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Informed Consent for the Orthopaedic Surgeon

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Abstract

» In the United States, orthopaedic surgeons have a legal obligation to obtain informed consent from patients before performing surgery; it is a process that includes a signed written document.

» There are specific legal requirements that vary somewhat by state but generally include disclosure and documentation of the diagnosis, an explanation of the recommended procedure, a conversation about the risks and benefits of the procedure, and a discussion about alternative treatments.

» Inadequate disclosure of risks and alternatives is associated with increased indemnity risk.

» Studies have shown that many consent processes and forms are suboptimal.

Informed consent is a legal and ethical obligation of all health-care professionals. This process encompasses the ethical principles of autonomy, beneficence, and nonmaleficence. The concept of patient autonomy allows patients who have adequate decision-making capacity to determine what will happen to their bodies. Beneficence focuses on the promotion of the well-being of others, and nonmaleficence means "to do no harm" and represents the patient's right to be free from harm and discomfort, as well as his or her right for protection from exploitation[1-3]. Physicians should educate patients on specific interventions, discuss the risks and benefits of the intervention, and assess for overall patient competency and comprehension[4]. While the informed consent process has been recognized as an important tenet in medicine for several decades, there are still many challenges to implementing an effective informed-consent process while providing high-quality care and avoiding litigation. This is particularly true in the field of orthopaedic surgery because malpractice claims that are paid to plaintiffs are higher than in most medical specialties, and failure to properly obtain informed consent is a frequent cause for these claims[5-7]. The purpose of this article is to provide a review of the current understanding of informed consent in orthopaedic surgery, with a focus on practical implementation.

Informed Consent Process

In order to respect the right of patients to make health-care decisions, it is paramount that physicians obtain informed consent prior to subjecting them to treatment and therapies. Informed consent should always be obtained prior to initiating surgical procedures, blood transfusions, anesthesia, radiation, chemotherapy, advanced medical testing (e.g., biopsies), and enrollment into clinical research. In order to make an informed decision, patients should be educated on their diagnosis, alternative treatments and therapies, the proposed benefits of treatment, and possible adverse events. It is important to note that the informed consent process and the informed consent document are 2 independent

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entities; the informed consent document is a component of the process, not the process itself. When determining what information should be provided to patients, 2 different legal approaches are widely accepted for obtaining informed consent: (1) the reasonable patient standard, and (2) the reasonable physician standard[4]. The reasonable patient standard is based on what information an average patient would need to know in order to provide informed consent. Similarly, the reasonable physician standard is based on what a reasonable physician would say about the procedure or treatment modality. In the United States, there is variability regarding which standard should be used, and it is essential for clinicians to determine which standard is followed in their jurisdiction[4,8,9]. In order to evaluate the difference in indemnity risk between the patient and physician standards, Studdert et al. performed an analysis of 714 jury verdicts across 25 states[10]. They found that a verdict for the plaintiff was significantly more frequent in states that utilized the patient standard. Furthermore, plaintiff verdicts were twice as likely in states that used the patient standard (odds ratio = 2.15, 95% confidence interval = 1.32-3.50).

When obtaining informed consent from a patient, it is important for the physician to acknowledge and respect the patient's role in decision-making[11]. Additionally, the patient should feel free to make decisions without coercion. Every step of obtaining consent should be properly documented in the patient's medical record. The 4 steps of informed consent include (1) a review of the diagnosis and the laterality of the ailment, (2) an explanation of the proposed procedure or the treatment/intervention that will be performed, (3) a discussion of the risks and benefits of the procedure as well as the probability of success, and (4) a discussion of the alternatives, including their risks and benefits (Table I). Following the completion of these steps, it is highly recommended that the physician evaluates the patient's comprehension of steps 1 through 4. The repeat-back technique can be used when evaluating patient comprehension as it has been demonstrated to aid in patient understanding[12]. Because it is possible that no intervention will be performed, the risks and benefits of no treatment should also be clearly delineated[11]. Patients should then provide verbal or signed consent for the procedure. The person obtaining the consent should also provide a signature. It is important to recognize that the length of time that an informed consent form remains valid after being signed by a patient varies by state and health-care system. In light of this variability, it is good practice to confirm consent with a patient on the day of surgery. If information pertaining to the physician performing the procedure changes, a different physician will perform the procedure, and/or the type of procedure changes after the consent form has been signed, a new form is required. While the level of detail in which the indicated procedure is described is institutionally dependent, details should be explained in layman's terms to aid in patient understanding and comprehension of the procedure. Lastly, all medically viable alternative procedures, as well as their benefits, risks, and probability of success, must be clearly delineated in order for the patient to make an informed decision. Physicians should also provide unbiased information to patients to allow them to make decisions without feeling pressured. This can be accomplished by providing patients with the facts surrounding the procedure or medical treatment/intervention in simple language. An assessment of patient comprehension of the overall informed consent process and the use of simplistic language are imperative for the process to be successful. If the patient does not completely understand any part of the process, additional discussion should occur before the patient can be considered informed enough to provide consent[11]. It is impossible for the patient to understand the entirety of the procedure from the brief consent process; however, the patient should have a general understanding of the procedure, including all of the major risks and possible complications. Each step of the informed consent process should be delivered in a clear manner, and medical jargon should be kept to a minimum to facilitate patient comprehension[13].

TABLE I The 4 Steps of the Informed Consent Process*

1. Review the diagnosis with the patient.
2. Explain the recommended procedure.
3. Review the possible risks and the probability of success.
4. Provide information about alternative treatments and their associated risks.

*Specific legal requirements may vary based on jurisdiction.

In a shared decision-making model of informed consent, surgeons disclose all of the necessary information about their patient's condition, including the associated risks and benefits, the various treatment options, and their professional insight, while patients express their goals, values, and preferences[11,14-16]. Shared decision-making shifts the focus from being based purely on scientific evidence to also including patient and family preferences[17]. No one should dominate the conversation. This communication tool helps to ensure that the patient's preferences are in alignment with the surgeon's advice. In an effort to streamline the training of clinicians on the core process of shared decision-making, a 3-talk decision model has been developed and is recommended[18-20]. This model, which was developed by Elwyn et al., involves (1) team talk (physicians and patients work together and discuss options and goals), (2) option talk (including a discussion of risk), and (3) decision talk (the physician elicits a patient's informed preferences)[19,20].

Common Pitfalls

Informed consent has become integral to the health-care system; however, there are several recurring issues that arise.

Some of the most prevalent challenges include inadequate consent forms and documentation, patient gaps in health literacy, language/cultural barriers, and a lack of standards when delegating the task of obtaining informed consent.

There are many key elements to obtaining informed consent from a patient that should be represented in the documentation, and for this reason, most hospital systems have consent document templates for health-care providers to use when obtaining consent. However, the current literature indicates that many consent forms are inadequate[21,22]. A study by Bajada et al. evaluated a consecutive series of 140 patients undergoing elective trauma procedures; they found that 62% of the consent forms did not have a sufficient complications sections, 25% of the consent forms were not fully legible to patients, and no patients were offered copies of the consent form[21]. The researchers implemented procedure-specific complication labels/stickers and focused departmental teaching, which eventually resulted in 100% of the consent forms being legible and having a sufficient complications section[21]. A systematic review by Lühnen et al. examined the quality and efficacy of consent forms via 14 content analyses; they found that the forms were lacking in an explanation of the risks, alternatives, benefits, option of no treatment, and numerical frequencies[22]. One recommendation for overcoming the issue of inadequate consent forms is to follow a procedure-specific approach (e.g., using procedure-specific complication labels/stickers).

The health literacy of patients is also important to consider when obtaining informed consent. Health literacy is a term that is used to describe a patient's abilities to receive, understand, and apply health-care information in order to make informed decisions and comply with provided instructions for disease prevention[23]. Mancuso and Rincon performed a cross-sectional study to assess the health literacy of 175 asthma patients and their desire to participate in decisions regarding their care[24]. They found that lower health literacy, as calculated with use of the Test of Functional Health Literacy in Adults[25], was associated with decreased satisfaction in the quality of care they received, the overall status of their disease, and a lower likelihood of patients participating in their own health-care decisions. In a prospective observational cohort study, Kadakia et al. evaluated the level of comprehension that orthopaedic trauma patients had regarding their injuries, surgeries, and postoperative treatment plans; they found that when patients were administered a questionnaire, the average graded comprehension was 2.54 ± 1.27 of 5[26]. Only 18.5% of patients knew how long it was expected for them to heal, and 47.9% knew what bone had been injured. Sherlock and Brownie performed a literature review regarding patient understanding and recollection of medical procedures following consent; they found that 21% to 86% of patients remembered what risks or complications had been discussed, and the degree of understanding decreased with patient age[27]. The challenges associated with health literacy can be mitigated with effective patient-physician communication. In a systematic review, Lin et al. found that risk recall and comprehension were greater in trauma patients when they had received both written and verbal information rather than verbal information alone, and patients were more satisfied with video-based information than written or verbal information[28]. Another study conducted by Fink et al. evaluated the predictive factors of patient comprehension during consent for surgical procedures[12]. They found that the use of the repeat-back technique, where patients repeat procedure details to the physician, was significantly associated with increased patient comprehension. Of these factors, physicians can control the length of time spent with patients and perform repeat-back methods. Therefore, it is recommended that clinicians use patient-tailored multimedia approaches and repeat-back techniques and spend adequate time with patients (between 15 and 30 minutes) when obtaining consent.

Informed consent should be obtained in a language that patients can understand[29,30]. Despite this standard, physicians often obtain informed consent from non-English-language-speaking patients by speaking in the patient's language without fluency or using ad hoc interpreters, such as a patient's family members or untrained medical staff[31,32]. In a cohort study, Hunt and de Voogd examined the informed consent process for 30 Latina patients who were scheduled to undergo amniocentesis[31]. When post-procedure interviews were conducted, it was found that 11 patients required a formal language interpreter but had not had one present at the time of consenting. Furthermore, only 1 of the 11 patients who lacked an interpreter met the parameters that were necessary to give informed consent. In a study by Patel et al., researchers surveyed orthopaedic surgeons and other surgical subspecialists about their language proficiency; 37.5% of physicians who reported using non-English-language skills while speaking with patients with limited English-language skills were found to be doing so without fluency[32]. When asked about their actions when obtaining informed consent in the ambulatory setting, 28% of these surgeons admitted that they would use their non-fluent language skills to obtain informed consent if the patient presented alone and it took >15 minutes for a medical interpreter to arrive. In addition to the underutilization of interpreters, the acquisition or documentation of informed consent for patients with limited English-language skills may not be adequate[33]. Schenker et al. performed a review of electronic medical records of patients with documented emergency procedures. They found that the charts for English-speaking patients had a 53% chance of possessing a fully documented informed consent note, whereas the charts of non-English-speaking patients had a 28%

chance ($p = 0.003$)[33]. It is imperative that surgeons utilize approved language interpreters and avoid the use of untrained interpreters or those with inadequate translation skills in order to improve patient care and lower indemnity risk. Interpreters are needed to complete informed consent notes in order to ensure an adequate informed consent process.

While not legally required, it is an ethical obligation for surgeons to take the time to understand both the individual and faith-based desires of their patients prior to obtaining informed consent. For example, while Jehovah's Witnesses refuse blood transfusions, some may accept certain blood products such as albumin[34]. Additionally, some religions are flexible when it comes to their teachings about surgery, and, if inclined to do so, surgeons can enlist the help of a hospital chaplain to work with patients' respective religious advisors in order to determine their wishes regarding a certain procedure that would otherwise be refused based on religious virtue alone[34].

Legal Issues

As the concept and application of informed consent in a clinical setting have evolved, it has become an essential social and legal foundation that prevents patients from undergoing nonconsensual procedures[35]. It prevents physicians from committing assault or battery, which occurs when physicians perform procedures without a patient's consent, or procedures that are different or out of scope from the one for which the patient provided consent. Despite numerous revisions to the concept of informed consent, it is still one of the most cited reasons for malpractice lawsuits[30,35].

Malpractice is defined as negligence or substandard care by a physician, either through omission of an appropriate act or execution of an inappropriate act that causes harm to the patient while the patient is under his or her care[36]. Jena et al. conducted a study on malpractice claims in the United States from 1991 to 2005 that had been stored by a physician liability insurer; they demonstrated that 7.4% of physicians insured across all specialties had claims against them annually[37]. Additionally, several studies demonstrated that approximately 15% of orthopaedic surgeons face malpractice claims annually, which is among the highest rate when compared with other medical specialties[5,38]. Epstein performed a retrospective review of 78 malpractice lawsuits involving cervical spine surgery; 12 of the 63 surgeons who were implicated were orthopaedic surgeons, and 44 of the 78 total cases involved lack of informed consent[39].

Not all aspects of the informed consent process hold equivalent indemnity risk. In a retrospective cohort study, Grauberger et al. examined malpractice claims involving spinal surgery in the United States that were stored in a legal database; 153 of 233 claims from 1980 to 2015 involved improper informed consent as either the primary or secondary allegation, and insufficient explanation of the risks and adverse effects was the most common specific allegation (30.4%), followed by failure to explain alternative treatment options (9.9%)[7]. Similarly, in a claims analysis, Veerman et al. researched malpractice suits and medical disciplinary board complaints in the Netherlands between 2004 and 2013; in a random sample of 245 malpractice suits involving allegations of informed consent, they found that 67% of the cases involved allegations of insufficient disclosure regarding risk or complications, and 13% of the cases involved allegations of improper disclosure of alternative treatment[40]. Considering the findings of these studies, it is recommended that orthopaedic surgeons focus on the specific steps that are necessary to explain the potential risks and the alternative treatment options for a given procedure.

As stated above, failure to disclose the risks of a procedure in the informed consent process is associated with increased indemnity risk. In a closed claims analysis, Bhattacharyya et al. found 28 malpractice lawsuits against orthopaedic surgeons that cited improper informed consent as an allegation; 20 of the plaintiffs alleged that the surgical risks had not been properly disclosed[41]. However, this same study demonstrated that indemnity risk for informed consent lawsuits was significantly reduced when informed consent was obtained by the operating surgeon in an office setting rather than in perioperative holding areas ($p < 0.004$). This suggests that having the performing surgeon obtain informed consent in an office setting may prevent legal repercussions by avoiding situations where patients feel as though the risks had not properly been disclosed or may have other complaints regarding the informed consent process.

Medical malpractice lawsuits generally span many years, can be costly, and are emotionally difficult for the defending physician[36]. Schaffer et al. conducted an analysis on paid malpractice claims that were logged in the National Practitioner Data Bank from 2009 to 2014; as of 2014, there were >10,000 orthopaedic surgeons in the United States with paid malpractice claims against them. Payouts have increased more than $50,000 in the U.S. since 1992; the average payout was $283,979 in the time period from 2009 to 2014[5]. In a similar study, Studdert et al. examined malpractice claims that were logged in the National Practitioner Data Bank from 2005 to 2014; they demonstrated that orthopaedic surgeons who have at least 1 paid claim against them are twice as likely to have recurrent paid claims when compared with physicians in other specialties such as internal medicine[42]. Hence, it is growing increasingly important for orthopaedic surgeons to attenuate issues related to informed consent, thereby preventing the professional, social, and monetary burden of malpractice lawsuits.

Special Considerations

When dealing with a diverse patient population, several exceptions can be

made to the requirements of the informed consent process. These exceptions include instances when the patient is a minor, when the patient is incapacitated and is unable to consent, and when the patient lacks competency to make medical decisions.

The medical decision-making process for underage children belongs to parents or legal guardians[29]. Even for examinations that do not include procedures, providers should obtain consent from legal guardians either through direct conversation, written documentation, or telephone communication. There are several exceptions to this rule that enable minors to obtain informed consent for their own care[29,43]. One exception is when the underage person has been emancipated through a court order or through a situational circumstance (e.g., when said person is married, has children, or is in the military, or when a parent is not available to make time-sensitive medical decisions)[43].

There are instances when informed consent need not be obtained from the patient, an appointed surrogate, or a default surrogate in order for the surgeon to proceed with treatment[29,35]. In emergency situations when immediate treatment is necessary to save the life of a patient or the life functions of an incapacitated patient, surgeons are obligated to forgo the process of establishing informed consent in order to provide treatment in a timely manner[29,35]. If a surgeon fails to provide lifesaving treatment in these situations, he or she could be considered negligent[35]. The exception to this rule is when lifesaving treatment has been formally refused by the patient prior to the incident requiring intervention[29].

Patients with mental disorders require special consideration regarding informed consent[44]. Throughout the informed consent process, psychiatric patients may face issues with external pressure as well as problems with understanding, making decisions, and taking actions. However, these individuals should not be assumed to be incompetent to give consent to treatment, and their decisional capacity should be evaluated[44]. When an individual is deemed incompetent to make his or her own decisions by a court of law, his or her ability to consent to treatment will then be delegated to a surrogate, which is often a family member but may also be a guardian who is assigned by the court[45].

Overview

Informed consent is not a static concept. It has evolved tremendously over the past several decades and is subject to change. Although there are many challenges, legal limitations, and special considerations that are associated with the process of informed consent, there are also several proposed guidelines for each step that are important for all physicians, including orthopaedic surgeons, to acknowledge in order to provide high-quality patient care and avoid legal implications.

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