The regulation of complementary health: sacrificing integrity?

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ABSTRACT

- In response to the increasing use of complementary and alternative medicine (CAM), governments are exploring ways to ensure patients' safety and respond to complaints.
- One solution is to establish registration boards and procedures based on the model of existing health practitioner Acts.
- Registration will require defined minimum standards for competence, which will have to be based on scientific evidence.
- As scientific evidence accumulates, these modalities are likely to lose their identities as "alternative" and become assimilated into Western medicine.

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ON 23 OCTOBER 2002, the New South Wales Chief Health Officer released a discussion paper inviting submissions concerning the need to regulate complementary and alternative medicine (CAM) practitioners, and offering models for implementing regulation.[1] The motivation for introducing regulation is to ensure the safety of the public by establishing minimum standards and an effective system for handling complaints.

In this article, I argue that, to the extent that this is achieved, CAM practitioners will lose their claim to offer truly alternative modalities of healing. I consider the concepts involved in CAM, orthodox medicine, science, and regulation, and the connections between them, to reach this conclusion.

The NSW discussion paper describes CAM as a "heterogeneous collection of therapeutic substances and techniques based on theory and explanatory mechanisms that are not consistent with the Western clinical model of medicine".[1] Other commentators have provided similar definitions, based on the inconsistency of CAM with currently accepted scientific explanations.[2] The very terms "complementary" and "alternative" are terms of exclusion (from a scientifically based mainstream), or at least imply a lesser status relative to an accepted mainstream (from the point of view of that mainstream).

The discussion paper correctly states that, although the current absence of standards, regulation and surveillance of CAM conveys the impression that it poses few risks, there are real risks associated with CAM practices. These may be specific, such as organ puncture by acupuncture, or generic. Generic risks include the risk to patients of being withdrawn from appropriate medical therapy, and the failure of CAM practitioners to diagnose serious disease or to refer patients. It should be noted that these generic risks are considered in the context of having accepted the appropriateness of orthodox therapy.

Clinical competence

Medical registration Acts protect the public by:

- registering adequately trained practitioners and restricting others from representing themselves as registered practitioners;
- responding to physical and mental impairment in members of the profession;
- disciplining practitioners who behave unprofessionally; and
- ensuring the clinical competence of registrants.

Clinical competence has traditionally, and correctly, been regarded as an element of appropriate professional conduct, but the original legislation governing medical practitioners' standards, which was modelled on older English legislation, did not explicitly refer to incompetence under the category of "unprofessional conduct".[3] Medical boards have traditionally focused on the behavioural and, more recently, the impairment aspects of unprofessional conduct. However, following a worldwide trend, they have now embarked on a closer scrutiny of clinical competence, and more recent legislation includes clinical incompetence as a distinct type of unsatisfactory professional conduct. For example, in Queensland, unsatisfactory professional conduct is now defined, in part, as "professional conduct that demonstrates incompetence, or a lack of adequate knowledge, skill, judgement or care, in the practice of the registrant's profession".[4]

What would constitute adequate regulation of the clinical competence of CAM practitioners? Countries with predominantly Western medical systems are facing this question, but there has been little substantive legislation as yet, with some exceptions in China, Hong Kong, South Korea, Canada (Alberta) and some states of the United States.[5] Minimum requirements would arguably include some form of registration or licensure, the satisfactory completion of an accredited training program and/or licensing examination, continuing education, and evidence of malpractice insurance.[6]

Do we have an adequate model in the recently enacted *Chinese Medicine Registration Act 2000* (Vic), the first such Australian legislation? This legislation was modelled on the medical practice Acts, and establishes a registration board.[7] The board can respond to complaints about registrants, although, at the time of writing, the board's web page "How

See also pages 279, 297

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to make a complaint" remains "under development".[7] The Act authorises the board to investigate complaints about impairment, but does not specify clinical incompetence as a form of unprofessional conduct. However, as its investigation panels can impose requirements for further education, the monitoring of clinical competence is presumably considered part of the board's regulatory responsibility. Investigation of competence will be essentially a process of peer review. Will these provisions adequately protect public safety?

Defining standards: scientific evidence or peer review?

The dilemma facing the Chinese Medicine Registration Board, and any other CAM aspirants to registration status, is that peer review of a registrant's clinical competence could rely on:

- the history, traditions and accepted authority of the particular CAM, which are called upon by the practitioner's peers who are asked to investigate a complaint, or
- the kind of evidence that is increasingly being sought by the medical boards and the courts in relation to judging the competence of medical practitioners — that is, rigorous, scientific evidence.

To the extent that scientific evidence becomes relied on in investigating the clinical competence of CAM practitioners, so the ethos of particular CAMs and CAM in general must be diluted — given the understanding of CAM as being based on theories that are distinct from accepted scientific explanations.

Ironically, the aspiration of CAM modalities to be recognised and respected as more than "fringe" activities, chiefly through the achievement of registration status, will be self-defeating in terms of maintaining an identity that is distinct from orthodox medicine. The boundaries of those modalities that achieve registration may blur with those of orthodox medicine, as the insistence on evidence forces them to conform and as orthodox medicine appropriates treatments that are demonstrably effective. An example is the incorporation into general practice of acupuncture, and the coverage of acupuncture services by Medicare. Practitioners of traditional Chinese medicine (TCM) may consider this an example of the compatibility of Western medicine and TCM. However, this could more accurately be depicted as the provisional acceptance by Western practice of the efficacy of acupuncture, which will continue to be tested using scientific methods.

Education and training in CAM faces the same issue. The inquiry into TCM[8] in the mid-1990s, which recommended developing legislation such as the Chinese Medicine Registration Act, found considerable unevenness in training and a variety of professional associations catering for practitioners within the broad field of TCM.

By what criteria should training courses be judged and accredited? Presumably, no traditional modality would wish to yield ground to or be dominated by another, or be governed by a centralising movement that pronounced on standards that did not appear to apply to its practice. This would deny the venerable status of the different traditions. Nevertheless, at some point in the establishment of training courses and clinical practices, measurements and evidence would need to be gathered and deployed, to satisfy the requirement for minimum standards.

It should be noted that the Australian guidelines for TCM education, drafted by the National Academic Standards Committee for TCM, a broadly representative body, are "not intended to be a curriculum document for courses or as competency standards for TCM".[9] That several bachelor programs adhering to the guidelines exist is not relevant, because the pertinent issue is not whether a course follows a set of standards, but the status of those standards themselves.

That CAM faces these problems is not immediately apparent when we consider its substantial popularity in our increasingly pluralistic and postmodern society. Among the sociological reasons for the increase in use of CAM are:

- the resistance to authorities, including conventional medicine, beginning in the 1960s;
- the reaction to the perceived evils of 20th-century science and materialism, with a turn to more "natural" ways of living;
- the renewed search for a spiritual dimension in the wake of the waning of formal religion, and the associated rejection of the perceived mind–body dualism of science and scientific medicine;
- the perceived inability of orthodox medicine, as the official deliverer of the state's health services, to satisfy demands for compassion, equity and efficiency; and
- the popularity of individualised attention, in contrast to the perceived anonymity of scientific, population-based care.

Competition policy also encourages variety and choice, and the Internet now provides vast amounts of information about a wide variety of approaches.

However, in a world of pure postmodern particularity and choice, no perspective would command greater epistemic authority than another, and there would be no way of choosing critically between different healthcare modalities, distinguishing better from worse educational courses, or distinguishing competent from incompetent healthcare practitioners. The only way we can make these choices is through scientific assessment. Consequently, modalities that aspire to recognition through registration, and that purport to operate via assessable standards, are taking their first step along the road to scientific assimilation.

A possible outcome

The result may resemble the two-tiered structure that now protects the public from risks associated with complementary medicines. Most complementary medicines have not been assessed for efficacy,[10] even though their ingredients are assessed for safety and quality.[11] *Listed* alternative products do not have to satisfy the same levels of evidence as *registered* ones, which are assessed more rigorously because they make more substantial efficacy claims.[12]

CAM practitioners and associations will need to choose between the value of preserving their unique identity and offering a true alternative, and the benefits that flow from registration, but they will not be able to have things both ways.

The cost of maintaining the "purity" of alternative conceptualisations and practices is that there will be no way to set and maintain standards within the modalities that remain truly alternative. These areas would be the equivalent of the listed products, and will be characterised by vague and poorly substantiated claims about health, vitality, prevention, and, in some cases, disease management. Although they would generally cater for less serious conditions, there would be no requirement that people avoid them. It will be interesting to observe the incidence of litigation that arises from the areas that hold to their original, truly alternative, status.

Conclusions

Because of the increasing uptake of CAM, health departments and legislatures are taking steps to ensure that safety, competence and training are accorded the importance they deserve. This is unexceptionable. But the proper regulation of healthcare practitioners requires more than peer review.

Current Commonwealth funding to a number of groups of CAM practitioners to explore avenues for self-regulation will not result in the establishment of competence standards, unless that regulation includes mechanisms for demonstrating competence — and acceptable mechanisms are not part of these CAM modalities.

CAM practitioners who refuse to violate their professional integrity and identity should be understood as offering no warrant for the efficacy of their claims, apart from the variable dependability of traditions. Conversely, the sign of the effective regulation of CAM practitioners who purport to manage significant health conditions will be the gradual blurring of the boundaries between orthodox and CAM practice.

Competing interests

None identified.

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