



# Complementary and alternative medicine

## Part 2 – evidence and implications for GPs

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This second article in a 2 part series exploring the issues around the use of complementary and alternative medicine (CAM) in the Australian general practice context gives an overview of the available evidence for the benefits and risks of CAM, and how to access that evidence. It also outlines an approach to addressing the ethical considerations for general practitioners using CAM or discussing CAM with their patients.

Scientific evidence is pivotal in determining the good and the bad in complementary and alternative medicine (CAM). When scientific research supports these treatments as efficacious and safe – and they become accepted by our peers – then doctors are more likely to integrate these therapies into practice.

There are many CAMs and therapies that have been used for centuries by different societies and cultures (eg. traditional Chinese, Ayurvedic and Japanese medicines). Although there may be little scientific evidence for these therapies, there is some inherent safety considering their long term use.

In 1999, the National and Health Medical Research Council (NHMRC) created useful guidelines to identify the varying levels of scientific evidence for CAMs using a scale from I-IV.<sup>1</sup> These guidelines help to identify which medicines or therapies carry greater weight in research, with level I considered as superior research (Table 1).

### Finding the evidence for CAM

There is a growing body of clinical studies ranging from level I-IV scientific evidence for CAMs. These can be accessed through 'PubMed'.

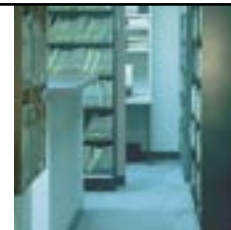
### Cochrane Collaboration

The Cochrane Collaboration prepare, disseminate and continuously update systematic reviews of randomised clinical trials in all areas of health care. A 'complementary medicine' field is now set up and is bringing together evidence for CAM. A list of CAM Cochrane reviews and protocols can be accessed at [www.compmed.umm.edu/cochrane/Reviews2002.pdf](http://www.compmed.umm.edu/cochrane/Reviews2002.pdf). To date, there are a total of 89 Cochrane reviews and 48 Cochrane protocols completed on CAM. However, for most CAM reviewed by the Cochrane library, studies were of poor quality and warranted further high quality studies. Examples of recent Cochrane reviews for CAM include:

- Glucosamine in the treatment of osteoarthritis.<sup>2</sup> A review of 20 randomised controlled trials (RCTs) found glucosamine sulphate was superior to placebo and comparable to nonsteroidal anti-inflammatories
- Herbal therapy for treating osteoarthritis.<sup>3</sup> A review of avocado soybean unsaponifiables were shown to have promising results in two RCTs. Single studies of other interventions, a willow bark preparation (Reumalex), topical capsaicin and tipi

tea, were inconclusive

- *Pygeum africanum* herb for the treatment of benign prostate hypertrophy.<sup>4</sup> A review of 18 RCTs showed *Pygeum africanum* superior to placebo
- Magnesium sulphate versus lytic cocktail for women with eclampsia.<sup>5</sup> A review of two trials concluded magnesium sulphate is the anticonvulsant of choice for women with eclampsia
- Calcium supplementation during pregnancy for preventing hypertensive disorders.<sup>6</sup> A review of 11 trials concluded calcium supplementation of at least 1 g per day appears to reduce the risk of high blood pressure in pregnancy, particularly for women at high risk of gestational hypertension, and in communities with low dietary calcium intake
- Acupuncture and idiopathic headache.<sup>7</sup> A review of 26 trials concluded the existing evidence supports the value of acupuncture for the treatment of idiopathic headaches. However, the quality and amount of evidence are not fully convincing
- Tai chi for treating rheumatoid arthritis.<sup>8</sup> A review of four trials concluded tai chi has statistically significant benefits on lower extremity range of motion, in particular ankle range of motion for people



with rheumatoid arthritis. The results also suggest tai chi does not exacerbate symptoms of rheumatoid arthritis

### Limitations in evidence base for CAM

Evidence based medicine has been described in the *British Medical Journal*<sup>9</sup> as: 'The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice'.

This definition emphasises that while scientific evidence is important in clinical judgment, clinical experience and expertise also play a major role in the care and choice of treatment for a patient.

Evidence based medicine encourages doctors to look for well structured, randomised, placebo controlled prospective studies (level II evidence) and systematic reviews of such studies (level I evidence) to support clinical practice, but as yet there are few of these for the majority of CAMs.

'Outcome studies' are more appropriate for holistic models of health such as traditional Chinese and Ayurvedic medicines. Very little good quality research exists for these therapies. Randomised control trials may be technically possible for the holistic approaches, but study design needs to be

creative. Lack of RCT evidence does not necessarily imply lack of patient benefit, and this is where clinical judgment and individual clinical experience come in to play.

Funding for research into CAM is a problem. Considering the widespread use for CAM, there is an urgent need for funding from governments, the NHMRC, and industry to support research to assess the safety and efficacy of CAM use, and the dissemination of knowledge to the public and medical profession. There are many private companies making substantial profits from the sales of supplements and products in Australia, and they should have a duty and obligation to perform well designed research. Only when appropriate research is done, can we confidently say whether a particular treatment or approach does or does not work.

In addition to lack of funding for research into CAM, the resources for promoting and disseminating existing knowledge in CAM is minimal compared with those used to promote pharmaceutical medication.

### Potential risks of CAM

The Federation of State Medical Boards of the United States<sup>10</sup> summarises potential harm of CAM in three possible ways:

**Economic harm:** many CAMs are marketed directly to the public through advertising and testimonials in the press, the internet, television, and through multi-level marketing. Australia leads the world for regulating CAMs. The Therapeutic Goods Administration (TGA) and the government's expert advisory committee have produced guidelines stipulating what evidence is

required when making claims about CAMs. The TGA and ACCC are making efforts to reprimand companies for any unjustifiable and unreasonable claims.

**Direct harm:** harm may result from a side effect of a CAM. For example, a herb-drug interaction or an adverse outcome (eg. the herb black cohosh [*Cimicifuga racemosa*] has been linked with liver impairment)<sup>11,12</sup> or a needle may penetrate the lung during acupuncture treatment.

**Indirect harm:** this results from the delay of appropriate treatment for a medical condition due to misinformation about unrealistic treatment of a condition. Indirect harm is often seen with cancer treatments.

### Ethical and legal issues

There are ethical and legal issues at the interface of CAM and conventional medicine. Doctors should:

- be honest with patients' direct questioning about CAM
- establish the patient's understanding of CAM and why they use it
- take into account the burden of their illness and provide material of their expressed preferences
- discuss the risks and benefits of both CAM and orthodox treatment
- adequately inform patients about any available CAMs shown to be safe and effective; and those shown to be ineffective
- become familiar with qualified and competent practitioners (both medical and nonmedical) to whom referrals can be made
- continue to monitor their patients' health, and
- keep communication with patients open and respectful.<sup>13</sup>

When a general practitioner integrates CAM into their practice, they cannot ignore their qualifications as a registered medical practitioner. They are expected to fulfil the requirements of all item numbers their patients claim from Medicare. A GP is expected to write thorough notes that justify the length of any consultation. These notes include history, physical examination performed, investigations ordered, diagnosis

**Table 1. NHMRC levels of evidence**

Level I	Evidence obtained from a systematic review of all relevant randomised controlled trials (includes Cochrane reviews, other systematic reviews and meta-analyses)
Level II	Evidence obtained from at least one properly designed RCT
Level III	Evidence obtained from: well designed controlled trials without randomisation; well designed cohort or case controlled analytic studies, preferably from more than one centre or research group; multiple time series with or without intervention
Level IV	Evidence obtained from case series, either post-test or pre-test and post-test

and management. Management may include lifestyle advice such as diet, exercise, stress management, complementary medicine, and orthodox medicine. If the patient refuses an orthodox treatment: 'informed refusal is as important as informed consent'.<sup>14</sup> The GP has a duty to properly assess the patient and fully inform them about the risks and benefits of conventional medical modalities, and if they refuse to document this in the notes.<sup>14</sup> Equally important is for GPs to inform patients of the benefits and risks of the CAM they propose to use; and being honest about their own experience and knowledge base (eg. 'I know very little about this CAM and the level of scientific evidence that exists for it'). It is important to document and ensure you have your patient's fully informed consent for any CAM treatment proposed.<sup>10</sup>

## Conclusion

The evidence base for CAM is increasing, but as yet there are relatively few RCTs or systematic reviews. It should be remembered that a lack of scientific evidence does not necessarily mean that the treatment is ineffective. Given the level of use of CAM in the community, we need to work in partnership with our patients to provide them with the best information available. We need to be honest with patient's direct questioning about CAM and about our own knowledge and experience. We need to adequately inform patients about CAM that has been shown to be safe and effective (or safe and ineffective), discuss the risks and benefits of both CAM and orthodox treatment, and become familiar with qualified and competent CAM practitioners (both medical and nonmedical) to whom referrals can be made.

Conflict of interest: none declared.

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