxious I don't think anyone could have made me feel better about the sensations I felt on my stomach
4. I wish he would have told me signs to look for that the epidural wasn't working – (i.e. you should not feel the catheter [catheter] or feel the sensation of urinating – both which I felt)
5. Provide reassurance during the actual placement of epidural
6. Talk through the process of putting in catheter [catheter] better

Technical/Medical:

1. Be quicker in the prep. process
  2. Get epidural earlier in labor
  3. He had a hard time getting it in which caused pain after birth
  4. He had to insert the needle a second time for my spinal and it was painful because I had partial feeling on one side of my body
  5. Epidural wore off. It numbed my body up to my shoulders. I was not even able to hold my baby when she was born. I was given a dose of epinephrine [epinephrine] to help
  6. Make the process of getting the epidural less painful
  7. Position of patient- He had me sitting up which was horrible [horrible]
  8. Put it in the correct place the 1<sup>st</sup> time
-

## CHAPTER 5

### DISCUSSION

The analysis of the questionnaire responses given by patients who received epidural analgesia revealed some expected and unexpected results. While this is a very homogeneous patient population in age, education and language, it is also, in general, a very satisfied population as well. I will focus on this patient population as it is concerned with the main questions of the study: the type or modality of that information (whether it was verbal only or written and verbal), the amount of information given to the patient in the informed consent process, and the timing of the information given to the patient. For purposes of this discussion, patient satisfaction, as defined by Capuzzo, Gilli, Paparella, Gritti, Gambi, Bianconi, Giunta, Buccoliero, and Alvisi (2007), is achieved by meeting the patient's expectations of the treatment process in the way that fits with the patient's perceptions. Therefore, for patients, having expectations met and being satisfied are interchangeable.

#### Modality of Information

Patients in this study received the informed consent for their labor epidurals in one of two ways: a verbal explanation from the anesthesiologist immediately prior to the insertion of the epidural or a verbal explanation and a detailed written risk/benefit document prepared by the anesthesia group and handed out to the patient by her obstetrician at the 36 week check up. Of the returned surveys, 24 respondents received only the verbal consent, while 51 respondents reported receiving both the written risk/benefit document and the verbal consent discussion. (Approximately the same number of surveys were sent out to patients who got their epidurals prior to the

dissemination of the treatment document as were sent out after the treatment document was handed out at the obstetrician's office). When compared to satisfaction or expectation levels with the epidural process using the Fisher's Exact test to show a relationship, the 2-sided test resulted in a  $p$  value of 0.101, not significant at the 0.05 level. In spite of this statistical observation, there were a much greater percentage of patients who reported that their expectations were completely met (they were completely satisfied) in the population that received the written informed consent document, 94% satisfied, 6% unsatisfied as compared to those who only received the verbal explanation, 79% satisfied, 21% unsatisfied. According to Cohen (1988), this represents an effect size ( $W$ ) of 0.23, which is a small to medium effect size. The compelling question that arises from the effect size, or difference in the groups is whether this is practically meaningful. It may be more instructive to compare the percentages using a hypothetical sample size of 100 for each group. If there were 100 patients in the group that only received the verbal informed consent and 79 (79%) were satisfied compared to 100 patients who received both the verbal and the written informed consent document and 94 (94%) of those patients were satisfied, then this might seem to be a practically meaningful difference. The increase in satisfaction from the first group to the second may indicate that changing the informed consent process would be beneficial for patients. In spite of this observation, further study with a larger sample size may be warranted to see if the effect size increased. It was interesting to note the high percentage of patients whose expectations of the epidural process were met in spite of comments that indicated that some patients had to have reinsertion of the epidural catheter, some felt nervous, one had shaking, some had unexpected pain

on insertion of the catheter, to mention a few. The negative comments were either technical/medical in nature or dealt with communication issues. Of the unsatisfied patients, only one negative comment dealt with communication, the other seven comments were about technical or medical problems. Other patients gave positive comments, which are in keeping with their feelings of satisfaction.

Of those whose expectations were partially met or not met at all (eight responders or 10.7%), all eight reported expectations prior to the epidural that were in line with both the verbal explanation and the written risk/benefit document. Those choices were pain-free, no sensation; pain free, some sensation such as pressure or squeezing; and some pain, some sensation such as pressure or squeezing. None of the responders chose the last option, which was not part of the informed consent discussion or the risk/benefit document. Therefore, even though they were dissatisfied with the epidural process, they still had appropriate expectations prior to the procedure.

Patients can be satisfied with their epidural process in spite of having an adverse outcome with their delivery. This effect can be seen by cross tabulating the outcome of the delivery and the expectations met or not met categories. Of the eight responders whose expectations were not met, only two fell into the adverse outcome categories (complications with the baby, mom or both). Six of those responders had an optimal outcome of a healthy baby and mom. In the category of met expectations, or satisfaction, 55 of the responders had optimal delivery outcomes, while 11 had adverse delivery outcomes. In spite of a less than optimal delivery, these 11 still reported that their expectations of the epidural process were met, meaning that they were satisfied with the process.

Another issue worth consideration is whether there was a halo effect at work in the minds of the survey responders. This problem is typically seen and researched in conjunction with consumer satisfaction. Morris Holbrook (1983) says that these effects “may occur, for example, when overall preferences color belief ratings and thereby obscure the underlying role of perceptions as bases for brand evaluations” (p. 247). He goes on to say that “some halo effects may be subconscious in origin and may simply reflect the subject’s tendency to maintain cognitive consistency” (p. 247). Put in terms of a patient about to deliver a child, that patient may relate the epidural process with the success or outcome of the delivery itself. Met expectations (or satisfaction) is about evaluation and judgment on the part of the consumer (in this case, the obstetric patient), so confusing or merging the two processes at work – the epidural and the delivery – may be a typical response. Because some patients did not have an optimal delivery but still reported having their expectations met of the epidural process (11 responders), this halo effect may have been minimized.

#### Amount of Information

The survey also focused on patient information needs and whether they had enough information after getting the written risk/benefit document and the verbal consent information. Most patients reported that they were either satisfied or very satisfied with the amount of information they received in the informed consent with 92% choosing those responses (51% reported being very satisfied and 41% satisfied). Of the patients who received the written risk/benefit document (51 of the 75 respondents), 39 respondents reported either reading or skimming the document and 30 respondents reported that the document contained enough information for them to make a decision



about whether to have an epidural for labor and delivery. Only 8 respondents reported looking for more information after receiving the written risk/benefit document. Another component of the information seeking process to look at whether patients reported being comfortable asking their doctors questions if they did not understand the information or felt it was incomplete. Most patients reported understanding the information given in the verbal informed consent (92%) and of those who did not understand some of the information, the two reasons given were because of pain or other distractions (4- pain; 2- other distractions). Patients also reported being comfortable asking their doctors questions (98.7%) and of the 36% of patients that had questions after the verbal informed consent, 34.7% were comfortable enough with the communication process to ask those questions. While the Fisher's Exact test between the satisfaction levels with the amount of information patients received and their overall satisfaction levels with the epidural process was not significant at 0.47, the fact that a large percentage of patients were satisfied with the amount of information they received in the informed consent process is meaningful.

#### Timing of the Delivery of Informed Consent Information

Patients usually get information on pain relief during labor and delivery several times during the course of their pregnancy. Most obstetricians include the pamphlet on pain relief prepared by the American Society of Anesthesiologists, which provides a brief overview of a patient's options. Some first time mothers will attend prepared childbirth classes (18 out of 26 or 69% of first time mothers in this study reported attending) where they will get information about pain relief options. All patients have the opportunity to ask their obstetrician about pain relief options at some point during their

regular pre-natal visits as well. Participants in this study reported that they got information on epidural analgesia from their obstetrician (26), friends (25) and family (18). Only 14 patients in this study reported getting information from Internet websites. Many patients come to the hospital for the delivery of their baby knowing whether they want an epidural for pain relief. Receiving reliable information is imperative for the patient prior to the hospital admission in case a patient decides to get epidural analgesia even if that patient had decided against it prior to the onset of labor.

In spite of the fact that the Fisher's Exact test did not show a relationship between the timing of the information in the informed consent and a patient's satisfaction with the epidural process ( $p=0.429$ ), the greatest percentage of survey responders reported that the best time to receive information about labor epidurals was during the last month of pregnancy (67%). That particular question on the survey (the best time to receive information on labor epidurals) had a variety of responses, from receiving information at the beginning of pregnancy to receiving it immediately prior to the placement of the epidural by the anesthesiologist. It is interesting to note that each of the less popular responses got a minimum of 8 positive responses, with the second most frequently chosen response being information given during prenatal classes (19 positive responses). The different possible times for patients to receive labor epidural information involve a variety of healthcare providers, those being the patient's obstetrician, the teacher of the prenatal class, the hospital and the anesthesia provider. At every step of the process, it may be beneficial for the patient to be offered information on labor and delivery pain relief, whether they use that information or not. As one patient wrote in the comment section regarding the timing of this type of

information, “repetition is best, gives more time to absorb info. It worked for me.”

### An Optimal Process of Information Dissemination

In spite of the fact that there was not a definite relationship between the amount and the timing of information and satisfaction, there may be a relationship between receiving a written risk/benefit document and satisfaction with the epidural process, because of the much lower  $p$  value at 0.10 (when calculated using  $p$  at the 0.05 level). If the study was conducted in the same manner but measurements were calculated using a larger sample size, this statistic may end up being significant. It is important to remember that when a patient received that document, it was given at the 36-week prenatal appointment and contained very detailed information. Therefore, not only were they given additional detailed information in a written format, the timing of that information coincided with patient’s preference of when to receive this information, according to the survey responses. Modality, timing and amount of information were all part of the response on modality, indicating that all three things were part of the patient’s expectations of the epidural process being met and their resulting satisfaction.

An optimal, standard process for disseminating risk/benefit information as part of the informed consent process would be helpful in creating patients who are informed enough about their treatment options to be active participants in their own care. As these obstetric patients have indicated, having complete information about their pain relief choices offered before the onset of labor is preferred. This is in keeping with anecdotal information from a previous study (Pattee, Ballantyne, & Milne, 1997). In this particular patient population, because pregnancy lasts approximately 40 weeks, it is important for patients to get epidural information closer to the end of the pregnancy,

because the closer the patient gets to labor and delivery, the more attention she will pay to the process of the actual birth. In the early months of pregnancy, most women are facing the challenges of morning sickness and adjusting to the pregnancy itself. In a discussion of information timing with Barbara Buckley, a Physician's Assistant at Drs. Neal, Cowan and Robert's offices, noted that patients have indicated to her that they don't usually look at any of the pain relief information found in the new patient packet; patients generally have the most questions on that topic closer to their due dates. This population of patients should receive detailed risk/benefit information about all of their pain relief options a month before their due date. They will have time to review the information, ask questions and look for more information if required. They then have time to make a decision about pain relief during labor and delivery. If they choose an epidural or end up having one because of a cesarean section, they will know the risks and benefits before the procedure and what they hear from the anesthesiologist will not be new information, but a review of information they already received. Key to this process is written information given as practically early as possible, with time for discussion and further investigation. A step-by-step illustration of this process:

Step 1: Patient needs treatment for a healthcare problem

Step 2: Patient receives written information about treatment options from a trusted source (physician), taking time to absorb and reflect on the information and investigate further if necessary

Step 3: Patient engages in discussion with healthcare provider, getting and giving feedback on his/her options and desires for treatment with that provider

Step 4: Patient has enough information and can reach a treatment decision with his/her healthcare provider

Step 5: Patient receives treatment

In the case of epidural analgesia, a procedure (the actual placement of the epidural catheter with the injection of an analgesic for pain) is the focus of this informed consent discussion. Discussing risk and benefit information with any patient who is about to be medically treated for any illness or injury normally occurs in most medical treatment encounters. Therefore, the informed consent process is part and parcel of the treatment discussion in that they both involve communicating to the patient information about the risks and benefits of a medical treatment. This discussion should follow the patient's individual information seeking process, part of which should include the provision of information to the patient by the person he or she trusts the most, the physician.

#### Practical Applications

This information process can be applied to many types of procedures and treatments. With the exception of emergency care, where time to make critical decisions is extremely limited, and simple, straightforward treatment of an injury where there is only one option, physicians should give patients detailed, written information about treatment as early as possible with time for them to absorb and reflect on the information and then come back to discuss treatment options with their provider. Doing this will allow patients to be a participant in their treatment plan and a partner with their healthcare provider. Patients faced with systemic diseases such as diabetes, coronary artery disease, and immune deficiency disorders and would be great candidates for this type of information process. Cancer patients would also have a need for this type of information process. Patients who are faced with potential orthopedic surgery with several treatment options are also candidates for this process of information delivery.

Although many in the healthcare industry may argue that patients are given enough information about treatment options, finding and using a consistent method to deliver information about those options will create more autonomous patients that can partner with their doctor in the decisions about their own care. Because we know that patients want to be more involved in their care (Adams, 2007) and that patient satisfaction is closely tied to respect for a patient's preferences (Jenkinson, Coulter, Bruster, Richards, & Chandola (2002), this process should create more satisfied patients.

#### Future Research

One of the limitations of this study was the sample size. Future research on the epidural informed consent process should involve a larger and more diverse population. Another modification of this study might involve the use of a different medium for the risk/benefit information. Because the use of the Internet is ubiquitous with the age demographic of pregnant women, a video that can be accessed online would be an interesting alternative. Patient autonomy is at the heart of informed consent; therefore, research on whether patients really want to be autonomous would be instructional and could be applied to the communication process that physicians use when helping patients through the treatment decision-making process.

#### Conclusion

While this study did not show a strong statistical relationship between patient satisfaction and a more detailed informed consent for epidural analgesia given at an earlier point in the pregnancy, patients have indicated that they want detailed

risk/benefit information earlier in their pregnancies. There is a meaningful difference between the percentage of those who received more information in the form of a written risk and benefit document and were satisfied with the epidural process and those who did not receive the additional information and were also satisfied. Whether they received the risk/benefit treatment document or not, the greatest percentage of patients in this study wanted information about epidural analgesia before the onset of labor, preferably during the last month of pregnancy. In spite of some negative comments about issues with the insertion of the epidural and complications and side effects, patients still reported overwhelmingly that their expectations with the epidural process were completely met. This may have occurred because patients were aware of the risks and benefits and because they still had pain relief, any negative technical problems with the procedure did not detract from their overall satisfaction.

This study speaks to the heart of the communication process between patients and their physicians. Patients' information seeking behavior and information needs have changed over the past 20 years. In the past, physicians made decisions about the information that would be shared with their patients and did not feel the need to carry on any type of discussion of options or choices. In the current era of open access, patients have access to as much medical information as their physician because of the availability of that information on the Internet. It is clear that they are seeking that information even if they cannot interpret it in a meaningful manner. It is also clear that when a procedure, such as a labor epidural, is imminent, patients would like to have their medical information needs met by their most trusted source, their physician. Physicians can help their patients become part of the medical decision-making team by

communicating information to them in a timely manner and in a form that they can understand, review, and if necessary, reinforce with other sources. An ongoing dialog between the physician and patient will foster a better relationship and should lead to better healthcare for the patient.

It is important that patients be fully informed of the risks and benefits of a treatment plan or procedure, giving them time to absorb the information. They should then be encouraged to discuss the treatment options with their doctor, participating in the decision-making process. This participation should lead to better-informed, more satisfied patients who partner with their doctor in the treatment process.



APPENDIX A  
INFORMMATION REVIEW BOARD (IRB) APPROVAL

---

OFFICE OF THE VICE PRESIDENT FOR RESEARCH  
Office of Research Services

October 31, 2007

Michelle Hicks  
School of Library and Information Sciences  
University of North Texas

RE: Human Subjects Application No. 07-398

Dear Ms. Hicks:

In accordance with 45 CFR Part 46 Section 46.101, your study titled "Informed Consent in Obstetric Anesthesia: Effect of Amount, Timing and Modality of Information on Patient Satisfaction" has been determined to qualify for an exemption from further review by the UNT Institutional Review Board (IRB).

Enclosed is the consent document with stamped IRB approval. Please copy and **use this form only** for your subjects.

No changes may be made to your study's procedures or forms without prior written approval from the UNT IRB. Please contact Shelia Bourns, Research Compliance Administrator, ext. 3940, if you wish to make any such changes.

Sincerely,



Kenneth W. Sewell, Ph.D.  
Chair  
Institutional Review Board

KS:sb

Cc: Dr. Maurice B. Wheeler

APPENDIX B  
PATIENT QUESTIONNAIRE

## Patient Questionnaire

This questionnaire is designed to assess your experience with your recent labor epidural. Please circle the appropriate answer or answers for each question. Be sure to fill out both sides of the questionnaire. This should only take about five minutes of your time.

### Information about you:

1. What is your age? \_\_\_\_\_
  
2. Education level:
  - a. Stopped before High School graduation
  - b. High School diploma or GED
  - c. Some college coursework
  - d. College degree (BS, BA or equivalent)
  - e. Coursework beyond Undergraduate degree
  - f. Masters Degree or higher
  
3. Language spoken at home:
  - a. English
  - b. Spanish
  - c. Other \_\_\_\_\_

### Labor and Delivery:

4. Is your obstetrician:
  - a. male
  - b. female
  
5. Is this your first baby?
  - a. yes
  - b. no
  
6. If this is not your first baby, how many children do you have? \_\_\_\_\_
  
7. When did you deliver your most recent baby?
  - a. less than 3 months ago?
  - b. from 3 to 6 months ago?
  - c. more than 6 months ago?

8. Type of delivery:
- a. vaginal delivery
  - b. cesarean section
9. Outcome of the delivery?
- a. healthy baby and healthy mom
  - b. healthy baby and complications with the mom
  - c. complications with the baby and healthy mom
  - d. complications with the baby and complications with the mom
10. What were your expectations of the effectiveness of a labor epidural prior to receiving it?
- a. pain free, no sensation
  - b. pain free, some sensation such as pressure or squeezing
  - c. some pain, some sensation such as pressure or squeezing
  - d. very little pain relief, a lot of sensation such as pressure or squeezing
11. How well did your labor epidural work?
- a. did not work, minimal pain relief
  - b. provided partial pain relief
  - c. provided complete pain relief
12. If the epidural did not work well, what did your anesthesiologist do to respond to this issue?
- 
- 
13. Were your expectations of the labor epidural process met?
- a. my expectations were not met at all
  - b. my expectations were partially met
  - c. my expectations were completely met
14. What could be done by the anesthesiologist to better meet your expectations of the epidural process? \_\_\_\_\_
- 
-

Information on labor epidural analgesia:

15. Was this your first labor epidural?
  - a. yes
  - b. no
  
16. Did you attend childbirth education classes during your most recent pregnancy?
  - a. yes
  - b. no
  
17. If you did attend childbirth education classes, how much information did you receive on epidural analgesia?
  - a. none
  - b. a little, but I wanted more
  - c. a little, but it was enough
  - d. a lot, but I wanted more
  - e. a lot, but it was enough
  
18. What type of informed consent was given to you for your labor epidural by the attending Anesthesiologist?
  - a. A verbal explanation at the time of the epidural
  - b. A written document given to you before you went into the hospital and a verbal explanation at the time of the epidural
  
19. If you received the written informed consent document, circle all of the answers that apply to your experience:
  - a. I read it completely
  - b. I skimmed it
  - c. I understood what the document said
  - d. I did not understand the document
  - e. I looked for more information on epidural analgesia risks and benefits after reading the informed consent document
  - f. The document contained enough information on epidural analgesia risks and benefits for me to make a decision about whether to have one or not
  
20. If you used other sources to get information on epidural analgesia what were they? Circle any that apply:
  - a. magazines
  - b. friends
  - c. family members

- d. current or past OB/GYN
- e. literature from the OB/GYN
- f. Internet websites
- g. library

21. If you circled any answers in question 20, which one provided you with the most information on epidural analgesia? \_\_\_\_\_
22. Did you understand the information the anesthesiologist discussed with you during the verbal informed consent?
- a. I understood everything
  - b. I did not understand anything
  - c. I understood some of it but not all of it
23. If you did not understand the information, what was the problem? Circle all that apply:
- a. I did not understand the language
  - b. I did not understand the terms the anesthesiologist used
  - c. I was not able to pay attention to the anesthesiologist because of pain
  - d. I was not able to pay attention because of other distractions
24. Do you feel comfortable asking your doctor questions that you may have about your care?
- a. yes; very comfortable
  - b. somewhat comfortable
  - c. would rather not ask a question, but will if absolutely necessary
  - d. no; unable to ask my doctor questions
25. Did you have any questions after the verbal informed consent was given? Did you ask them?
- a. I had questions; I asked them and they were answered by the anesthesiologist
  - b. I had questions; I asked but they were not answered by the anesthesiologist
  - c. I had questions; they were answered by another healthcare provider
  - d. I had questions; I did not ask the anesthesiologist
  - e. I had no questions
26. How did you feel about the amount of information you received during the informed consent process? Circle all of the answers that describe your feelings:
- a. not satisfied
  - b. satisfied
  - c. very satisfied

- d. not enough information
- e. enough information
- f. more information than I wanted
- g. information given at the right time
- h. information not given at the right time

27. In your opinion, when is the best time for a pregnant woman to receive information about labor epidurals?

- a. prenatal class
- b. regular OB visit during the beginning of the pregnancy
- c. regular OB visit during the last month of the pregnancy
- d. admission to the hospital for delivery of the baby
- e. immediately prior to receiving the epidural
- f. other \_\_\_\_\_

Thank you for taking the time to fill out this survey. Please mail it back in the enclosed, postage paid envelope.



APPENDIX C  
FREQUENCY TABLES

Table C.1

*Education Level*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	High School diploma or GED	4	5.3	5.3	5.3
	Some college coursework	19	25.3	25.3	30.7
	College degree (BS, BA or equivalent)	37	49.3	49.3	80.0
	Coursework beyond Undergraduate degree	7	9.3	9.3	89.3
	Masters Degree or higher	8	10.7	10.7	100.0
	Total	75	100.0	100.0	

Table C.2

*Primary Language*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	English	75	100.0	100.0	100.0

Table C.3

OB Gender

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	male	51	68.0	68.0	68.0
	female	24	32.0	32.0	100.0
	Total	75	100.0	100.0	

Table C.4

*First Baby*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	26	34.7	34.7	34.7
	no	49	65.3	65.3	100.0
	Total	75	100.0	100.0	

Table C.5

*How Many Children*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	25	33.3	33.3	33.3
	2	34	45.3	45.3	78.7
	3	12	16.0	16.0	94.7
	4	3	4.0	4.0	98.7
	5	1	1.3	1.3	100.0
	Total	75	100.0	100.0	

Table C.6

*Type of Delivery*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	vaginal delivery	40	53.3	53.3	53.3
	cesarean section	35	46.7	46.7	100.0
	Total	75	100.0	100.0	

Table C.7

*Outcome of the Delivery*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	healthy baby and healthy mom	61	81.3	81.3	81.3
	healthy baby and complications with the mom	4	5.3	5.3	86.7
	complications with the baby and healthy mom	8	10.7	10.7	97.3
	complications with the baby and complications with the mom	1	1.3	1.3	98.7
	No response	1	1.3	1.3	100.0
	Total	75	100.0	100.0	

Table C.8

*Expectations of Effectiveness of Epidural*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	pain free, no sensation	14	18.7	18.7	18.7
	pain free, some sensation such as pressure or squeezing	42	56.0	56.0	74.7
	some pain, some sensation such as pressure or squeezing	18	24.0	24.0	98.7
	very little pain relief, a lot of sensation such as pressure or squeezing	1	1.3	1.3	100.0
	Total	75	100.0	100.0	

Table C.9

How Well Did Epidural Work

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	did not work, minimal pain relief	2	2.7	2.7	2.7
	provided partial pain relief	7	9.3	9.3	12.0
	provided complete pain relief	66	88.0	88.0	100.0
	Total	75	100.0	100.0	

Table C.10

*First Labor Epidural*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	26	34.7	34.7	34.7
	No	49	65.3	65.3	100.0

Table C.11

*Were Your Expectations of the Epidural Met*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	my expectations were not met at all	1	1.3	1.3	1.3
	my expectations were partially met	7	9.3	9.3	10.7
	my expectations were completely met	67	89.3	89.3	100.0
	Total	75	100.0	100.0	

Table C.12

*Attend Childbirth Education Classes*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	18	24.0	24.0	24.0
	no	57	76.0	76.0	100.0
	Total	75	100.0	100.0	

Table C.13

*Amount of Information from Education Classes*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		57	76.0	76.0	76.0
	a little, but I wanted more	1	1.3	1.3	77.3
	a little, but it was enough	9	12.0	12.0	89.3
	a lot, but I wanted more	1	1.3	1.3	90.7
	a lot, but it was enough	7	9.3	9.3	100.0
	Total	75	100.0	100.0	

Table C.14

*Type of Informed Consent*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	a verbal explanation at the time of the epidural	24	32.0	32.0	32.0
	a written document given to you before you went into the hospital and a verbal explanation at the time of the epidural	51	68.0	68.0	100.0
	Total	75	100.0	100.0	

Table C.15

*Informed Consent Document-Read Completely*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	11	14.7	14.7	14.7
	Response not chosen	64	85.3	85.3	100.0
	Total	75	100.0	100.0	

Table C.16

*Informed Consent-Skimmed Over It*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	28	37.3	37.3	37.3
	Response not chosen	47	62.7	62.7	100.0
	Total	75	100.0	100.0	

Table C.17

*Informed Consent-Understood Document*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	33	44.0	44.0	44.0
	Response not chosen	18	56.0	56.0	100.0
	Total	51	100.0	100.0	

Table C.18

*Informed Consent-Did Not Understand Document*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	1	1.3	1.3	1.3
	Response not chosen	74	98.7	98.7	100.0
	Total	75	100.0	100.0	



Table C.19

*Informed Consent-Looked for More Information after Reading Document*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	8	10.7	10.7	10.7
	Response not chosen	67	89.3	89.3	100.0
	Total	75	100.0	100.0	

Table C.20

*Informed Consent-Document Contained Enough Information to Make a Decision*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	30	40.0	40.0	40.0
	Response not chosen	45	60.0	60.0	100.0
	Total	75	100.0	100.0	

Table C.21

*Other Sources-Magazines*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	3	4.0	4.0	4.0
	Response not chosen	48	96.0	96.0	100.0
	Total	51	100.0	100.0	

Table C.22

*Other Sources-Friends*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	25	33.3	33.3	33.3
	Response not chosen	26	66.7	66.7	100.0
	Total	51	100.0	100.0	

Table C.23

*Other Sources-Family Members*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	18	24.0	24.0	24.0
	Response not chosen	33	76.0	76.0	100.0
	Total	51	100.0	100.0	

Table C.24

*Other Sources-Current or Past OB/GYN*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	26	34.7	34.7	34.7
	Response not chosen	25	65.3	65.3	100.0
	Total	51	100.0	100.0	

Table C.25

*Other Sources-Literature from the OB/GYN*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	4	5.3	5.3	5.3
	Response not chosen	47	94.7	94.7	100.0
	Total	51	100.0	100.0	

Table C.26

*Other Sources-Internet Websites*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	14	18.7	18.7	18.7
	Response not chosen	37	81.3	81.3	100.0
	Total	51	100.0	100.0	

Table C.27

*Other Sources-Library*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	3	4.0	4.1	4.1
	Response not chosen	47	94.7	95.9	100.0
	Total	50	98.7	100.0	
Missing	System	1	1.3		
Total		51	100.0		

Table C.28

*Most Information*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		35	46.7	46.7	46.7
	anesthesiologist	1	1.3	1.3	48.0
	Anesthesiologist	1	1.3	1.3	49.3
	books	1	1.3	1.3	50.7
	both	1	1.3	1.3	52.0
	both the form and web were equally informative	1	1.3	1.3	53.3
	current OB/GYN	1	1.3	1.3	54.7
	d - current or past OB/GYN	1	1.3	1.3	56.0
	D - current or past OB/GYN	1	1.3	1.3	57.3
	family	2	2.7	2.7	60.0
	family and current OB/GYN	1	1.3	1.3	61.3
	Family member	1	1.3	1.3	62.7
	Family member - my brother is a CRNA	1	1.3	1.3	64.0
	family members	2	2.7	2.7	66.7
	friends	3	4.0	4.0	70.7
	Friends	1	1.3	1.3	72.0
	I am a nurse, most info from nursing studies	1	1.3	1.3	73.3
	internet	1	1.3	1.3	74.7
	Internet	1	1.3	1.3	76.0
	Internet websites	1	1.3	1.3	77.3
	literature from doctors office	1	1.3	1.3	78.7
	literature/books	1	1.3	1.3	80.0
	magazine	1	1.3	1.3	81.3
	mostly the paper from the anesthesiologist gave me	1	1.3	1.3	82.7
	mother	1	1.3	1.3	84.0
	My doctor	1	1.3	1.3	85.3
	my OB - I had questions on the difference between epidural and spinal block (epidural with baby #1 but had spinal this time around with baby #2)	1	1.3	1.3	86.7
OB	2	2.7	2.7	89.3	
OB/GYN	7	9.3	9.3	98.7	
sister-in-law who is an anesthesiologist	1	1.3	1.3	100.0	
Total	75	100.0	100.0		

Table C.29

*Understand Information from Anesthesiologist*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	I understood everything	69	92.0	93.2	93.2
	I did not understand anything	1	1.3	1.4	94.6
	I understood some of it but not all of it	4	5.3	5.4	100.0
	Total	74	98.7	100.0	
Missing	no response	1	1.3		
Total		75	100.0		

Table C.30

*Did Not Understand Language*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Response not chosen	75	100.0	100.0	100.0

Table C.31

*Did Not Understand Terms*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Response not chosen	75	100.0	100.0	100.0

Table C.32

*Did Not Understand Because of Pain*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	4	5.3	5.3	5.3
	Response not chosen	71	94.7	94.7	100.0
	Total	75	100.0	100.0	

Table C.33

*Did Not Understand Because of Other Distractions*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	2	2.7	2.7	2.7
	Response not chosen	73	97.3	97.3	100.0
	Total	75	100.0	100.0	

Table C.34

*Asking Doctor Questions*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes; very comfortable	67	89.3	89.3	89.3
	somewhat comfortable	7	9.3	9.3	98.7
	would rather not ask a questions, but will if absolutely necessary	1	1.3	1.3	100.0
	Total	75	100.0	100.0	

Table C.35

## Any Questions After Verbal Informed Consent

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	I had questions; I asked them and they were answered by the anesthesiologist	24	32.0	32.0	32.0
	I had questions; I asked them but they were not answered by the anesthesiologist	1	1.3	1.3	33.3
	I had questions; they were answered by another healthcare provider	1	1.3	1.3	34.7
	I had questions; I did not ask the anesthesiologist	1	1.3	1.3	36.0
	I had no questions	47	62.7	62.7	98.7
	No response	1	1.3	1.3	100.0
	Total	75	100.0	100.0	

Table C.36

## Amount of Information During Informed Consent-Not Satisfied

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Response not chosen	74	98.7	100.0	100.0
Missing	System	1	1.3		
Total		75	100.0		

Table C.37

Amount of Information during Informed Consent-Satisfied

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	38	50.7	50.7	50.7
	Response not chosen	37	49.3	49.3	100.0
	Total	75	100.0	100.0	

Table C.38

*Amount of Information during Informed Consent-Very Satisfied*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	31	41.3	41.3	41.3
	Response not chosen	44	58.7	58.7	100.0
	Total	75	100.0	100.0	

Table C.39

*Amount of Information during Informed Consent-Not Enough Information*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	2	2.7	2.7	2.7
	Response not chosen	73	97.3	97.3	100.0
	Total	75	100.0	100.0	



Table C.40

*Amount of Information during Informed Consent-Enough Information*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	29	38.7	38.7	38.7
	Response not chosen	46	61.3	61.3	100.0
	Total	75	100.0	100.0	

Table C.41

*Amount of Information during Informed Consent-More Info Than I Wanted*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	2	2.7	2.7	2.7
	Response not chosen	73	97.3	97.3	100.0
	Total	75	100.0	100.0	

Table C.42

*Amount of Information during Informed Consent-Information Given at the Right Time*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	24	32.0	32.0	32.0
	Response not chosen	51	68.0	68.0	100.0
	Total	75	100.0	100.0	

Table C.43

Amount of Information during Informed Consent-Information Not Given at the Right Time

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Response not chosen	75	100.0	100.0	100.0

Table C.44

*Best Time to Receive Epidural Information-Prenatal Class*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	19	25.3	25.3	25.3
	Response not chosen	56	74.7	74.7	100.0
	Total	75	100.0	100.0	

Table C.45

*Best Time to Receive Epidural Information-OB Visit Beginning of Pregnancy*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	12	16.0	16.0	16.0
	Response not chosen	63	84.0	84.0	100.0
	Total	75	100.0	100.0	

Table C.46

*Best Time to Receive Epidural Information-OB Visit Last Month of Pregnancy*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	50	66.7	66.7	66.7
	Response not chosen	25	33.3	33.3	100.0
	Total	75	100.0	100.0	

Table C.47

*Best Time to Receive Epidural Information-Admission to Hospital for Delivery*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	9	12.0	12.0	12.0
	Response not chosen	66	88.0	88.0	100.0
	Total	75	100.0	100.0	

Table C.48

*Best Time to Receive Epidural Information-Immediately Prior to Receiving Epidural*

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	8	10.7	10.7	10.7
	Response not chosen	67	89.3	89.3	100.0
	Total	75	100.0	100.0	

APPENDIX D  
DESCRIPTIVE STATISTICS

Table D.1

Descriptive Statistics

	<i>N</i>		Mean	Std. Deviation	Minimum	Maximum
	Valid	Missing				
Age	75	0	31.61	4.623	19	45
When did you deliver most recent baby	75	0	3.44	2.068	1	9

## REFERENCES

- Adams, D. (2007). Patients today want to be more involved in care. *American Medical News*, 50(40), 15.
- American College of Obstetricians and Gynecologists [ACOG] (2004). Surgery and Patient Choice. In *Ethics in Obstetrics and Gynecology* (pp. 21-25). Washington: American College of Obstetricians and Gynecologists.
- Andrews, P.H., & Baird, J.E., Jr. (2005). *Communications for business and the professions* (8<sup>th</sup> ed.). Long Grove, IL: Waveland Press.
- Asadi-Lari, M., Tamburini, M., & Gray, D. (2004, June 29). Patients' needs, satisfaction, and health related quality of life: Towards a comprehensive model. *Health and Quality of Life Outcomes*, 2(32). Retrieved June 30, 2008, from <http://www.hqlo.com/content/2/1/32>
- Bernat, James L. (2001). Informed consent. *Muscle and Nerve*, May. 612-621.
- Bernzweig, J., Takayama, J., Phibbs, C., Lewis, C., & Pantell, R. (1997). Gender differences in physician-patient communication. Evidence from pediatric visits. *Archives of Pediatric and Adolescent Medicine*, 151, 586-591.
- Bethune, L., Harper, N., Lucas, D., Robinson, N., Cox, M., Lilley, A., & Yentis, S. (2004). Complications of obstetric regional analgesia: How much information is enough? *International Journal of Obstetric Anesthesia*, 13, 30-34.
- Bierstein, K. (2006). Informed consent and the Medicare interpretive guidelines. *American Society of Anesthesiologists NEWSLETTER*, 70(7), 13-14.
- Branch, W. (2000). Is the therapeutic nature of the patient-physician relationship being undermined? A primary care physician's perspective. *Archives of Internal Medicine*, 160, 2257-2260.
- Brown, J., Boles, M., Mulloony, J., & Levinson, W. (1999). Effect of clinician communication skills training on patient satisfaction. A randomized, controlled trial. *Annals of Internal Medicine*, 131, 822-829.
- Capuzzo, M., Gilli, G., Paparella, L., Gritti, G., Gambi, D., Bianconi, M., Giunta, F., Buccoliero, C., & Alvisi, R. (2007). Factors predictive of patient satisfaction and anesthesia. *Anesthesia & Analgesia*, 105(2), 435-442.
- Cegala, D., (1997). A study of doctors' and patients' communication during a primary care consultation: implications for communication training. *Journal of Health Communication*, 2(3), 169-194.

- Cheney, F. (2006). A separate written consent document for anesthesia: What is the indication? *American Society of Anesthesiologists NEWSLETTER*, 70(7), 17-18.
- Chapman, J., & Wolff, A. (2002). Consent for anaesthesia. *Anaesthesia*, 57, 710.
- Cohen, J. (1988). *Statistical power analysis for the behavioral sciences*. Hillsdale, New Jersey: Lawrence Erlbaum Associates.
- Delany, C. (2005). Respecting patient autonomy and obtaining the informed consent: Ethical theory – missing in action. *Physiotherapy*, 91, 197-203.
- Dervin, B., & Nilan, M. (1986). Information needs and uses. M. E. Williams, (Ed.). *Annual Review of Information Science and Technology (Vol 21)*. (pp.3-33). Los Angeles: Knowledge Industry Publications.
- Dickenson, A. (2002). Editorial I: Gate Control Theory of pain stands the test of time. *British Journal of Anaesthesia*, 88(6), 755-757.
- Durieux, P., Bissery, A., Dubois, S., Gasquet, I., & Coste, J. (2004). Comparison of health care professionals; self-assessments of standards of care and patients' opinions on the care they received in hospital: observational study. *Quality and Safety in Health Care*, 13, 198-202.
- Eberle, R. & Norris, M. (1996). Labour analgesia: A risk-benefit analysis. *Drug Safety*, 14(4), 239-251.
- Fallis, D. (2004). On verifying the accuracy of information: Philosophical perspectives. *Library Trends*, 52(3), 463-487.
- Fink, B. (1998). History of neural blockade. M. J. Cousins & P. O. Bridenbaugh, (Eds.). *Neural Blockade in Clinical Anesthesia and Management of Pain*, (2<sup>nd</sup> ed.). (pp. 3-21). Philadelphia: Lippincott.
- Frost, E. (1985). *Essays on the history of anesthesia*. Georgetown, CT: McMahon.
- Fuller, J. & Matzler, K. (2008). Customer delight and market segmentation: An application of the three-factor theory of customer satisfaction on life style groups. *Tourism Management*, 29, 116-126.
- Geist, P. & Dreyer, J. (1993). The demise of dialogue: A critique of medical encounter ideology. *Western Journal of Communication*, 57, 233-246.
- Gerancher, J., Grice, S., Dewan, D. & Eisenach, J. (2000). An evaluation of informed consent prior to epidural analgesia for labor and delivery. *International Journal of Obstetrical Anesthesia*, 9, 168-173.

- General Medical Council, (2006). Good Medical Practice (2006). Retrieved October 4, 2007 from [http://www.gmc-uk.org/guidance/good\\_medical\\_practice/index.asp](http://www.gmc-uk.org/guidance/good_medical_practice/index.asp)
- Gilbert, S. (1997, October 21). No caesarean risk is found for a labor pain medication. *New York Times*.
- Goold, S. & Lipkin, Jr., Mack. (1999). The doctor-patient relationship: Challenges, opportunities, and strategies. *Journal of General Internal Medicine*, 14, (Supp. 1), S26-S33.
- Griffin, E. (2006). *A first look at communication theory* (6<sup>th</sup> ed.). New York: McGraw-Hill.
- Harris, R. (1998), Introduction to decision-making. Retrieved July 29, 2008, from <http://www.virtualsalt.com/crebook5.htm>
- Hesse, B., Nelson, D., Kreps, G., Croyle, R., Arora, J., Rimer, R., & Viswanath, K. (2005). Trust and sources of health information. The impact of the Internet and its implications for health care providers: Findings from the first health information national trends survey. *Archives of Internal Medicine*, 165, 2618-2624.
- Hoehner, P. (2003). Ethical aspects of informed consent in obstetric anesthesia -new challenges and solutions. *Journal of Clinical Anesthesia*, 15(6), 587-600.
- Holbrook, M. (1983). Using a structural model of halo effect to assess perceptual Distortion due to affective overtones. *Journal of Consumer Research*, 10, 247-252.
- Howell, E., Gardiner, B., & Concato, J. (2002). Do women prefer female obstetricians? *Obstetrics & Gynecology*, 99(6), 1031-1035.
- Jackson, A., Henry, R., Avery, N., VanDenKerkhof, E., & Milne, B. (2000). Informed consent for labour epidurals: What labouring women want to know. *Canadian Journal of Anesthesia*, 47(11), 1068-1073.
- Jenkinson, C., Coulter, A., Bruster, S., Richards, N., & Chandola, T. (2002). Patients' experiences and satisfaction with health care: Results of a questionnaire study of specific aspects of care. *Quality and Safety in Healthcare*, 11, 335-339.
- Kelly, G., Blunt, C., Moore, P., & Lewis, M. (2004). Consent for regional anaesthesia in the United Kingdom: What is material risk? *International Journal of Obstetric Anesthesia*, 13, 71-74.
- Kuhlthau, C. (1993). *Seeking meaning: A process approach to library and information services*. Norwood, New Jersey: Ablex.
- Larson, M. (2005). History of anesthetic practice. R. D. Miller, (Ed). *Miller's Anesthesia*



- (6<sup>th</sup> ed.) (Vol. 1). (pp. 3-54). Philadelphia: Elsevier.
- Leighton, B. & Halpern, S. (2002). The effects of epidural analgesia on labor, maternal and neonatal outcomes: A systematic review. *American Journal of Obstetric Gynecology*, 186, S69-77.
- Mahapatra, R. & Panda, K. (2001). Information seeking behavior: a conjectural approach. *ARELS Journal of Information Management*, 38(2), 121-138.
- Matzler, K & Sauerwein, E. (2002). The factor structure of customer satisfaction. An empirical test of the importance grid and the penalty-reward-contrast analysis. *International Journal of Service Industry Management*, 13(4), 314-332.
- Nandi, P. (2000). Ethical aspects of clinical practice. *Archives of Surgery*, 135, 22-25.
- National Library of Medicine, History of Medicine, (2002). Greek Medicine. Retrieved October 4, 2007 from [http://www.nlm.nih.gov/hmd/greek/greek\\_oath.html](http://www.nlm.nih.gov/hmd/greek/greek_oath.html)
- Neuberger, J. (2000). The educated patient: New challenges for the medical profession. *Journal of Internal Medicine*, 247, 6-10.
- O'Leary, C. (2006). Informed consent for anesthesia: Has the time come for a separate written consent document? *American Society of Anesthesiologists Newsletter*, 70(7), 11-12.
- Oliver, R. (1980). A cognitive model of the antecedents and consequences of satisfaction decisions. *Journal of Marketing Research*, 17, 460-469.
- Oliver, R. (1981). Measurement and evaluation of satisfaction processes in retail settings. *Journal of Retailing*, 57(3), 25-47.
- Pace, N. & Hendry, R. (2006). Consent: Ethical considerations. *Anaesthesia and Intensive Care Medicine*, 7(4), 107-113.
- Pape, T. (1997). Legal and ethical considerations of informed consent. *AORN Journal*, June, 65(6), 1122-1127.
- Pattee, C., Ballantyne, M. & Milne, B. (1997). Epidural analgesia for labour and delivery: Informed consent issues. *Canadian Journal of Anaesthesia*, 44(9), 918-923.
- Peduzzi, P, Concato, J., Kemper, E., Holford, T. & Feinstein, A. (1996). A simulation study of the number of events per variable in logistic regression analysis. *Journal of Clinical Epidemiology*, Vol. 49, No. 12, pp. 1373-1379.
- Plunkett, B., Kohli, P., & Milad, M. (2002). The importance of physician gender in the selection of an obstetrician or gynecologist. *American Journal of Obstetric*

- Gynecology*, 186(5), 926-928.
- Roter, D., Hall, J., & Aoki, Y. (2002). Physician gender effects in medical communication. *Journal of the American Medical Association*, 288(6), 756-764.
- Roter, D., Hall, J., & Katz, N. (1987). Relations between physicians' behaviors and analogue patients' satisfaction, recall, and impressions. *Medical Care*, 22(5), 437-451.
- Saracevic, T. (2007). Relevance: A review of the literature and a framework for think on the notion in information science. Part II: Nature and manifestations of relevance. *Journal of the American Society for Information Science and Technology*, 58(13), 1915-1933.
- Shannon, C. (1948). A mathematical theory of communication. *The Bell Systems Technical Journal*, 27, 379-423, 623-656.
- Siddiqui, M., Siddiqui, S., Ranasinghe, S., Steadman, J. & Shera, A. (2005). Does labor pain and labor epidural analgesia impair decision capabilities of parturients? *The Internet Journal of Anesthesiology*, 10(1).
- Swan, H., & Borshoff, D. (1994). Informed consent – recall of risk information following epidural analgesia in labor. *Anaesthesia and Intensive Care*, 22(2). 139-141.
- Thiedke, C. (2007). What do we really know about patient satisfaction? *Family Practice Management* 14(1), 33-36.
- Underwood, M. (2003). CCMS - Communication studies, cultural studies, media studies infobase by Mick Underwood. Retrieved September 30, 2007 from <http://www.cultsock.ndirect.co.uk/MUHome/cshtml/index.html>
- Vincent, R. & Chestnut, D. (1998). Epidural analgesia during labor. *American Family Physician*, 58(8), 1785-1792.
- Vlessides, M. (2007). Document pushes more informative consent. *Anesthesiology News*, 33(7), 9.
- Waisel, D. & Truog, R. (2005). Ethical and legal aspects of anesthesia care. In R.D. Miller (Ed.) *Miller's anesthesia (6<sup>th</sup> ed.)*, (Vol. 2), (pp. 3175-3198). Philadelphia: Elsevier.
- Weiss, R., Feinstein, A., & Dalbor, M. (2004). Customer satisfaction of theme restaurant attributes and their influence on return intent. *Journal of Foodservice Business Research*, 7(1), 23-41.
- West, J. & Palmer, S. (2007). Practical ethics for the informed consent process for

anesthetic care. *American Society of Anesthesiologists NEWSLETTER*, 12(5). 15-16, 27.

White, S. & Baldwin, T. (2003). Consent for anaesthesia. *Anaesthesia*, 58. 760-774.

White, L., Gorton, M., Wee, Y., & Mandal, N. (2003). Written information about epidural analgesia for women in labour: did it improve knowledge? *International Journal of Obstetric Anesthesia*, 12, 93-97.

Wilson, P. (1973). Situational relevance. *Information Storage and Retrieval*, 9(8), 457-471.

Wilson, T., Ford, N., Ellis, D., Foster, A., & Spink, A. (2002). Information seeking and mediated searching. Part 2. Uncertainty and its correlates. *Journal of the American Society for Information Science and Technology*, 53(9), 704-715.

Zhang, J. (2006, August 9). Medicare to cut doctor payments in effort to rein in rapid growth. *The Wall Street Journal*, p. D3.