COMMENTARY

Informed Consent in Complementary and Alternative Medicine

THE INCREASING popularity of complementary and alternative medicine (CAM) poses serious challenges for the physician, not the least being the issue of informed consent. Herein, we review the implications of informed consent. Informed consent should include adequate information about the risks and benefits of all treatment options. The information about potential risks, including frequent, nonserious adverse affects as well as infrequent serious complications, is crucial for patients to know. Failure to disclose the availability, benefits, and risks of CAM treatments could give rise to malpractice claims. We discuss the existing US case law and several hypothetical scenarios. The ethical rules physicians follow in conventional care usually can be applied to treatment with CAM. The focus must be on expressing risks clearly, documenting informed consent adequately, and keeping up-to-date with the emerging evidence on CAM.

As CAM becomes accepted by and integrated into mainstream health care, it will pose a number of serious problems for the physician. One formidable challenge is to formulate and adhere to ethical standards for CAM that compare favorably with those of conventional medicine. Ethical standards, in turn, are a precondition for physicians and other health care providers to assess whether and when to refer their patients to CAM practitioners. We will briefly discuss one particular ethical issue, informed consent, which clinicians are called on to provide on a daily basis. Moreover, there are prominent legal implications.

WHAT IS INFORMED CONSENT?

Respect for patient autonomy is an essential ethical component in every aspect of medicine. One of the practical implications of autonomy is informed consent, which means that before clinicians may carry out diagnostic or therapeutic procedures, they must have the patient's agreement to do so.[1] Its obvious purpose is to prevent patients from being treated against their will. Its more subtle implications are that patients should be given sufficient information to be put in a position where they can make the right decisions.

The discussion below assumes that the patient is competent to give informed consent. Initially, the clinician must assess competence: a competent patient can, if properly informed, consent to (or forgo) medical treatments, including those involving research, experimental treatments, or treatments not yet scientifically validated. If the patient's competence is questionable, the patient lacks capacity to give informed consent. In such a case, the designated surrogate's treatment decision, based on disclosed information, does not satisfy the notion of informed consent.

Informed consent can be obtained verbally, in writing, or it can be implied. Whenever the procedures about to take place entail risks, it is advisable, even necessary for the practitioner to obtain consent in writing. The completion of a standard consent form does not, however, constitute consent itself; it is merely evidence that consent has been given.[2] In other words, it does not free the practitioner from providing all the necessary information the patient may require for coming to an informed decision. In daily practice, informed consent is frequently formulaic, authoritarian, and bureaucratic. Strictly speaking, therefore, it does not fulfill its role of stimulating conversation and dialogue between patient and physician/therapist.

WHAT INFORMATION?

What constitutes "all the necessary information"? The exact answer to this question is crucial to much of the debate relating to informed consent in CAM. The interpretation of the answer will determine the extent of informed consent in each clinical situation. Generally, the patient needs to know

- The probability of benefiting from the procedure
- The probability of risks associated with the procedure
- The alternative options feasible and available as well as their risks and benefits.

Parenthetically, in deciding that providers must offer patients "feasible and available options," US courts typically have not included a requirement that such options involve CAM therapies, which are outside consensus and conventional standards.[3] For instance, US courts have rejected a requirement that physicians disclose in-home birth as a viable alternative to managing childbirth in a hospital or alternatives in cancer care to chemotherapy.[4] Certainly, US courts have not yet had occasion to address whether combinations of conventional and CAM therapies must be included in the range of feasible and

available options that must be disclosed to the patient.

In any event,

> information should include what the treatment entails, . . . how many sessions it should take for the therapy to work, and information about the therapist, including the therapist's background, qualifications, training and experience.[5]

Of particular medical and legal relevance is, of course, the information regarding potential risks. Frequent and serious risks are not typically associated with CAM, but it is also rarely totally devoid of adverse effects.[6] The question therefore is at what level of risk does a practitioner need to convey information to the patient—if an adverse event occurs in 1 of 1000 or in 1 of a million patients? Minor bleeding after acupuncture probably belongs to the former category while a stroke after upper spinal manipulation could fall into the latter.

Common sense tells us that it is not the incidence figure alone that matters in this instance but a complex formula including the incidence and the severity of risk. "A lot of people would want to know if there is a risk of death, however small the risk may be."[5] Thus, a serious risk with a very low incidence requires informed consent as much as a nonserious risk with a high incidence. The practitioner has an obligation to ensure the adequacy of the information she conveys.[7]

WHO DECIDES?

Is it the therapist or the patient who decides what constitutes adequate information? Therapists, who are usually in a private practice and therefore may have a conflict of interest, are not in the best position to make this decision. In the United States, about half the states require the health care practitioner to disclose what a reasonable patient would find material to a treatment decision, while about half the states require the practitioner to disclose what a reasonable therapist would find material. According to British law, the latter requirement must be fulfilled.[2]

LEGAL IMPLICATIONS

The legal implications for the health care provider of gauging the adequacy of informed consent are complex, especially in CAM. In conventional medicine, the failure to provide adequate information can result in an action for negligence (malpractice).[2] Similarly, in CAM, courts are likely to find that failure to provide sufficient disclosure creates a situation of liability. It should be noted that existing cases are not definitive as to the use of established CAM therapies, but merely provide a basis for extrapolation from existing principles.

Courts are likely to use the materiality standard above (using either the reasonable patient or reasonable health care provider) to judge the adequacy of disclosure regarding CAM therapeutic methods. For example, courts might ask whether a reasonable patient (or reasonable provider) would find it material to a treatment decision that the "Ornish program" (which incorporates yoga, meditation, and lifestyle changes) is effective for the prevention and treatment of coronary heart disease. Or would a reasonable patient (or provider) find it material that social support plays a meaningful role in recovery from breast cancer and other medical problems?[8]

If the answer to these questions is yes, then failure to disclose the availability, benefits, and risks of such therapies could give rise to a malpractice claim based on lack of adequate informed consent. It should be remembered, however, that the patient must be able to show causative injury. In other words, the patient needs to demonstrate that he or she would have declined the conventional treatment had he or she received full information about such CAM options.[8]

The question of materiality becomes more complex when an informed consent claim is based on failure to disclose a combination of conventional treatment with CAM. This is because clinicians by and large have not yet developed standardized protocols for such integrative practices, and typically neither patients nor providers yet consider the availability of such practices material to treatment decisions. One example, however, of where informed consent might be required relates to the ability of acupuncture to reduce nausea following chemotherapy.[9] This is because the scientific evidence of efficacy and safety are strong, and medical consensus is developing around the materiality of such a procedure. Another example is the possibility of an adverse herb-drug interaction; this should be discussed because disclosure of the herb's adverse interaction with a necessary conventional drug is likely to affect the patient's decision to use or forgo the herb (or the drug).[10]

CASE LAW

In the United States, 3 cases have provided some preliminary guidance on issues of informed consent in CAM and its related doctrine, assumption of risk. In the first case, *Charell v Gonzales*,[11] a physician used hair analysis and nutritional therapies to diagnose and treat a cancer patient. The cancer metastasized, and the patient developed blindness and back problems. The patient sued, presenting 2 claims: (1) negligence, arguing that the physician persuaded her to forgo conventional care and to rely solely on the nutritional protocol, and (2) failure to provide informed consent. The patient also sought punitive damages.

The jury found that the physician had departed from accepted medical practice, and that this departure had caused the patient injury, thus satisfying both elements of malpractice. The jury awarded the patient several million dollars; the court let the verdict stand, based on the plaintiff's evidence that the physician had provided treatment below the standard of care. The court also noted that the physician had failed to provide adequate informed consent, and that adequate informed consent might have protected the physician against a claim of negligence. Notably, the physician failed to describe to the patient the risk of substituting a CAM therapy without strong evidence for efficacy for known conventional

therapies. The patient's agreement to the CAM therapy, therefore, was anything but informed.

In the second case, *Schneider v Revici*,[12] the physician delivered nutritional and other nonsurgical treatments for breast cancer after the patient signed a consent form releasing the physician from liability. Following the treatment, the tumor spread, and the patient sued. The jury found the physician liable for malpractice but halved the award, finding the patient 50% comparatively negligent for choosing the CAM therapy. The appellate court reversed the decision because the trial judge should have instructed the jury that "express assumption of risk" was a complete defense to malpractice, and thus would have negated the physician's liability entirely. Express assumption of risk means that the patient agrees in advance that the physician may deviate from conventional standards of care for the patient's benefit.

Even though the case did not involve informed consent, it suggests that physicians may, in some jurisdictions, have a defense to malpractice involving CAM provided they not only engage in meaningful conversations with patients about risks and benefits, but also document patient agreement to the CAM therapy in question. Assumption of risk thus is related to informed consent in that both entail discussion of relevant risks and benefits with the patient.

In the third case, *Moore v Baker*,[13] a patient sued for malpractice based on the physician's failure to disclose the possibility that EDTA chelation therapy was an allegedly safer, equally effective alternative to a carotid endarterectomy. The trial court held that the plaintiff failed to show that reasonably prudent physicians generally recognized and accepted the treatment as doing more good than harm. The appellate court affirmed, based on a finding that the mainstream medical community did not recognize the claimed alternative as an effective therapy for coronary heart disease. The court suggested that it would have decided the case differently had the medical evidence been more favorable toward the therapy in question.[14]

Since the appellate court in *Moore* did not delineate exactly what would qualify as sufficient validation of a CAM treatment to justify its required inclusion in informed consent disclosure, one wonders what type of evidence would satisfy the requirement. In these days of evidence-based medicine, it seems possible that systematic reviews and meta-analyses of randomized clinical trials (which constitute the highest level of evidence in evidence-based medicine) will become the gold standard for evidence on effectiveness of CAM sufficient to require informed consent disclosure. This seems especially true if materiality is judged from the perspective of the reasonable physician, whose professional training requires reliance on the best evidence to make therapeutic recommendations regarding CAM.

It should be noted that none of these cases involved discussion and disclosure of integrative therapies, and risks pertaining thereto, such as those involving adverse herb-drug interactions. However, taken together, *Charell*, *Schneider*, and *Moore* do provide a set of working principles for CAM care either alone or in combination with conventional care. Specifically, the cases suggest that (1) physicians have a legal obligation to disclose to patients all relevant benefits and risks of a CAM treatment decision as well the risks and benefits of a decision to forgo conventional care in favor of a feasible and available CAM treatment[3,8]; (2) while courts may evaluate such an obligation through the materiality standard, some US courts will adopt the perspective of the reasonable patient, while others may adopt the perspective of the reasonable health care provider. The latter perspective should be guided by scientific rules regarding best evidence, while in the former case, such rules of evidence may be less significant; (3) provided adequate informed consent is given, physicians also may have, in some jurisdictions, a complete defense to malpractice if the patient signs a written form acknowledging a knowing, voluntary, and intelligent decision to try the CAM therapy; (4) in clinical practice, it may be difficult to describe the risks and benefits of integrative practices, given the relative paucity of data, or even to determine which, if any, risks and benefits are material to a treatment decision. On the other hand, at the very least, physicians should disclose the potential direct adverse effect of substituting a CAM therapy of unknown safety and efficacy for conventional options of demonstrated safety and efficacy, particularly if, as in terminal cancer care, the patient's condition is rapidly deteriorating. Physicians also should disclose any research concerning direct adverse effects of integrative therapies (eg, the interactions of St John's wort with prescribed drugs[10]; and (5) neither adequate informed consent nor express assumption of risk will protect the physician who is reckless or who has failed to use due care in selecting or executing the CAM therapy (eg, by choosing a therapy that was generally considered unduly hazardous and/or ineffective). Courts typically dislike patient waivers that allow negligent care or contravene public policy notions of patient protection.[4] Thus, even if consent is informed, treatment still must not deviate from standards of care so as to cause the patient injury.[5]

HYPOTHETICAL SCENARIOS

Parenthetically, to simplify our analysis, we have assumed in the above discussion 2 important aspects of informed consent, namely, the requirement that consent be given freely and that it be given by a patient who is competent to so give it (eg, is able to understand the issues involved). Below we present hypothetical clinical situations in which a competent individual freely considers consenting to be treated by a clinician. This section is meant to highlight practical issues in relation to informed consent rather than provide conclusive answers to novel questions at the boundary of legal, regulatory, and ethical rules.

Case 1: Chiropractic Spinal Manipulation for Neck Pain

In the first scenario, a patient sees a chiropractor who diagnoses neck pain deemed to be amenable to spinal manipulation (SM) of the up-

per spine. Spinal manipulation is associated with rare but serious risks (eg, stroke), including risk of death.[15] The exact incidence figures of such events have been estimated but cannot yet be precisely determined. Spinal manipulation is also associated with nonserious risks (eg, transient local discomfort) in about 50% of cases.[16]

From the above discussion it would seem to follow that the chiropractor should, as a minimum requirement, include the frequent, nonserious risks in informed consent. But what about informing the patients that in some probably rare cases serious complications, even deaths, have occurred after SM of the upper spine? It is fair to assume that many patients would want to know about this too.[5] If the chiropractor fails to include this information in informed consent, and the court adopts the reasonable patient standard for materiality, that chiropractor will have failed to offer adequate informed consent. Potentially the therapist is then liable for malpractice if the disclosure would have changed the patient's treatment decision.

On the other hand, there are cases in which health care providers are advised not to disclose some serious but remote risk on the ground that it will unduly frighten the patient and that disclosure potentially causes emotional or even somatic harm. Moreover, as indicated above, serious complications of upper SM that are performed nonnegligently are probably rare. Thus, in case 1, adopting a conservative liability management strategy (ie, favoring disclosure) may be disadvantageous clinically.

Case 2: Chiropractic SM for Lower Back Pain

In the second scenario, our patient sees a chiropractor who diagnoses low back pain and obtains consent to treat it with SM. The patient understands that lower back pain will be treated with SM of the lower back, which (as the patient happens to know) is associated with less frequent serious risks than SM of the upper spine.[17] The chiropractor, however, finds it necessary to treat the upper spine because she views (as most chiropractors would) the spinal column as a functional entity. If the patient suffers a serious complication from upper SM, one might argue that informed consent was inadequate in that it was confined to the lower spine only. The patient could therefore decide to sue for negligence.

Using the materiality standard described earlier, the chiropractor should disclose the intent to perform upper as well as lower SM. She should also inform the patient about any attendant benefits and risks, because these are material to the patient's decision to undergo or not undergo chiropractic care.

Case 3: Treatment by a CAM Provider Without Proof of Safety or Efficacy

In the third scenario, a CAM provider treats a patient with a therapy for which neither the efficacy nor the safety has been established with any degree of certainty; arguably, this is the case for many if not most therapies used in CAM. An example would be craniosacral therapy for a child with cerebral palsy.[18]

Such scenarios do not present a black-and-white choice between therapies proven safe and effective, and those that have not been proven or have been proven unsafe and ineffective. Different levels of evidence are deemed relatively satisfactory or unsatisfactory to different communities for different purposes. For example, legislators may license certain classes of CAM providers on the grounds of increasing patient access to therapies, even if medical evidence of safety and efficacy are insufficient for most physicians to feel comfortable recommending the treatments these practitioners provide.[19] Therefore, in cases of uncertainty, a prudent strategy for the CAM provider would be to tell patients about the degree of uncertainty associated with the efficacy and safety of the treatment, as well as the availability and risk-benefit ratio of other treatment options.

In other words, our view of informed consent, based on the cases discussed above, is that it obliges the provider to discuss the risks associated with displacing conventional treatment with CAM therapies (eg, delaying surgery for several months while the patient uses nutritional therapy, meditation/visualization, and Reiki). Such a disclosure, in fact, makes the clinician's choice more subtle: it is not about providing or not providing CAM, but rather about providing CAM with ethical disclosure while continuing to monitor the patient by conventional means. This, in turn, allows patients to make their own choices, without abandoning the clinician's obligation to do no harm.[20]

Case 4: Physician Disclosure of Herbal Remedies

In the fourth scenario, an orthodox primary care physician diagnoses Alzheimer disease in a patient. He prescribes synthetic drugs, which are not well tolerated, so the patient eventually discontinues treatment. The patient deteriorates quickly and soon requires full-time nursing care. At this stage the patient's next of kin learn about an herbal remedy (*Ginkgo biloba*) that has been shown to significantly delay clinical deterioration in patients with Alzheimer disease.[21] The physician, however, did not consider herbal medicines and therefore never discussed this option with the patient or her family. The family argues that the doctor should have been aware of the *Ginkgo* data, not least because high-quality trials and even positive meta-analyses of several trials[21,22] have been published. Therefore they sue for negligence, based on failure of informed consent.

This is analogous to the fact pattern in *Moore*: the patient sued, alleging that treatment would have been equally or more effective and less traumatic had the physician disclosed the possibility of using a CAM therapy over conventional care. To the extent that *Ginkgo* is generally accepted within the medical community as safe and effective, failure to disclose its availability constitutes a lack of adequate informed consent, and the physician conceivably could be held liable in malpractice for the patient's consequent injury.[8]

Furthermore, the physician in such a case may be liable for malpractice not only for failure to inform, but also for failure to provide the herbal remedy.[3] In other words,

> if herbal or homeopathic remedies are found to be as or more safe and efficacious than prescription medication for certain conditions, then using such remedies will fall within the standard of care . . . [and] physicians might be held liable in medical malpractice for providing professional healing below the standard of care.[3]

Thus, in scenario 4, informed consent and malpractice liability rules militate in favor of disclosure and/or providing the herbal therapy.

CONCLUSIONS

Ethical analysis of CAM in general and the discussion of informed consent in particular are in their infancy. In several ways, ethical rules used in conventional care can also be employed in CAM care, for example, use of the materiality standard to determine what should be disclosed so as to satisfy the obligations of informed consent. In other ways, prevailing ethical norms may not fully fit CAM therapies, for example, deciding what to tell patients about therapies that operate along principles unfamiliar to Western science or knowing what to say about CAM treatments for which neither efficacy nor safety has yet been satisfactorily established.

So far, case law is sparse and underdeveloped. Physicians and patients often disagree on what kind and what level of evidence makes a therapy demonstrably safe and effective enough for the physician to tolerate or recommend the therapy, although there are evolving standards in CAM.[23] In addition, the medical, legal, and political communities frequently disagree on what makes a treatment or a provider clinically acceptable.[18]

In spite of all these uncertainties, the clinician can meet emerging informed consent obligations, and thus reduce the risk of malpractice liability, by disclosing the availability of CAM therapies that have sufficient evidence of safety and efficacy to make their availability material to a particular treatment decision. To the extent the treatment decision involves substituting CAM therapies for conventional care for a given period of time, the clinician should specifically describe the risks of such substitution and the uncertainties involved in therapeutic outcome. To the extent the treatment decision involves combining CAM therapies with conventional therapies, the clinician should describe, according the best available evidence and knowledge, the risks and benefits of providing such an integrated approach to the patient's condition. We hope this analysis, based on the present state of the law, will help to further frame the discussion regarding informed consent and related ethical obligations related to CAM.

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