Ethical and legal issues at the interface of complementary and conventional medicine

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ABSTRACT

Doctors should:

- Honestly answer patients' direct questions about CAM and elicit information about their use of it.
- Establish patients' understanding of the conventional and complementary therapies, both those available to them, and those that they may already be using.
- Establish why the patient uses CAM, and their goals for both complementary and conventional therapies.
- Reflect on whether information about CAM would be *material* for *that* patient at *that* time, taking into account the patient's burden of illness, his or her expressed preferences and the risks and benefits of both conventional and complementary therapy.
- Take steps to become adequately informed about available CAM that has consistently been shown to be safe and effective; has consistently been shown to be ineffective and/or harmful; or is consistently enquired about by patients.
- Become familiar with qualified and competent CAM practitioners (medical and non-medical) to whom referrals can be made when necessary.
- Continue a relationship with the patient, while continuing to monitor the patient conventionally and staying open to further discussions about CAM.

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Community surveys from Australia, North America and Europe indicate that 35%–50% of the population attend complementary therapists or use complementary or alternative medicine (CAM). The full implications of the popularity of CAM have only recently been recognised, as it has existed largely as an independent, parallel and disparate healthcare system, largely ignored by conventional medical practitioners on the grounds that it had no compelling evidence base and that what research had been done had substantial methodological flaws or systematic biases.[1,2]

As the risks and benefits of CAM and its interaction with allopathic (conventional) medicines become better understood, various ethical and legal issues are raised. Moreover, recent events in law, professional practice, healthcare policy and industry have focused attention on the interface between complementary and conventional medicine and the roles and responsibilities of medical practitioners, and have threatened the trust that Australians appear to have in the safety, quality and philosophy of CAM. These events include the Pan Pharmaceuticals recall,[3] a recent criminal case concerning the death of an infant being treated by a naturopath,[4] increased concern regarding medical liability arising from failure to refer to complementary therapists,[5] moves to regulate complementary therapists,[6,7] and a Position Statement from the Australian Medical Association (AMA) on complementary medicine.[8] These developments present complex challenges for conventional healthcare systems and those who practise within them. However, they also raise questions about the nature of evidence, the creation of consensus in clinical practice, and the very meaning and function of complementary medicine.[9]

One of the more contentious, but central, concerns is the possibility that conventional medical practitioners may risk legal liability by ignoring patient use of and preference for CAM.[10]

Complementary medicine and consent

Medical practitioners are ethically and legally obliged to provide patients with enough information to make adequately informed healthcare decisions and valid consent to treatment. This information includes the risks and benefits of the proposed treatment and any relevant alternative treatments (Box).

Given the widespread use of CAM (often together with prescription medications),[12] the importance attached to its use by the public, the blurring of distinctions between CAM and conventional medicine and the growing research into the efficacy of CAM, a strong case can be made where information exists about the benefits, risks and potential drug interactions of CAM. Doctors should be aware of this information and should be able to advise patients of these options.[13] Indeed, while no cases yet exist where a doctor has been found liable for failure to advise a patient of CAM treatment options, it is arguable that a doctor's common law obligation to provide information requires that he or she has a duty to provide information about CAM therapy where that information would be material to a particular patient.[14]

Recent legal developments have clarified the responsibilities of medical practitioners regarding the provision of treatment and of information. The 2002 Ipp Report made a number of recommendations about how the law should approach the issue of establishing an appropriate standard of care in cases of medical negligence.[15] It concluded that, in relation to establishing the standard of care, "the distinction between treatment, on the one hand, and the provision of information, on the other, is a very important one, and that the law should deal with these two activities in different ways".

With respect to treatment, the Ipp Report recommended that the law in Australia should be amended in such a way as to reflect the House of Lords decision in *Bolitho v City and Hackney Health Authority*.[16] According to that decision, conduct will meet an appropriate standard of care where the conduct was in accordance with an opinion widely held by a significant number of respected practitioners in the relevant field, as long as that opinion, in the view

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Summary of the case *McGroder v Maguire*,[11] illustrating that, before referral, it is essential to perform adequate clinical assessment and fully inform patients of the risks and benefits of any proposed treatments

The patient (Maguire) injured his neck when he hit his head on the roof of a truck cabin while driving over a bump. Despite treatment he continued to suffer from tingling in one arm. Two years after the original injury he attended the employer's consultant general practitioner (McGroder), who referred him to a chiropractor (Ayscough).

The GP did not carry out a physical examination and probably did not refer to the medical records held by the employer. After chiropractic manipulation, the condition of the patient's neck and back deteriorated markedly. He underwent surgery, but, two years later, a neurosurgeon concluded he was permanently unfit for work.

The patient sued in the NSW Supreme Court. At trial, his neurosurgeon and orthopaedic surgeon both gave expert medical evidence that, in light of his condition, he should not have been referred for chiropractic treatment. The trial judge found that the GP had negligently referred the plaintiff to the chiropractor and the chiropractor had negligently treated him.

The GP appealed, arguing that there was no breach of duty of care involved in making the referral and that, even if there was, the chiropractor's negligent treatment was a "new intervening act" which severed the chain of causation between any negligence by the GP and the deterioration of the patient's condition.

The GP lost the appeal. The Court of Appeal held that "[the] referral was negligent. His [GP] negligence generated the risk of injury by referring him [the patient] for inappropriate treatment. It is no answer that the treatment was administered negligently".

Teaching points:

- When referring a patient to another healthcare provider for treatment, it is advisable to obtain a thorough history, perform a relevant physical examination and review any available medical records first.
- Negligence by another healthcare provider may not relieve referring doctors of responsibility for their own conduct.

of a court, is not irrational. It was recommended that the standard of care for giving information to patients remain the same as the current common law standard as explained in *Rogers v Whitaker*.[17] The Ipp Report did, however, refer to the duty to inform as being "proactive" and "reactive" — proactive referring to what a reasonable person in the patient's position might wish to know; while reactive is providing information that includes what "the patient has asked for or otherwise communicated a desire to be given".

These recommendations have been adopted, to varying extents, in most jurisdictions. In New South Wales, these recommendations have been incorporated into the *Civil Liability Act* 2002. This means that medical practitioners should provide information about CAM where that information may be considered to be "material" to the patient. Information is material where a *reasonable person in the patient's position* would attach significance to it, or where there is an indication that *this particular patient* would likely attach significance to information regarding complementary medicine. Thus, CAM should not only be discussed with patients who directly ask questions about it, but also at other times when discussions of CAM may become more significant for patients. Examples are where the burden of illness is substantial; where there is no proven conventional therapy available; where the therapy that is available is invasive or associated with minimal benefit or major toxicity; where complementary therapy may be of benefit and has few risks; and where the patient has expressed an interest in, or preference for, alternative therapies.[18]

This also means that doctors must know enough about CAM to meet the patient's information needs. While neither the law, the profession nor the general public expect doctors to be experts on CAM, both the law and the profession (as shown by the AMA's position statement on complementary medicine[8]) expect that doctors should have *some* knowledge of CAM to properly inform their patients about therapeutic alternatives. The question then becomes *what should* doctors know about CAM? This is particularly difficult to answer, as the degree of knowledge required of a doctor may vary according to his or her specialty and to the degree to which they incorporate CAM within their own practice. For example, oncologists may have a greater obligation to know about CAM used in cancer care than GPs, while those who use acupuncture in their own practice will have a greater obligation to understand the evidence relating to its risks and benefits than doctors who do not use it.

Evidence, regulation and integration

The issue of how much medical practitioners should know about CAM is made more complex because of real questions about the availability, quality and accessibility of evidence on its efficacy, risks and benefits. Simply asserting that medical practitioners should assess the appropriateness of CAM therapies and discuss proven alternative treatment options with their patients does not account for the lack of clear standardisation and regulation of CAM, the general lack of data about CAM therapies, the lack of discourse between patients and doctors about CAM therapies, and the lack of awareness of the evidence for CAM.

Regulation of complementary practitioners

The regulation of medicines (including complementary medicines) in Australia is the responsibility of the Commonwealth Therapeutic Goods Administration (TGA). In 1999, the TGA established the Office of Complementary Medicines, which focuses exclusively on the regulation of complementary medicines and is responsible for recalls of faulty or potentially dangerous products. While the federal government has funded some groups of CAM practitioners to explore avenues for self-regulation, at present the regulation of complementary practitioners remains the responsibility of state governments.[19] Currently, Victoria is the only Australian jurisdiction to formally regulate CAM therapists, requiring practitioners using the title "acupuncturist", "Chinese herbal medicine practitioner" or "Chinese medicine practitioner" to register with the Chinese Medicine Registration Board. However, all state jurisdictions have legislation (with varying requirements) for registration of chiropractors and osteopaths. Most CAM practitioners are therefore subject only to varying forms of professional self-regulation.

As with conventional medical practitioners, the practices of complementary practitioners may also be subject to review through healthcare complaints bodies and, where something has gone wrong, by the courts.[20]

Irreducible differences between conventional and complementary medicine

While the ingredients of listed and registered complementary medicines are assessed for safety and quality, most have not been rigorously assessed for efficacy, and there are very limited data on potential interactions between complementary medicines and con-

ventional therapies.[21] However, more attention is now being given to research, and CAM therapies are increasingly being tested in randomised trials and systematic reviews.[22]

But increasing the evidence base for CAM is unlikely to resolve questions relating to the incorporation of CAM into the medical practitioner's lexicon of therapy. Literature from the US suggests that most doctors have limited knowledge of CAM therapies, and this may be primarily determined by their beliefs about the legitimacy of the therapies.[23] There is also evidence that many conventional medical practitioners are unaware of the evidence that does already exist for CAM.[24] This suggests that attention to medical education and to bridging the epistemological and linguistic gulf between conventional and complementary medicine is necessary. Overemphasis on evidence, regulation or integration fails to appreciate the substantial differences between allopathic and complementary medicine, including differences in the meaning and context of health and illness; in methods, language and culture; and in the relationship to science.[25]

The history and philosophy of Western medicine shows that, while conventional and complementary medicine share various historical features, such as reference to vitalism, holism and humoral balance, an enormous gulf exists between the two. This is accentuated by the absence of a common language between complementary and alternative therapies because of their heterogeneity.[26]

Is integrating proven CAM into conventional medicine the answer?

While government, the AMA and others appear to support the integration of *evidence-based* CAM, such an approach has significant implications. Integration may actually mean subjugation, disintegration or marginalisation; may fail to account for difference; and may fundamentally alter CAM practice (by emphasising standardisation, efficiency and generality at the expense of communication and individualised care).[27] For these reasons, not only is it unclear whether a true integration of conventional and unconventional medicines is possible, but, more importantly, whether it is even desirable. If part of the attraction of CAM is its uniqueness, or its non-biomedical conceptions of health and disease, then integration might result in the loss of this alternative, or (more likely) it may result in the expansion of conventional medicine as it absorbs evidence-based CAM and the reshaping, shrinking and marginalisation of the CAM modalities that remain.

Conclusion

It remains to be seen whether an Australian court will find that a doctor has acted negligently in failing to disclose information and advice about CAM options. However, both the profession and individual doctors should reflect on the issues raised by CAM and should discuss use of CAM with their patients.

CAM is likely to remain popular with the Australian public, and, while it may become more or less integrated with conventional medicine, CAM will not disappear and medical practitioners will never have the same skills and knowledge of CAM as complementary therapists.

While major questions remain about the evidence for CAM, the regulation of CAM practitioners and the legal obligations of conventional practitioners in relation to CAM, medical practitioners and students no longer have any choice but to gain some knowledge about CAM and the interface between conventional and complementary medicine. In so doing, the profession will be better able to provide care that accords with patients' values and needs, satisfy the ethical dimensions of healthcare decision-making and reduce the likelihood of litigation.

Competing interests

None identified.

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