

# Obstacles to research in complementary and alternative medicine

*If we address the obstacles, high quality CAM research is possible*

ABOUT HALF THE general population in developed countries uses complementary and alternative medicine (CAM).<sup>1</sup> Yet many conventional healthcare professionals refuse to take CAM seriously — one often-voiced argument is “there is no research in CAM”.<sup>2</sup> Certainly, for some modalities there is no compelling evidence base,<sup>3</sup> and some of the research into CAM has methodological flaws and biases.<sup>4,5</sup> On the other hand, many doctors and medical educators are uninformed about the quality evidence that does exist.<sup>6</sup> In this article, I discuss some of the obstacles to developing an evidence base for CAM.

## Financial obstacles

In most countries, CAM research funding is on a very small scale. For instance, only 0.08% of the British National Health Service research budget goes towards CAM research.<sup>7</sup> Even though recent initiatives in the United Kingdom, United States and Australia have specifically freed up funds for CAM research, these amounts are minute compared with funding in other areas of medicine. It is likely that lack of plausibility of many CAM therapies deters scientific review committees from defining CAM as a priority. A vicious circle may ensue: little plausibility means no funds, therefore no preliminary research, therefore little plausibility.

Clinical trials of CAM can be even more expensive than those of conventional medicine. CAM treatments are often therapist-led, effect sizes are often small (requiring large sample sizes), and therapeutic effects may appear only after long treatment periods, all of which mean greater expense. For most CAM modalities, intellectual property cannot be protected; thus commercial investments are rarely forthcoming.

This shortage of CAM research funds has three important consequences:

- it prevents relevant projects from happening;
- it hinders the development of a research infrastructure similar to that of conventional medicine; and
- it keeps well-trained career scientists from entering into the field.

## Methodological obstacles

Many CAM therapies (eg, massage therapy) are physical by nature, which creates methodological challenges. What, for instance, is an acceptable “placebo” control for a trial of massage treatments? Like several other areas of conventional medicine (eg, physiotherapy, surgery, psychotherapy), blinding patients in clinical trials can be difficult or even impossible. Thus the highest level of scientific rigour can be barred to trials of CAM. Many CAM researchers also believe that their holistic approach can not be readily put into the “straightjacket” of a randomised controlled trial (RCT).<sup>8</sup> This argument is demonstrably wrong, and its persistence in CAM circles continues to impede efficacy research. One can, of course, conduct an RCT comparing a

complex, individualised, “holistic” treatment package to the standard care for that condition. This may require some innovative adaptations to the standard design, but, in principle, RCTs are usually feasible.<sup>9</sup>

For many people, CAM is an emotive subject. As a result, patients may not want to take a chance with randomisation, and many CAM practitioners may oppose scientific evaluation of their treatments, further hindering clinical trials.

There is more to most CAM interventions than meets the eye. For instance, some are based on theories that fly in the face of science. Researchers might conduct a clinical trial of traditional acupuncture, spiritual healing or homoeopathy and see this as a relatively straightforward exercise. Proponents of these therapies may, however, view it as a test of some ancient theories of life forces, spiritual energies or ultramolecular phenomena. Such discrepancies can (and usually do) create unforeseeable methodological problems, as well as obstacles for research and interpretation of results.

## Ethical obstacles

It is an important ethical requirement for randomised clinical trials that the investigators be in the state of equipoise (ie, they must believe that the test intervention is at least as good as the control intervention or placebo). If this is not the case (as for many CAM researchers), it is, strictly speaking, unethical for investigators to conduct the study. “Randomisation is only ethical if there is substantial uncertainty about the best treatment for that patient”.<sup>10</sup>

A further important ethical requirement for clinical research is informed consent from patients or healthy volunteers.<sup>11</sup> As mentioned above, this may be difficult or impossible to obtain in an environment where patients’ enthusiasm is strongly in favour of CAM and against receiving a control (placebo or non-CAM) treatment. Such problems constitute further impediments to good CAM research.

## Conclusion

Although high quality CAM research does exist,<sup>3</sup> many projects have, in the past, been less rigorous than they could have been. Before we condemn CAM for this situation, we should ask what the obstacles to CAM research are. Removing these obstacles will require dedicating adequate funds to CAM research, attracting career scientists into the field, adequately addressing the complexity of CAM and minimising bias with carefully designed studies.

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1. Ernst E. Prevalence of use of complementary/alternative medicine: a systematic review. *Bull World Health Organ* 2000; 78: 252-257.
2. Evans D. Placebo, the belief effect. London: Harper Collins, 2003: 141-164.
3. Ernst E, Pittler MH, Stevinson C, White AR. The desktop guide to complementary and alternative medicine. Edinburgh: Mosby, 2001.

4. Tang JL, Zhan SY, Ernst E. Review of randomised controlled trials of traditional Chinese medicine. *BMJ* 1999; 319: 160-161.
5. Linde K, Jonas WB, Melchart D, Willich S. The methodological quality of randomised controlled trials of homeopathy, herbal medicine and acupuncture. *Int J Epidemiol* 2001; 30: 526-531.
6. Hyodo I, Eguchi K, Nishina T, et al. Perceptions and attitudes of clinical oncologists on complementary and alternative medicine. *Cancer* 2003; 97: 2861-2868.
7. Ernst E, Wider B. Only 0.08% of funding for research in NHS goes to complementary medicine. *BMJ* 1996; 313: 882.
8. Lewith GT, Jonas WB, Walach H. Clinical research in complementary therapies. Edinburgh: Churchill Livingstone, 2002.
9. Vickers A, Cassileth B, Ernst E, et al. How should we research unconventional therapies? A panel report from the conference on Complementary and Alternative Medicine Research Methodology, National Institute of Health. *Int J Technol Assess Health Care* 1997; 13: 111-121.
10. British Medical Association. Medical ethics today, its practice and philosophy. London: BMA, 1993.
11. Ernst E, Cohen MH. Informed consent in complementary and alternative medicine. *Arch Intern Med* 2001; 161: 2288-2292. □

## Australian healthcare reform: in need of political courage and champions

### *All is not well with Australia's health system*

INTERNATIONALLY, AUSTRALIA'S HEALTH SYSTEM is held in high regard. Our citizens enjoy life spans second only to those in Japan.<sup>1</sup> The World Health Organization measures a nation's health attainment as a composite of the average level of population health and the general distribution of population health or health equality, the level and extent of the health system responsiveness, and the fairness of contributions to health financing by households. According to the WHO's benchmark — the overall health system attainment index — in 1997, we ranked 12th among 191 nations.<sup>1</sup>

But all is not well with Australia's health system. Its edifice is cracking under the strains of a growing mismatch between its capacity to deliver quality healthcare and the changing demands of our communities. Symptoms of the system's stresses include:

- the free fall in the number of general practitioners who bulk bill,<sup>2</sup> and the consequent threat to Medicare's principles of universality and equity of access;
- the short supply of health professionals, particularly nurses<sup>3</sup> and general practitioners;<sup>4</sup>
- the increasing occurrence of hospital access block and hospital ambulance bypass,<sup>5</sup> and the growing elective surgery queues;
- the problem of hospital exit block, reflecting the short supply of community-care services, particularly for older people,<sup>6</sup> and the breakdown in social networks;
- the inherent inability of a system organised for acute, episodic care to efficiently provide continuous long-term care;<sup>7</sup> and finally
- the conflict between society's increasing demand for health services, the high cost of technology-driven medicine and new pharmaceuticals, and the political and fiscal imperatives of the guardians of the public purse.

Critical to the viability of our health system are the Australian Health Care Agreements (AHCAs). These 5-yearly political pacts define the joint funding responsibilities of federal and state or territory governments in providing free public hospital services.<sup>8</sup> One of the drawbacks of the AHCAs is their impotence in promoting reform. And our health system is sorely in need of reform!

This imperative was recognised by Australian ministers of health in April 2002, when they collectively adopted a reform commitment, underpinned by the principles that the

federal and state or territory relationship in health funding should ensure that:

- the provision of optimal care and health outcomes be independent of jurisdictional boundaries;
- the respective jurisdictions work cooperatively to improve the health and wellbeing of the community; and
- the next round of AHCAs (2003–2008) be outcome-oriented.<sup>8</sup>

Suddenly, the winds of change were stirring in Australian healthcare and fanning expectation of reform. The ministers promptly established nine reference groups to address and advise on issues affecting current healthcare. These briefs included the continuum across preventive, primary, chronic and acute care; improving the interface between aged care and acute care; cross jurisdictional cooperation on workforce training and education; the interaction between hospital funding and private insurance; improving Indigenous health, mental health and rural health; quality and safety; and, concluding this impressive and inclusive list was, information technology and research.<sup>8</sup>

The nine expert groups met, deliberated, and, in record time, in September 2002, presented to Australia's health ministers a comprehensive agenda for reform.<sup>9</sup> The ministers considered the road maps for reforms, and highways were identified for their implementation, but, to date, the reform vehicles have remained locked up in bureaucratic and ministerial garages.

In the meantime, the ministers have resumed their adversarial political rhetoric, punctuated as always by fiscal bickering and buck-passing. This return to tiresome political form has undoubtedly fuelled widespread mistrust and cynicism among health professionals and consumers.

One outcome of this despair and discontent has been the Australian Health Care Summit held in Canberra on August 17–19, 2003. The Summit was attended by more than 250 delegates, drawn from across the healthcare spectrum. They included academics; administrators; allied health and other professionals; clinicians; consumers, economists; experts in health policy, mental and public health; politicians; and people and health professionals from Indigenous, rural and remote communities. Despite the Summit's claim to be an independent, bipartisan gathering, the absence of the Federal Minister for Health and Ageing, Senator Kay Patterson,