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The Effects of Pain on Informed Consent

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Abstract

It is common for providers to withhold pain medication as opposed to treating pain prior to obtaining informed consent due to the concern of invalid informed consent. Pain's influence on cognition can significantly impact the cognitive domains required to obtain valid informed consent. Determining if a patient has the capacity or competence to participate in the informed consent process has medical, ethical, and legal implications. The medical use of competence and capacity is not equivalent to the legal use of the same terminology. Legal implications concerning consent include signing consent while in duress or pain, signing under the influence of opioids, and determining if withholding treatment until consent is obtained may be considered coercion. While the legal system has the final say, the onus is with anesthesia providers to determine if the patient is able to participate in the informed consent process. Other factors that should be considered include the validity of obtaining consent from a chronic opioid user, who has taken medication on the day of surgery or on the day of the anesthesia screening. The complexities of anesthesia, along with the patient's comorbidities also must be considered when evaluating a patient's understanding of informed consent. Developing or incorporating a standard guideline during the anesthesia screening may be helpful in determining if a patient is cognitively able to participate in the consent process. Research suggests that optimizing pain relief can improve decision-making while obtaining consent.

Introduction

Pain has several implications for anesthesia providers. Understanding the pathophysiology of pain helps the providers appreciate its physiological effects on patient homeostasis and cognition. In addition, it is important to understand the mechanisms of action for pharmacological agents, such as opioids, and their influence on patient cognition. Awareness of cognition and patient decision-making capability are important when providers are obtaining informed consent. The process of obtaining informed consent is an ethical, medical, and legal responsibility of anesthesia providers. From a legal standpoint, it is important to consider the implications that may result from withholding treatment, obtaining consent under the influence of medication, or the level of patient distress due to pain.

Research supports that pain of various etiologies is associated with poorer cognitive function (Moriarty, McGuire, & Fin, 2011). Impaired cognitive function is also associated with opioid consumption (Schiltenswolf et al., 2014). If pain impairs decision-making, and opioids used to treat pain also impair decision-making, then the validity of informed consent could be questioned in these situations. Opioid doses that alleviate pain tend to be lower than those that impair cognition (Lucha, Kropcho, Schneider, & Francis, 2006), but studies vary. Some research suggests that patients have the cognitive ability to consent to surgery but may not be able to consent to the more abstract concepts involved in understanding anesthesia consent (Marcucci, Seagull, Loreck, Bourke, & Sanderson, 2010). This suggests that there may be a spectrum of cognitive function when discussing the influence of pain and opioids while obtaining informed consent. Memory, mental flexibility, emotional decision-making, and attention are included when referring to poorer cognition. These components of cognitive function are essential to obtaining valid informed consent (Fields & Calvert, 2015). Informed consent can be invalid if

patients are cognitively impaired either by pain or opioids (Appelbaum, 2007). Informed consent is a legal document between the medical provider and the patient that incorporates medical, legal, and ethical criteria (Hall, Prochazka, & Fink, 2012). The ability of a patient to participate in the informed consent process is based on their competence or capacity to understand the situation.

In the medical-legal world, competence and capacity are often used interchangeably, however; medical use of the terminology is not equivalent to the legal use of the terminology. The medical-legal components that make up informed consent do not share a common definition to validate if the patient has the capacity to participate in the informed consent process (Appelbaum, 2007). Waiting to treat pain until informed consent is obtained could be considered coercion, to the extent that the patient will sign consent simply to have his or her pain treated.

This paper will explore if anesthesia providers are at risk for legal, ethical, or medical ramifications by obtaining informed consent that may be invalid due to pain or pharmacological influences that impair cognition. A patient's pain may not be completely eliminated. However, the patient's pain level could be minimized with opioids or other adjuncts while optimizing decision-making capabilities during the consenting process. Additionally, the physiology of pain, opioids' mechanisms of action, and current research on the effects pain and opioids have on decision-making and the possible legal implications will be considered. Specifically, in preoperative patients who are experiencing pain, does treating pain as compared to not treating pain improve decision-making during the informed consent process?

A Review of Literature

Due to the overlapping of intricate pathways, pain and cognition are closely related as pain may have a significant influence on the decision-making required for informed consent

(Moriarty et al., 2011). Moriarty, McGuire, and Finn cite the International Association for the Study of Pain (IASP) to define pain as “an unpleasant sensory or emotional experience associated with actual or potential tissue damage, or described in such damage” (Moriarty et al., 2011, p. 386). Moriarty et al. (2011) support the close relationship between pain and cognition, suggesting cognitive processing is required for pain to be consciously experienced. A systematic review of the literature examined 30 clinical studies, 11 of which showed a significant correlation between pain and cognitive performance (Moriarty et al., 2011). The remaining clinical studies did not find a statistically significant correlation between different variables that affect cognition (Moriarty et al., 2011). Investigators also gathered information from 10 preclinical animal studies and found the effect of pain to correlate with cognition in nine out of 10 of the preclinical studies (Moriarty et al., 2011). The review also presented a table with the cognitive effects of various analgesic medications. The table included 36 studies; 15 of the studies looked at opioids, and the remaining 22 included non-opioid medications (Moriarty et al., 2011). Of the 36 studies, 16 found that analgesic medications impaired cognitive function, eight found analgesic medications to have no effect on cognition, and 12 found that analgesic medications improved cognitive function (Moriarty et al., 2011). The findings of this systematic review support the notion that pain impairs cognitive function, and various analgesic medication are available to treat pain without impairing the cognitive function required to obtain valid informed consent.

Providers often feel that narcotics impair the patient’s judgment when obtaining informed consent, and this leads to the undertreatment of pain. From a legal perspective, some view this behavior as coercive (Garrison, 2007). The Department of General Surgery at the Naval Medical Center in Portsmouth, Virginia conducted a trial that included 27 patients in acute pain to see if

narcotic use impaired the ability to provide informed consent. Researchers found narcotics did not impair the ability to provide informed consent in 26 of the 27 patients. Outcomes from this trial were based on the Hopkins Competency Assessment Tool (HCAT). Though the results of this trial support the use of narcotics to treat pain before obtaining informed consent, the small sample size fails to provide statistically significant data (Lucha et al., 2006). While a larger study may provide additional support for treating pain prior to obtaining informed consent, optimizing a patient's cognitive status before obtaining informed consent should be the primary goal for the anesthetist.

In contrast, Cowan, Klerman, & Ma (2015) conducted a pilot study to determine if patients experiencing acute pain presented to the emergency department with the capacity to consent. The study of 34 patients utilized the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) and found that a patient experiencing acute pain maintained the capacity to consent to research (Cowan et al., 2015). Although this study contrasts with previously mentioned studies, the results should be viewed with caution. Limitations to this study included the small sample size and an inability to determine if a specific level of pain would change the outcomes of the study. Patients included in the study had pain ranging from one to ten on the numerical pain scale. Logically it seems those with lower pain scores would be more inclined to have the capacity to consent. Additionally, the complexity of the information being presented may also influence the ability to understand and give informed consent.

Just as pain is viewed on a spectrum, cognitive components required for decision-making need to be considered on a spectrum. A case report by Marcucci et al. (2010) suggests that surgical consent and anesthesia consent should be considered separately as having the capacity to give surgical consent does not equal the capacity to give anesthesia consent. When obtaining

informed consent, the complexity of the surgical procedure's description may not require the same level of cognition required to comprehend the more complex and less concrete concepts of anesthesia (Marcucci et al., 2010). The authors of this case report explain these differences through the context of Jean Piaget's stages of cognitive development. According Piaget, the level of cognition required to understand the surgical procedure, such as removing a tangible object like a tumor to prevent its spreading, can be understood with the cognitive development of a seven-year-old. This contrasts with the cognitive development of a 12-year-old that is required to understand less concrete concepts such as consciousness and awareness (Marcucci et al., 2010). This becomes important when obtaining informed consent for anesthesia, and considering the legally recognized decision-making abilities of an adult including comprehension, rationalizing options, and conveying decisions (Marcucci et al., 2010). The higher level of cognition required for understanding the concepts involved with anesthesia strengthen the need to optimize the patients understanding and decision-making capabilities during the consenting process.

Landro et al. (2013) looked at the cognitive dysfunction in 72 patients with nonmalignant pain who were enrolled at a multidisciplinary pain center. They concluded that a significant portion of these patients with severe, chronic, nonmalignant pain had impaired neurocognitive function (Landro et al., 2013). While they noted some studies implied that opioids negatively affect cognitive function, patients who received opioids did not perform worse than patients not treated with opioids. Although various studies support the use of opioids to improve cognitive function in patients with chronic pain, Landro et al. (2013) concluded that there is limited evidence to support or refute the claim that opioids improve cognition in patients experiencing

chronic pain. While it remains unclear how opioids affect cognition, it appears that pain does impair cognitive function.

Further support for the negative effects of pain on cognition comes from Karp et al. (2015). The study focuses on mental flexibility in older adults, which is important when discussing the abstract nature of anesthesia. While a previous study by Cowen et al. (2015) found that patients experiencing acute pain maintained the ability to consent to research, Karp et al. (2006) found the severity of pain correlated inversely with mental flexibility. The findings by Karp et al. (2006) could represent the limitation of the study by Cowen et al. (2015). Using the McGill Pain Questionnaire, Mini Mental State Exam, Delis-Kaplan Executive Function System Trial Making Test, and the Wechsler Adult Intelligence Scale-III, they concluded that persistent pain and its severity was associated with decreased mental flexibility (Karp et al., 2006). While methods to improve decreases in mental flexibility were not suggested, Karp et al (2006) did propose that pain is a reversible cause of cognitive impairment.

As mentioned previously, the close relationship between pain and cognition could be related to the pathways and areas of the brain required for interpretation of such experiences. One study examined the close relationship between brain structures and pathways involved in pain and cognitive function, providing physiological support for the effects of pain on cognition (Oosterman, De Vries, Dijkerman, De Haan, & Scherder, 2009). Oosterman et al. (2009) cite studies by Karp et al. and Tassain et al., demonstrating pain relief's positive influence on cognitive function. The study found pain relief resulting from analgesic medications, opioid and non-opioid, have no association with cognitive function (Oosterman et al., 2009).

The close relationship between pain and cognition is demonstrated in a cohort study by Leeuw et al. (2016), which included 765 participants. Results from this study support the

hypothesis that chronic pain competes with cognitive task performance. The hypothesis is reinforced by the cognitive affective theory, which argues that pain takes precedence over other cognitive processes that demand attention (Leeuw et al., 2016). As indicated by earlier studies, pain intensity can be associated with the degree of cognitive impairment. However, Leeuw et al. (2016) found no linear association between the level of pain experienced and the severity of cognitive impairment (2016). Apkarian and colleagues, as cited by Leeuw et al., demonstrated that the prefrontal cortex is involved with many higher brain functions including chronic pain (Leeuw et al., 2016). Leeuw and colleagues conclude by indicating the need for further studies to examine the effects of pain control interventions and their impact on cognitive function (2016).

The negative effect pain has on cognition has been demonstrated in women with fibromyalgia (Verdejo-Garcia, Lopez-Torrecillas, Calandre, Delgado-Rodriguez, & Bechara, 2009), geriatric patients (Leeuw et al., 2016), those experiencing chronic pain (Schiltenswolf et al., 2014), and those with neuropathic, localized, or generalized pain (Landro et al., 2013). Because of the diverse populations who have impaired cognition related to pain, it is important to consider how best to optimize their cognition to meet the medical, ethical, and legal responsibilities for obtaining informed consent. While it is evident that pain does impair cognitive function, to date there is a lack of studies representing the direct effect pain poses on obtaining informed consent. Due to the direct correlation between pain and impaired cognition, it is essential to look at how patients are assessed to determine if they have the decision-making capacity to participate in informed consent.

Simple consent, which was established as a legal precedent in 1914 “entails that a patient (or surrogate) with decision-making capacity freely authorizes a treatment plan aimed at a

mutually acknowledged treatment goal” (Hall et al., 2012, p. 533). It was not until the 1950s when the law required physicians to obtain informed consent, a process of disclosing treatment options, risks, benefits, and the patient’s understanding of the diagnosis (Hall et al., 2012). Currently the Joint Commission defines informed consent as an “agreement or permission accompanied by full notice about the care, treatment or service that is the subject of consent” (“The Joint Commission,” 2016, p.1). The Joint Commission (2016) further describes the process of informed consent to ensure that a patient is advised of the nature, risks, and alternatives of a treatment and has the right to consent or refuse before treatment is begun.

Informed consent provides a platform to ensure patients are able to have autonomous decision-making and defined goals. In addition, informed consent prevents unwanted procedures and protects the provider from legal implications involving assault. Informed consent includes documentation of those involved in the process and ensures that ethical and legal requirements were met (Hall et al., 2012). The extent of detail and elements for informed consent varies between legal, medical, ethical, and administrative stakeholders. However, stakeholders agree that informed consent should include four elements: the decision maker should 1) have capacity to make decisions; 2) have enough information disclosed to make an informed decision; 3) demonstrate understanding of information; and 4) be able to freely authorize treatment (Hall et al., 2012).

Many, if not all, of these elements require the patient to have the cognitive ability to comprehend the information. Comprehension would require the patient to have pain control optimized prior to participating in the informed consent process. Not treating pain until after informed consent is obtained could result in an invalid consent process, and may be considered coercive, as the patient may not freely authorize the treatment plan. Providers must be able to

evaluate the patient's decision-making capacity to consent. For this discussion, it is important to note that competence and capacity are used interchangeably, although competence pertains to legal judgment while capacity refers to clinical judgment (Appelbaum, 2007). This presents a clinical problem when the informed consent process is reflected in a single document and is required to fulfill multiple criteria for various stakeholders. Informed consent is a medical-legal process that does not consistently use common language reflected in either system (Appelbaum, 2007). Providers are presented with the task of not only ensuring the patient does not have impaired decision-making abilities from a medical standpoint, but must be sure a patient's decision-making capacity is optimized from a legally relevant perspective. Appelbaum (2007) identified that providers should perform assessments in a manner that is consistent with how a court would decide on the case. The legally relevant criteria for decision-making capacity presented by Appelbaum (2007) reflect the same cognitive functions that are impaired by pain including, the ability to communicate a choice, understand the relevant information, appreciate the situation and its consequences, and reason about treatment options.

A systematic review and meta-analysis by Berryman et al. (2013) helps to explain how pain interferes with cognition, specifically working memory, which is required for the consenting process. Berryman et al. (2013) described working memory to be a network of neurons that bridge perception and memory and attention and action. Berryman et al. (2013) further described that working memory is necessary for guiding behavior, making decisions, learning language, reasoning, and planning. The systematic review and meta-analysis by Berryman et al. (2013) provides level I evidence to support that pain can impair aspects of working memory required to meet the legally relevant criteria for decision-making capacity involved in the informed consent process discussed by Appelbaum (2007).

Physiology of Pain

Pain serves as a protective mechanism when tissue is being damaged, according to *Guyton and Hall's Textbook of Medical Physiology* (Hall, 2011). The nervous system plays an intricate role in protecting the body from tissue damage (Netter, 2014). The spinal column contains a canal to carry cerebrospinal fluid (CSF) and travels from the medulla oblongata and ends at the second lumbar vertebrae with the conus medullaris to become the cauda equina (Netter, 2014). There are eight cervical, 12 thoracic, five lumbar, five sacral, and one coccygeal pairs of spinal nerves (Netter, 2014). Each spinal nerve is made up of a dorsal root with sensory neurons, while the efferent or motor neurons are contained in the ventral root and make up the ascending and descending tracts respectively (Netter, 2014). The afferent pathway carries the signal from the area of tissue damage to the cortex, where the stimulus is perceived as pain (Ranalli & Taylor, 2014). The fibers that make up the pathway range from the largest A alpha fibers to the smallest C fibers (Ranalli & Taylor, 2014). Alpha fibers are typically associated with acute pain and have the fastest conduction velocity, while C fibers are usually associated with chronic pain, have the slowest conduction velocity (Ranalli & Taylor, 2014). In addition to the pain pathways and various nerve fibers, there are several neurotransmitters and chemicals involved in the transmission of pain. Some of these neurotransmitters and chemical mediators include: bradykinin, serotonin, histamine, potassium ions, lactic acid, acetylcholine, prostaglandins, substance P, and glutamate (Hall, 2011). Of these, it is thought that glutamate correlates with the pathways made of the alpha-fibers, while substance P correlates with pathways of the C-fibers (Hall, 2011). Regions of the brain involved in pain processing include the reticular area of the medulla, pons, mesencephalon, periaqueductal grey (PAG) region, thalamus, and hypothalamus (Hall, 2011). In these regions, the body has the natural ability to

suppress pain by utilizing the innate chemicals: enkephalins, serotonin, and endorphins (Hall, 2011). These regions of the brain are intertwined and work in conjunction with the cerebral cortex, which plays an intricate role in memory, intellect, cognition, behavior, and emotion (Hall, 2011).

According to Hall (2011), memory is dependent upon chemical changes at the facilitator and sensory terminals in the cerebral cortex. The facilitator terminal located presynaptically, stimulates the sensory terminal located at the neuronal membrane. Repeated signaling contributes to the formation of a memory, and as stimulation increases, the signal becomes stronger, which further contributes to memory or impression (Hall, 2011). Noxious stimuli can prevent the memory from being recollected as it excites the facilitator terminal at the same time as the sensory terminal (Hall, 2011). It is evident by this intricate network of signaling that pain does influence brain activity. One area of the brain that is important in decision-making and informed consent is what Hall refers to as working memory. Working memory is the ability to keep track of many pieces of information and to recall that information when the need arises (Hall, 2011). The effect of pain on cognition is undeniable. Grossman and Wheeler's work goes on to say that endorphins and oxytocin, two of the body's natural chemicals that provide analgesia, disrupt the consolidation of memories, blocking them from consciousness (Wheeler & Grossman, 2014).

Opioid Mechanism of Action

When discussing the mechanisms of action for narcotics such as opioids, it is important to keep in mind their influence on the ability to make decisions. Opioids stimulate Mu receptors, in addition to Delta and Kappa, which can be found in the presynaptic and postsynaptic sites of the spinal dorsal horn, and are responsible for pain processing (Bautista & Grossman, 2014).

Other locations for Mu receptors include the ascending pathways of the brainstem, thalamus, cortex, and the descending inhibitory system, which play a role in pain perception (Bautista & Grossman, 2014). Opioids such as morphine can be natural and derived from opium plants or synthetic such as fentanyl. As mentioned previously, pain is elicited by the release of chemicals such as substance P from the pain producing presynaptic neuron, where they cross the synapse and bind to the postsynaptic substance P receptor (Nagelhout, 2014). The inhibition of substance P entering the synapse breaks the conduction of pain from traveling to the post-synaptic neuron for transmission and recognition (Nagelhout, 2014). The high concentrations of opioid receptors in locations such as the PAG region are responsible for the analgesic properties of opioids. The PAG region is closely associated with the limbic system, which is linked with emotional experience (Bautista & Grossman, 2014). The close relationship between pain and cognition allows the use of cognitive-behavioral interventions such as distraction or relaxation techniques for pain relief (Bautista & Grossman, 2014).

Opioids have several well-known adverse effects, including sedation, nausea and vomiting, constipation, histamine release, euphoria, and dysphoria (Nagelhout, 2014). Adverse effects related to chronic use of opioids include physical dependence and tolerance (Roenquist & Vroom, 2013). Patients who have developed an opioid tolerance require higher doses to achieve the same analgesic effect (Roenquist & Vroom, 2013). These adverse effects, in addition to respiratory depression, miosis, and alterations in cognition are also regulated by the Mu receptor (Bautista & Grossman, 2014).

Consent and Decision-Making While Under the Influence

It seems to be common practice to withhold narcotics when obtaining informed consent due to the concern of impaired judgment (Norman, 2008). An article by Lucha, Kropcho,

Schneider, & Francis (2006) addresses obtaining informed consent and timely pain relief with narcotics. The article considers whether patients can give informed consent though analgesic medications are being withheld or if they are being persuaded to consent for surgical procedures with the promise of narcotic analgesia after signing consent (Lucha et al., 2006). Utilizing the HCAT, a tool developed to determine if patients were competent enough to write advance directives or to give informed consent, Lucha, et al. (2006) concluded that narcotics given for the purpose of controlling pain did not impair the ability to obtain informed consent. Studies determined that HCAT was a legitimate tool to test patient's ability to participate in decisions related to their treatment.

A pilot study by Cowan et al. (2015) referenced patient's ability to consent to research while in acute pain. The goal of the study was to determine if such patients were fit to fulfill the ethical requirements regarding consent (Cowan et al., 2015). While the study does not address the patient consenting to surgery or anesthesia, it may be relevant as they evaluate patients' ability to make informed decisions. The authors acknowledged that few studies have been completed to evaluate a patient's ability to provide consent while in acute pain (Cowan et al., 2015). The pilot study utilized the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR), a tool specifically designed to assess decision-making capabilities required for informed consent. The authors found there to be no statistically significant correlation between a patient's pain level and his or her MacCAT-CR score (Cowan et al., 2015).

In contrast, Apkarian et al. (2004) found that while acute pain had minimal involvement of the prefrontal cortex, patients in chronic pain had significantly more involvement in the same area. Chronic pain was competing with other cognitive abilities. The Iowa Gambling Task, the Wisconsin card sorting test, and the Wechsler Memory Scale were utilized to conclude that

patients who experience chronic pain do have a cognitive deficit when it comes to emotional decision-making (Apkarian et al., 2004). In the discussion section, the authors acknowledge, while pain levels are high neurocognitive function declines (Apkarian et al., 2004). This acknowledgement does not specify chronic opposed to acute pain or acute-on-chronic pain.

It is well known to anesthesia providers that the occurrence of anxiety and depression are higher in chronic pain patients (Apkarian et al., 2004). To this end, Apkarian, et al. reference another study providing evidence that anxiety and depression may have opposing effects on gambling behavior. Finding that those who are experiencing depression based on their decision-making in favor of high-risk/high-reward, while those who are experiencing anxiety favored low-risk/low-reward options (Apkarian et al., 2004). The study never determined that acute pain did not interfere with emotional decision-making, but that chronic pain interfered more with decision-making.

Severe pain can redirect all of a person's attention and disrupt behavior during informed consent (Bautista & Grossman, 2014). Attention is a cognitive domain that is involved in obtaining informed consent. Some of the characteristics involved in evaluating cognitive function such as, carefully thinking about, listening, or watching something, are found in the Merriam-Webster definition of attention ("Merriam-Webster," n.d.). Moriarty et al. (2011) authored a review of clinical and preclinical research discussing the effects of pain on cognitive function. The authors reviewed areas of cognition including learning and memory, speed of information processing, psychomotor ability, and executive function. Moriarty et al. (2011) identified that pain and cognition share similar cognitive evaluative components including learning, recall of past experiences, and active decision-making. The review concluded that there was enough evidence to associate pain with impaired cognitive function. While there are a

number of studies that could be used to support withholding pain medication until informed consent is obtained or treating pain prior to obtaining informed consent, it is evident that pain and cognition are intricately related. The ethics department at the University of Washington indicates that it is common practice to withhold pain medication prior to obtaining consent for concern of the legal implications related to use of narcotics and their impact on judgment (Norman, 2008).

Legal Implications

Medical-legal issues are extremely complex and have become more complex as society tries to find a balance between beneficence and autonomy. Legal implications regarding the impact of pain, and being cognitively appropriate to be informed for consent are not commonly discussed. Coercion and obtaining consent while in severe pain have the potential for legal action against the anesthesia provider as severe pain can impact the patient's understanding. The importance of a patient's understanding is demonstrated in the court case *Canterbury v. Spence*, a historical case ruled in favor of the patient (Dantas, 2011). Patients are instructed to take certain home medications prior to coming to the hospital for surgery. Some of these medications include: opioids such as methadone, anxiolytics, and other classes of medication to help decrease the physiological effects of surgery. If these medications are withheld, patients may experience pain wind-up, possible withdrawal and/or the rebound effects of stopping medications.

Informed consent is an ethical responsibility of anesthesia providers to be patient advocates and act in such a way that best serves the patient. Part of this responsibility is to empower the patient and afford them autonomy to provide them with an anesthetic plan to best meet their needs. This is in addition to an alternate plan and the risks involved with each of these. If the anesthetic plan has limitations it is appropriate to ensure the patient understands

these limitations. While informed consent can be viewed as an ethical responsibility, informed consent plays an important role in protecting the anesthesia provider from a legal standpoint.

The American Association of Nurse Anesthetists (AANA) provides information about liability theory that is covered when obtaining informed consent. Two legal terms defined in the AANA statement include common law battery and negligent failure. Common law battery can be declared if a procedure is done without valid consent. Negligent failure can be declared if the healthcare professional does not explain procedural risks or alternative treatments (American Association of Nurse Anesthetists [AANA], 2013). While obtaining informed consent helps to protect anesthesia providers against such liabilities, it does not completely absolve anesthesia providers from such burdens.

Insightful of the AANA's standards, an article by Pascarella, Walls, Liu, & Chen (2009) discusses the obligations of the anesthesia provider when obtaining consent. Of all the claims brought against anesthesiologists, only about 1% of them are related to informed consent, validating that a patient who signs consent does not pardon the anesthesia provider from liability (Pascarella et al., 2014). Despite having signed consent, a patient can dispute that elements of the consent were never discussed or understood, in addition to the consent being signed under duress or cognitive impairment by medication (Pascarella et al., 2014).

The AANA created guidelines for the issue of obtaining consent from patients whose ability to understand may be impaired. These guidelines apply to several circumstances: 1) impairment from alcohol, drugs, or medication; 2) ability to speak and understand English; 3) mental or emotional conditions, and 4) physical status (AANA, 2013). These are conditions the AANA believes to have legal implications and impair patient's decision-making capabilities when obtaining informed consent. It is evident, by addressing such circumstances, that

anesthesia providers should look at more than the pharmacological implications on decision-making and consider the effects pain has on a patient's decision-making and emotional state. The AANA published an outline regarding informed consent that addressed competence, however it did not mention legal implications of coercion.

Failure of anesthesia providers to treat a patient's pain prior to consent may run the risk of being charged for coercion. An article by Garrison in *William and Mary Law Review* (2007) discusses competence and coercion in healthcare decision-making. While it may not be the intent of the provider, the patient could argue that they had to sign consent in order to have their pain treated. In such circumstances the anesthesia providers are taking away the patient's autonomy by using the patient's ailments, such as pain, to enforce a decision that conflicts with the patient's medical interest (Garrison, 2007). It is difficult to determine the significance or occurrence of litigation that occurs in this legal realm as the number of claims related to informed consent are already a small percentage of total claims (Pascarella et al., 2014). However, informed consent claims do take into account coercive informational influences. While law tends to vary depending on the underlying goal, bioethics literature does stress voluntariness and conditions free of coercion and undue influence, which are necessary factors of autonomous decision-making (Garrison, 2007). While the medical and legal community may have varying criteria to determine if the patient is competent and autonomous in their decision-making, it is the court that ultimately determines if the patient has enough liberty (autonomy) and capacity to make medical decisions (Garrison, 2007). It is therefore prudent for anesthesia providers, based on the circumstances, to take reasonable action and provide pain relief so the patient can be in an optimal state of mind to make an informed decision. Anesthesia providers should consider appropriate and possible alternative interventions to control a patient's pain, as

withholding treatment or obtaining consent while the patient is in pain can have legal implications.

Alleviating Pain with Minimal Effects to Cognition

If pain control is required prior to obtaining informed consent, anesthesia providers should consider analgesic treatments that have minimal effect on cognitive function. The anesthesia provider also needs to exercise judgment and consider a patient's comorbidities, age, procedure, and risk/benefit status to determine if pain or pharmacological influence would impact the patient's decision-making capabilities more. The review about the effects of pain on cognition by Moriarty et al. (2011) provides a listing of a number of medications and their effects on cognitive function. While it is an extensive list, for the purpose of this paper, drugs that improve or do not change cognition in human subject will be discussed. The study cites Grodstein et al. (2008), which demonstrated that ibuprofen, improved cognitive function in elderly patients experiencing pain. Moriarty et al. (2011) also cited a study where gabapentin either showed improved or unchanged cognitive function in healthy individuals. Studies by Tassain et al., Jamison et al., and Lorenz et al. were all cited by Moriarty et al. (2011) and showed that opioids such as morphine, oxycodone, and fentanyl improve cognitive function in chronic pain patients (Moriarty et al., 2011). This is not an exhaustive list and anesthesia providers are encouraged to consider other pharmacological agents that may be appropriate prior to the surgical procedure. Determining an appropriate intervention to improve cognition related to pain in the pre-anesthetic evaluation period is just as important as the intraoperative plan. Preoperative pain control can have intraoperative benefits for homeostasis.

Discussion

This paper provides strong evidence that pain significantly impairs cognition. However, it is still unclear how best to optimize a patient's decision-making ability when impaired by pain. Further research or investigation is required to determine if opioids are an appropriate intervention to improve decision-making capabilities. Additional research would be of benefit to establish if other pharmacological or non-pharmacological modalities exist to optimize decision-making during the informed consent process. This paper suggests there is a close association between the legal criteria involved in the decision-making process during informed consent and the medical or clinical criteria. However, there lacks a common language between the medical and legal community and this has the potential to create conflict in how patients are evaluated to determine if they pose the ability to participate in the informed consent process. Terms such as capacity and comprehension need to be evaluated to be sure they are being used correctly in future studies and cases. Both capacity and comprehension play an important role in decision-making and the validity of informed consent. Standardized tools and guidelines for assessing decision-making could be beneficial to all the stakeholders involved in the informed consent process. Creating a standard guideline that is appropriate for the production pressure of the clinical setting while meeting the legal criteria should be the focus of future studies.

Conclusion

In conclusion, pain has several implications for anesthesia providers. Having an understanding of the pathophysiology of pain helps the provider to understand the physiological effects of pain on homeostasis and cognition. In addition, it is important to appreciate the mechanism of action for pharmacological agents such as opioids and their influence on cognition. Cognition and a patient's decision-making capability play an important role when the

provider is obtaining informed consent. Obtaining informed consent is an ethical and legal responsibility of the anesthesia provider. It is important to consider the legal implication that may ensue for withholding treatment, obtaining consent under the influence of medication, or states of duress such as pain. Analgesic medications may cause cognitive impairment, however, evidence in the literature does demonstrate that effective pain relief can improve associated cognitive impairment (Moriarty et al., 2011). Anesthesia providers should seek out alternatives for alleviating pain with an end goal of improving a patient's judgment and ability to truly be informed during the process of obtaining consent.

Appendix



American Association of Nurse Anesthetists
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Informed Consent in Anesthesia

Use of Model Consent Forms can Help Protect Providers from Liability

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

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

Importance of Documenting Evidence of Communication

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

Subjective Nature of Communication Creates Barriers to Understanding

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

Model Forms Help Establish Strong Presumption of Consent

When informed consent is an element in a legal dispute, the question of whether the patient was adequately informed and consented to the procedure often shifts to the quality of the evidence. If the evidence is weak or insubstantial, then the debate can focus on communication, which is always subject to the interpretation of the patient. Predictably, the patient will testify that he/she did not understand what was said, even if the evidence indicates that a meeting between provider and patient took place. The fact that a meeting took place does not necessarily mean there was a meeting of the minds.

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

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

Importance of Merging Communication and Evidence

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

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

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

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

Obtaining Informed Consent from Impaired Patients

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

Substitute can Provide Consent when Patient is Unable

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

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

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

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

Implied Consent Rule Enables Provider to Act in an Emergency

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

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

Preanesthetic Evaluation Integral to Informed Consent Process

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

provision of quality anesthetic care. The information elicited from such an evaluation concerning the patient's history might influence the requisite disclosure."

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

The degree of specificity regarding risks has always been an issue. In *Lindquist v. Ayerst Laboratories, Inc.*,⁷ the court said, "The anesthesia provider is not required to inform the patient of every conceivable risk, but only significant risks." The model consent forms include all significant risks; however, space constraints preclude adding all information that might be desirable in order to answer most questions a patient might ask. A frequently asked question is, "What are the chances of dying or sustaining a serious anesthesia complication?" In order to relieve anxiety and maintain good patient rapport, it is generally wise to attempt to answer such a question by quoting statistics and emphasizing the improved safety of anesthesia due to newer technology and monitoring techniques. Estimates of anesthesia mortality rates vary according to which study is quoted. According to E. C. Pierce⁸ and Richard Keenan,⁹ reports published between 1954 and 1985 established mortality rates at somewhere between 1 per 1,560¹⁰ to about 1 per 10,000 anesthetics administered. Recent studies^{11, 8, 12} have shown a dramatic reduction in anesthesia mortality rates, with ranges between 1 per 185,000 and 1 per 280,000.

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

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

Provider, not Hospital, must Obtain Informed Consent

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

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

Model Consent Forms Available for Anesthesia Professional's Use

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

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

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