Commentary

Should the chiropractic profession embrace the doctrine of informed consent?

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Abstract

This commentary provides a narrative review of the literature focusing on the use of a health care informed consent process in the United States. This article reviews the current positions of the World Medical Association, American Medical Association, American Chiropractic Association, Wisconsin and New Jersey State Courts, US Federal Government Office of Health Policy and Clinical Outcomes, and 1 college of chiropractic regarding the doctrine of informed consent. The authors recommend that the chiropractic profession embrace the doctrine of informed consent and promulgate it as a standard of care. The implementation of this doctrine by chiropractic physicians promotes and improves the safety of chiropractic interventions.

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Introduction

This narrative review attempts to address the question of whether the chiropractic profession should embrace the doctrine of informed consent by presenting legal discussions, professional association recommendations, legislative action, current academic positions, and Federal Government recommendations. The overwhelming and convincing evidence mutes

concerns and refutations of a vocal minority that argues against the informed consent doctrine. This review provides the clarity in which to embrace our contention that the informed consent doctrine be promulgated as the standard of care within the chiropractic profession.

Discussion

Doctrine of informed consent

Hippocratic tradition stressed a paternalistic behavior that directed physicians to use their expertise

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and determine appropriate medical or surgical care without patient involvement in the decision-making process.¹ Because of the medical research atrocities performed by Nazi physicians, a Doctrine of Informed Consent evolved with its roots in the Nuremberg Code of 1948 and the World Medical Association's Declaration of Helsinki in 1964.^{2,3} This doctrine provides guidelines that attempt to protect human subjects involved in medical research projects. In direct conflict to the benevolent paternalism of hippocratic teachings, the advanced medical directive legislation of 1990 (Patient Self-Determination Act) promulgates a patient decision-making process that provides medical guidelines and directives to the involved physicians.⁴

Medical malpractice crisis

During the 1970s and 1980s, allopathic physicians claimed a malpractice crisis; and Thorpe⁵ wrote recently that the United States may be in the midst of its third "crisis" in medical malpractice. Although chiropractic physicians have never claimed such a malpractice crisis, the chiropractic profession has experienced a significant amount of negative publicity in both the United States and Canada due to a small number of malpractice claims.^{6,7} Yale has reported that surgeons at a Bridgeport, CT, hospital continue to perform certain invasive procedures without informed consent.⁸ Because the local media have not expressed concerns, reasonable individuals might question the possibility of hegemonic influence by political medicine as a cause for unwarranted media coverage of 2 chiropractic malpractice claims. Yet, we wonder if the lack of informed consent is to blame.

American Medical Association

According to the American Medical Association (AMA), a physician has an obligation to reveal and discuss any known diagnosis and the treatment or examination procedure recommended. In addition, the physician should present the risks and benefits of any proposed treatment or procedure and alternative treatments that would include their risks and benefits. Finally, the patient should be informed of the risks and benefits of not receiving treatment or examination procedures.⁹ Interestingly, the AMA suggests that proper record keeping, which documents the informed consent communications between physician and patient, is more likely to

reduce risk of liability than a sophisticated informed consent form.

American Chiropractic Association

The American Chiropractic Association (ACA), which is the largest organization representing the chiropractic profession in the United States, approved ethical recommendations regarding informed consent in 1975 as promulgated in the association's policy for that year.¹⁰ These cursory comments by the profession's largest American trade association delineated consent, informed consent, and the importance of the process relevant to malpractice but lacked specific recommendations. Moreau and Stoos¹¹ offered survey data regarding chiropractic practice behavior and a comprehensive set of informed consent guidelines for chiropractic physicians in 1996. The small study revealed that 73% of the responding chiropractors used informed consent documents when patients presented with more serious conditions. Obviously, this report indicates a perfunctory use of a routine informed consent process by chiropractic physicians. The ACA reported in 2000 that the average length of time spent in practice by a chiropractic physician was 17 years, with 10% of respondents in practice for 4 years or less and 10% in practice for 30 years or more.¹² We question whether this chiropractic practice behavior is the outcome of academic training for most of the chiropractic physicians before 1996 or related to the rare incidence of malpractice claims experienced by individual chiropractors?

The ACA attempted to educate its membership regarding informed consent before 1976 with the following policy statement.

Informed consent is generally applied, from a legal standpoint, when measuring the degree of responsibility and/or liability of a doctor in malpractice cases. In other words, the fact that a patient submits to treatment and does so voluntarily does not in itself lessen the liability of the doctor. Today, the stand by which the doctor is judged is that of "informed consent." By that is meant, to what degree has the patient been informed of all of the potential consequences, dangers, and other factors, so that his consent is given with full knowledge of the inherent dangers to which he is exposed. Full knowledge in this sense could be construed as "informed consent" and would relieve the doctor of much liability, as there would be an assumption of the risk on the part of the patient. The concept of "informed

consent” can also be applied to other contractual relationships such as those for examination and treatment, which are every day occurrences in the doctor’s office. (Approved, July 1975)

A reasonable health care provider might consider the informed consent process to be appropriate; however, the 1975 ACA policy statement does not acknowledge this process to be a standard of care.

Informed consent

As reported by Walter¹³ in the *St John's Review*, the “Doctrine of Informed Consent” became a law with the enactment of the medical malpractice act by the New York Legislature 3 decades ago. Judge Benjamin Cardozo clarified the concept of self-determination and informed consent with his decision in *Schloendorff v New York* when he noted: “every human being of adult years and sound mind has a right to determine what shall be done to his body.” Some 15 years later, Faden and Beauchamp¹⁴ defined informed consent as “...an individual’s autonomous authorization of a medical intervention or of participation in research.” The AMA further depicts informed consent on its official Web site as a process:

Informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and physician that results in the patient’s authorization or agreement to undergo a specific medical intervention. (<http://www.ama-assn.org/ama/pub/category/4608.html>)

Redwood and Cleveland¹⁵ define informed consent in their text, *Fundamentals of Chiropractic*, and imply that health care providers must obtain informed consent for treatment.

Informed consent—a legal doctrine that requires that health care providers obtain consent for treatment based on an informed and knowledgeable understanding by the patient of the risks, benefits, and alternative to treatment.

Should chiropractic physicians conform to the same legal and ethical constraints as other health care providers, such as allopathic physicians, and provide an informed consent process? According to Lauretti,¹⁶ contemporary chiropractic training stresses the safety of chiropractic interventions; he questions whether routinely advising patients of potential adverse reactions before cervical manipulation or adjustment is

reasonable, unless the patient presents with a specific risk factor. Although scientific and practice data may indicate chiropractic interventions to be much safer than common pharmaceutical treatments,^{17,18} 2 court systems have determined an informed consent process to be mandatory for chiropractic care.

Chiropractic profession

Langworthy and Cambron¹⁹ surveyed chiropractors in the United States and the United Kingdom with intent to explore their implementation of medical consent. Their research revealed that some responding chiropractors did not embrace the doctrine of informed consent. The results suggested that the chiropractic patients were not provided an appropriate informed consent process because of the paternalistic concepts of the chiropractors. The doctors determined that the safety of chiropractic treatment procedures rendered the routine discussion of major risk unnecessary.¹⁹ Results from this survey suggest that a patient’s autonomy and right to self-determination may be compromised when seeking chiropractic care. Difficulties and omissions in the implementation of valid consent processes appear common, particularly in relation to risk. Practitioners felt that a serious adverse event occurred so infrequently that this, coupled with a lack of convincing evidence regarding the risk associated with certain treatment, rendered the routine discussion of major risk unnecessary.

Wisconsin Supreme Court decision

Pizzi et al²⁰ questioned whether it was necessary to seek informed consent with routine medical procedures. The Court concluded that it was reasonable for both medical doctors and chiropractors to discuss the risks of the proposed treatment. This legal decision issued by the Wisconsin Supreme Court on June 29, 2005, succinctly stated that chiropractors must obtain informed consent from their patients.²¹ Its decision in the case of *Hannemann v Boyson* answered a key question regarding the chiropractor’s informed consent duty to chiropractic patients in Wisconsin. The Court decided that chiropractic physicians are obligated to inform their patients of the risks and benefits of chiropractic treatment, similar to the informed consent given by (allopathic) physicians to their patients.

The Court stated²¹:

We conclude that although the practice of chiropractic and the practice of medicine are distinct

health care professions, the obligation of the practitioners of both to disclose the risks of the treatment and care they provide should be the same. While the actual disclosures will inevitably vary between doctors and chiropractors, the nature of the duty and limitations thereon should be the same. A patient of chiropractic has the same right as a patient of medical practice to be informed of the material risks of the proposed treatment or procedure so that he may make an informed decision whether to consent to the procedure or treatment. As such, we hold that the scope of a chiropractor's duty to obtain informed consent is the same as that of a medical doctor.

New Jersey Supreme Court

In 1999, Judge Pollock ruled that a patient has the right to be informed of both invasive and noninvasive procedures, which is bittersweet for the chiropractic profession and problematic for the surgeons in the "Garden State." This decision certainly provides a legal opinion that requires an effort by a physician to inform the patient of alternative treatments before provision of medically necessary care²²:

Because the patient has a right to be fully informed about medically reasonable courses of treatment, we are unpersuaded that a cause of action predicated on the physician's breach of a standard of care adequately protects the patient's right to be informed of treatment alternatives. A physician may select a method of treatment that is medically reasonable, but not the one that the patient would have selected if informed of alternative methods. Like the deviation from a standard of care, the physician's failure to obtain informed consent is a form of medical negligence....

This New Jersey ruling directs physicians to discuss both surgical and nonsurgical care with the patient, which might include chiropractic services. Likewise, it appears that if they were considered to be physicians, chiropractors would be responsible to inform the patient of both surgical and nonsurgical care. The chiropractic profession in New Jersey must question how likely a medical malpractice claim due to negligence is when a chiropractic physician fails to comply with the recommended informed consent process.

Connecticut case law

All health care providers in Connecticut should implement the use of the informed consent process to

comply with the current case law, which protects and respects the rights of all individuals seeking medical treatment. We wonder if allopaths and chiropractors recognize the existence of this case law. The Connecticut consent issues are detailed in a legal digest, which attempts to explain the health care provider responsibilities in the "Constitution State."²³

In the case of adults, Connecticut case law has established a common law right of bodily self-determination entitled to respect and protection. Health care providers have no common law right or obligation to thrust unwanted medical care on a patient who, having been sufficiently informed of the consequences, competently and clearly declines that care. As long as a patient is sufficiently informed of the consequences of her decision, is competent to make such a decision, and freely chooses to refuse treatment, the health care provider is required to respect her choice.

Professional chiropractic practice

Landenheim et al²⁴ advised the profession in this risk management text that informed consent was a prerequisite for chiropractic treatment. In addition to this explicit recommendation, the authors discussed the risks of treatment and the significance of explaining the probability of those risks occurring with chiropractic care. Dr Lou Sportelli²⁵ explained the need to provide a patient consent form to comply with Federal Guidelines for the Health Insurance Privacy and Accountability Act. It is essential that chiropractic physicians understand the 2 standards as described in the *Professional Chiropractic Practice* text.

The Physician Standard

The physician standard requires that the doctor provide such information as a reasonable physician would under the same or similar circumstances. Focusing as it does on what doctors would reasonably do, this approach tends to be clinically objective and emotionally detached. Because it ignores emotional patient consideration, it is generally more forgiving of the doctor.²⁴

The Patient Standard

In contrast, the patient standard requires the physician to provide such information as a reasonable patient under the same or similar circumstances would need to make an informed and prudent decision.²⁴

The patient standard and the physician standard relative to material risk are germane. The informed

consent requirement appears to answer the question posed to the profession in this paper, “should a chiropractor provide an informed consent process?” These authors also suggest that the possibility or probability of adverse reactions be explained before care, which empowers the patient to make an informed decision.

Whatever else the doctor may say or do, the patient’s decisions will not be truly informed and voluntary if the risk is not quantified in some manner.²⁴

Chiropractic physicians might find these 2 standards to be confusing because they are quite difficult to discern without legal training. Yet, neither standard should impact our clinical decisions or negate our responsibility to inform the patients of their conditions and our medical management recommendations. A malpractice case in Connecticut exemplifies the alleged nonuse of the patient standard by a chiropractic physician. The patient claimed that if she knew there was a possibility of a stroke with a chiropractic adjustment of the neck, she would have declined the treatment.²⁶ This malpractice case generated an extensive attack on the profession and generated antichiropractic legislative activities.^{27,28}

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Currently, the Small Business Procedures class uses the *Professional Chiropractic Practice* textbook to teach senior students ethics, business, jurisprudence, and risk management. Chiropractic students are taught that chiropractic physicians must perform a competent and continuing informed consent process, which not only addresses the working diagnosis but also any future changes in the patient’s condition. It is suggested that the signing of an informed consent form by a patient is only 1 aspect of the informed consent process. Students are advised to complete record keeping with a standard progress notes process and then make the notes available to the patient and his/her primary care physician. It has been suggested that this procedure provides for improved patient compliance and a reduction in malpractice allegations due to negligence.²⁹

Government position on informed consent

Pizzi et al³⁰ of Thomas Jefferson University School of Medicine wrote the *Procedures for Obtaining Informed Consent for the Office of Health Policy & Clinical Outcomes*. The purpose of this extensive

research effort was to improve patient safety. In terms of the research agenda for patient safety, 1 of the 12 most highly rated practices involved the process of informed consent. The researchers were interested in patient recall of the informed consent discussion with the health care provider. The patients were asked to recall and restate what they have been told during the informed consent process. Some excerpts are provided to depict the government’s rationale for concern about safety and to describe its explanation of informed consent.

Informed consent is a process through which a physician informs a patient about the risks and benefits of a proposed therapy and allows the patient to decide whether the therapy will be undertaken. It may be received in one sitting, or over a period of time, either orally or in writing or a combination of the two. Informed consent procedures have been instituted in both research and clinical medicine. In the former case, federal regulations establish strict guidelines for informed consent that are monitored by a special board at each institution (Institutional Review Board). In addition, risks and adverse events that occur while research is in progress are followed closely and reported. As such, informed consent in the research setting differs greatly from informed consent in the clinical setting. In clinical practice, formal efforts, such as the signing of a consent form (presumably preceded by adequate exchange of information), are only undertaken in some circumstances, notably prior to major invasive procedures such as radiologic procedures and surgery. Less well appreciated is that all medical care, including pharmacy prescriptions or laboratory tests, requires informal informed consent, except when the patient is incompetent to make a decision or relinquishes the right to provide it. Studies suggest that in practice only minimal formal efforts are made to obtain informed consent for routine interventions.³⁰

Practical informed consent process

Informed consent is simply a verbal discussion with the doctor and the patient concerning the benefits and risks of the medically necessary treatment that is based upon the presenting complaints, examination findings, and diagnosis. Documenting your patient’s verbal consent to treatment is essential and usually involves the use of a consent form and/or the recording of said discussion in the patient chart. We suggest that the most detailed if not preferred method for obtaining and documenting informed consent is through the use of a

consent form that is completed by the doctor in front of the patient after a thorough discussion of the recommended treatment. Every health care provider should consult his or her State statutes to clarify local requirements regarding the informed consent process.

The consent form might substantiate that an informed consent process has been attempted by the provider. We recommend that the doctor and the patient sign the consent form. If verbal consent is obtained rather than using a written consent form, documentation in the initial examination or narrative report of the information provided to the patient and his or her acceptance to proceed with treatment recommendations must be clearly stated in the record.

Initially, the doctor discusses with the patient the recommended and/or necessary treatment(s) or procedures and the indications for treatment. Afterward, the doctor discusses with the patient the most common risks associated with the recommended evaluation and management procedures. Common risks should include any potential benign or mild adverse effects such as temporary soreness or stiffness secondary to high-velocity, low-amplitude, closed reduction manipulation. A discussion about common risks should be followed by a thorough discussion of the more significant risks associated with the recommended procedures. A significant risk discussion may include the potential for rib fracture with high-velocity, low-amplitude, closed reduction manipulation of the thoracic spine. It is the responsibility of the treating doctor to be aware of and be capable of discussing with and educating the patient regarding common and significant risks for the evaluation and management procedures the doctor is recommending. We suggest that this educational discussion is not an ethical choice but a standard of care for all physicians.

After a thorough discussion of the common and significant risks associated with the evaluation and management recommendations, the doctor must also provide the patient with available treatment alternatives. Treatment alternatives may include options such as strength and conditioning programs, massage therapy, acupuncture, referral for physical therapy, allopathic or osteopathic referral, and further diagnostic testing. This discussion should also include the option of doing nothing. The doctor should discuss the possibility that the patient may not respond to the recommended treatment. Specific time frames (number of visits) for positive response to treatment should be discussed with the patient. Should the patient be refractory to the recommended treatment, more aggressive and/or invasive potential

future treatment options should be discussed with the patient. This discussion may include invasive procedures such as future medial branch block, trigger point injection, ablation, and surgery. Finally, the patient should be fully informed of the lack of a guarantee with the recommended evaluation and management procedures.

Informed consent process guidelines

We offer the following guidelines for consideration by the chiropractic profession.

Doctor/patient discussion—including (1) necessary treatment(s)/procedure(s), (2) indication(s) for treatment, (3) common risk(s), (4) significant risk(s), (5) treatment alternatives, (6) potential future treatment (s)/procedure(s) options, (7) lack of a guarantee, and (8) patient questions—should be answered. This discussion should be documented in the patient's chart, and the consent form should be signed by doctor and patient.

The patient should be encouraged to ask questions regarding evaluation and management recommendations, alternative treatment options, risks involving treatment, and potential outcome. It is imperative that the chiropractic physician take the time to properly inform the patient and obtain written or verbal informed consent before initiating evaluation and management procedures. However, there is a legal onus on the practitioner to actually initiate disclosure of all information that might reasonably be considered necessary to make an informed decision. This legal onus does not end after the initial visit. The informed consent process is a continuum, which enables the patient to determine the value of evaluation and management procedures throughout the entire treatment plan. Informed consent must clearly document in the patient chart any significant change in the treatment plan. Use of the above guidelines might improve the patient safety and the quality of a chiropractic intervention.

Possibly, some North American chiropractors do not acknowledge a need to provide an informed consent process because of their excellent safety records in practice and the infrequent occurrences of serious adverse reactions with chiropractic care. It is our opinion that this posture may present the profession with a false sense of security. We propose that an informed consent process should be a standard of care for all chiropractors to empower patients, improve patient safety, elevate our profession's level of cultural authority, and reduce the

- Does the chiropractic profession's perception of positive clinical outcomes and belief that the minimal numbers of chiropractic malpractice claims negate the desire for embracing the informed consent doctrine?
- Do chiropractic leaders have an obligation to enable and encourage ethical implementation of the informed consent doctrine?
- What will be the impact on society's perceptions if the chiropractic profession avoids recognition of its ethical and legal responsibilities regarding the implementation of an informed consent process?
- Will the absence of a standard of care, one that embraces the informed consent doctrine, create further obstacles for the chiropractic profession?

Fig 1. Questions for the chiropractic profession to consider and discuss.

potential for claims of provider negligence. We propose the questions in Fig 1 to the chiropractic profession for consideration and discussion.

We purport that doctors of chiropractic are ethical health care providers but many are unaware of the value placed on the informed consent process by health care consumers. A rational profession must consider the pursuit of cultural authority and improved patient safety as pragmatic strategies. We suggest that promulgation of a contemporary informed consent process by the Association of Chiropractic Colleges would better train our future chiropractors and enhance patient safety. It is sensible to contend that the elimination of paternalistic behavior and the practice of evidence-based medicine with a patient-centered focus might augment patient safety and advance the profession's level of cultural authority. Is it not reasonable to assume that the embracing of the informed consent doctrine would demonstrate an ethical behavior by chiropractors, which might plant the seeds of appreciation and possibly harvest a well-deserved respect for the chiropractic profession?

Conclusions

Informed consent procedures have been instituted in both research and clinical medicine. Additional research should attempt to confirm the attitudes and practice behaviors of chiropractors relative to the implementation of the informed consent process. We recommend that the chiropractic profession in the United States comply with the Federal and State

regulations and laws, which attempt to improve patient safety through the implementation of an informed consent process.

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