



Complementary medicine research in Australia: a strategy for the future

Alan Bensoussan and George T Lewith

About half the Australian population use complementary and alternative medicine (CAM), with an estimated \$2.3 billion being spent on CAM in 2000; this was nearly four times the public contribution to all pharmaceuticals.¹ Total CAM consultations in 2000 were estimated to cost \$616 million,¹ and represented 1.9 million naturopathic and Western herbal medicine consultations in 2003.² Similar patterns are seen in other developed countries.³

CAM attracts avid media attention and is a rapidly expanding industry, with company mergers and acquisitions and venture capital investment. CAM-dedicated journals, research citations, government reviews and university courses have multiplied.⁴ The reasons behind this growth have been previously documented, such as patients receiving greater individual attention from CAM practitioners and an accommodation of holistic values, but, above all, a pragmatic desire for improved health and disease resolution, particularly in those with chronic disease.^{4,5}

Evidence is mounting in support of the use of various CAM modalities to treat a wide variety of disorders. For example, the Chinese herbal remedy *Artemisa annua* has been found effective against resistant malaria.^{6,7} Systematic reviews support the use of acupuncture for nausea and vomiting associated with chemotherapy and dental pain, and the use of specific herbs in mild depression (St John's wort), benign prostatic hyperplasia (saw palmetto) and dementia (gingko biloba).⁸ Preliminary research indicates that CAM may be useful in treating hepatitis C infection,⁹ rheumatological illness,¹⁰ perimenopausal symptoms,¹¹ and chronic heart failure.¹² However, there is a substantial gap between consumer belief and use of CAM and the strength of evidence supporting that use.

We believe government has a social and ethical obligation to respond appropriately to community needs. Furthermore, the demonstrated potential of CAM in managing chronic illness, in preventive care (CAM includes self-care and is associated with taking more responsibility for one's own health), as well as in aged care, all represent vital national research priorities.¹³ Yet only \$850 000 of about \$1 billion of National Health and Medical Research Council (NHMRC) research funding has been allocated to CAM research in total in Australia since 2001.¹⁴ Government cannot rely on industry alone to develop new CAM therapeutic options, largely because of difficulties in performing and sustaining CAM research. Lack of funding minimises opportunities for relevant research, results in inadequate research infrastructure, and diminishes the appeal of a research career in CAM.¹⁴

ABSTRACT

- Research funding for CAM is inadequate, resulting in too few good quality studies to support its use.
- Widespread use of CAM, as well as its media promotion, make this a vital public health issue, and the Australian government has a social and ethical obligation to respond by developing a research infrastructure (as has been done by the United Kingdom and United States governments).
- We propose a funding model that neither draws directly from the CAM industry nor from current health research budgets, yet would strengthen Australia's international role in CAM research.
- Establishing and applying focused research methods in CAM is imperative for strengthening its evidence base and creating fresh options for safe and effective patient care.

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The United Kingdom solution

The 2000 House of Lords Select Committee on Science and Technology report on complementary and alternative medicine recommended that government should provide seed funding for research into CAM.¹⁵ Dedicated research funding (an estimated £5 million over three years) is being provided to create centres of excellence and develop the infrastructure for high-quality research. The focus of this program is on research capacity building. Host institutions have been identified to give methodological advice, help develop appropriate skills, provide research support, and house postdoctoral and doctoral research awards. This process creates a supportive environment that allows for mentoring, appropriate review and the generation of high quality proposals. Before this, less than one-tenth of one per cent of the British National Health Service research budget went towards CAM research. This dedicated seed funding more than doubles previous allocations. Research funding from UK medical charities has also increased from £70 000 (0.05% of the research budget) in 1999 to more than £400 000 (0.31%) in 2002.¹⁶

The United States solution

The US White House Commission on Complementary and Alternative Medicine Policy recommended that federal agencies should receive increased funding for CAM research and, in addition, that the US Congress create appropriate incentives for the private and non-profit sector to support CAM research, with a focus on improving self-care, promoting wellness and tackling areas of scientific debate raised by CAM.¹⁷ As a result, the US Senate has set aside money for CAM research. The Office of Complementary Medicine, established in 1992, has grown to become the National Centre for Complementary and Alternative Medicine (NCCAM), the 27th Institute of the NIH, with a research budget of about \$US113 million in 2003. In commenting on these issues (page 335), NCCAM Directors Chesney and Straus give an account of the benefits as CAM practitioners and experts are drawn into the fold of a larger research enterprise.¹⁸

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1 Proposed funding strategy for CAM research in Australia

- Australian CAM research needs to be established over a limited 5–10-year period through a mechanism of setting aside funds or seed-funding (as in the United States or the United Kingdom).
- Equivalent of 5% of GST raised from the CAM industry should go to CAM research (so that the profession and its clients pay for their own research).
- These funds should be managed through the National Health and Medical Research Council, which, with CAM experts, will develop infrastructure and evaluate priorities and projects.
- Funding agencies should support appropriately trained CAM researchers to act as referees and members of selection panels, thus creating equity, and encouraging strong collaborations between CAM clinicians and medical researchers.

An Australian strategy

The level of CAM use in Australia makes a compelling case for a distinct CAM research support strategy. However, two main problems arise when trying to allocate funds for CAM research.

The first is that the CAM industry, despite its rapid growth, does not easily see the advantage of investing in research instead of marketing. Research is viewed with some uncertainty, perhaps because companies may not readily protect their intellectual property — any research investment on public domain herbs may benefit their competitors as much as or more than themselves. Furthermore, companies are not able to protect medicines against negative or equivocal research findings. Executive directors within the CAM industry are often untrained in CAM, and may be ignorant of the emerging public health implications of CAM. Few CAM executives have come from conventional pharmaceutical companies, and so do not embrace a research culture or have an adequate working knowledge of intellectual property protection. Corporate CAM is therefore struggling to understand the importance of funding research for its own growth.

The second problem is that Commonwealth funding agencies, such as the NHMRC and the Australian Research Council, are hesitant to fund research in areas where they have little understanding, such as the best approaches to CAM research or how it should be prioritised in relation to conventional medicine. This is further complicated by the fact that CAM addresses an extremely wide range of health concerns. Why fund a contentious area when there are so many others to fund?

So, if neither corporate CAM nor competitive funding agencies have yet developed the vision or mechanism to adequately fund CAM research, an appropriate alternative and interim solution is required. It would be sensible to use a mechanism that generates research funds from within the growing CAM industry, but manages them equitably and competitively, and acknowledges national health priorities.

Specifically, since July 2001 an estimated \$160 million of Goods and Services Tax (GST) is collected each year from sales of CAM products and services in Australia (10% of \$1671 million).¹ As this represents a direct tax on the industry, it would be appropriate to allocate some return of these funds to research and development. This would sustain research not only of CAM products, such as herbal and nutritional products, but also of techniques such as acupuncture, osteopathy and chiropractic.

If 5% of the GST raised from the Australian CAM industry were invested in CAM research annually over the next five years, this would

create an annual budget of about \$8 million (assuming no growth). The proposed scheme (see Box 1) would represent about 1% of expenditure on other national health research priorities, and would not draw from the existing pool of funding. However, it would still fall short of the current annual investment in CAM research by the US National Institutes of Health (about 46 US cents per capita versus 38 Australian cents per capita with this proposal).

However, an annual investment of \$8 million in CAM research will have a significant effect on the research productivity of the industry, while drawing minimally on CAM-related GST revenue. Furthermore, it is very likely that an investment of 5% GST will be repaid manifold in additional GST raised by the increased use of CAM goods and services as better evidence is developed for them.

Australia as a potential leader in CAM research

Australia has enormous potential to be an international leader in evidence-based CAM products and services. Australian medical research expertise is high and clinical trial costs are relatively low, making Australia an important and appealing research environment, particularly for Asian CAM products. Furthermore, Australia's Therapeutic Goods Administration (TGA) regulations are neither as "soft" as the dietary supplement approach of the US Dietary Supplement Health and Education Act of 1994 (DSHEA), nor so harsh as to mandate evidence for new chemical entities that hold no history of clinical use. Intellectual property law is also well developed in Australia, offering companies good security.

A recent international profiling exercise showed that there were seven CAM centres of research excellence (defined as having primary researchers with more than 20 MEDLINE publications), with three in the US, two in the UK, and one each in Germany and Switzerland. These are all conspicuous locations where there is relatively good access to CAM research funds.¹⁹ As the "clever country", Australia should not be left behind.

Some Australian initiatives have already commenced or been proposed. The Victorian government has recently announced an initial grant of \$500 000 to develop an Australian Research Centre for Complementary and Alternative Medicines, although this initiative is still embryonic.²⁰ In 2000, the Australian government signalled its willingness to provide \$1 million over three years on the condition that the CAM industry matched this funding. The industry declined to contribute because of recent increases in TGA fees, and concern over a predicted downturn with the introduction of the GST (draft outcome note for the third meeting of the Complementary Healthcare Consultative Forum, 14 April, 2000 [available from the Complementary Healthcare Council]).

Priorities for CAM research

Priorities for CAM research need to be established for evidence-based CAM use. However, most CAM practitioners lack sufficient expertise in scientific research, while medical researchers may not have considered CAM as a potentially fruitful area of investigation, and have limited knowledge of CAM practices. Effective applied clinical research will require strong collaborations between CAM clinicians and medical researchers, reflected in research teams on grant applications. In the long run, this will also help the emergence of CAM practitioner researchers.

Research should provide answers to the questions "Does it work?", "Is it safe?", and "How does it compare with current treatment (in patient perceptions, actual benefit, safety and cost)?". However, key

2 CAM research needs medical mentors

The homocysteine theory of heart disease proposes that people with high blood homocysteine levels were at increased risk of heart disease. Taking supplements of homocysteine's metabolic cofactors — vitamin B₆, folic acid and vitamin B₁₂ — should lower homocysteine levels and decrease risk of heart disease.

This theory, first put forward in 1969, was rejected vigorously by mainstream medical science and research on it virtually halted. The primary author, McCully, a research pathologist at Harvard Medical School, was challenged by peers and lost his academic research position.

It wasn't until medical researchers took up this field in earnest in the 1990s that the theory gained popularity.²²

priorities may differ for different stakeholders. For example, government would wish to know whether CAM can contribute cost-effective healthcare, while patients seek to extend their healthcare choices, CAM practitioners to establish the unique knowledge base of their discipline, and scientists to extend their own knowledge boundaries. Evaluation of CAM therapies versus placebo, and versus conventional treatment, as well as of safety and quality assurance, must continue. We also need to understand better the mechanisms of action, health-economic implications and the potential diagnostic or prognostic value of CAM approaches.²¹

However, specific methodological difficulties in performing CAM research need to be recognised. Many CAM trials have been criticised as methodologically weak, so special attention to research design is crucial. For instance, CAM practices, including acupuncture and chiropractic, often involve significant interaction between patient and practitioner. Research within these practices has been plagued with the difficulty of creating a suitable placebo. CAM treatments are often individually tailored to the patient, and based on a different diagnostic process from Western medicine. Interventions are often complex, such as the combination of acupuncture, herbs, dietary and lifestyle advice in a traditional Chinese medicine consultation. The effect of studying each component separately or in combination as part of a whole system needs to be considered. Strong collaborative teams between research scientists and CAM practitioners are vital to effectively address such methodological concerns.

Why the slow medical uptake of useful CAM?

Some CAM therapies boast credible preliminary research. Why are such encouraging initial findings not replicated or extended? The homocysteine theory of heart disease has been described as one such example (see Box 2), where the potential of an alternative intervention only gained prominence when conceptually adopted by an influential medical mentor.²² The important lesson is that CAM research needs not only specific skills and teamwork, but, in particular, prominent medical alliances. It requires a deliberate policy that supports a collegiate approach, whereby those involved in CAM and in conventional medicine genuinely communicate with each other to develop the research agenda.

Conclusion

In this article we have not attempted to be entirely comprehensive, but rather hope to initiate a debate about the strategic development of CAM research in Australia. The need for this debate lies in the

sustained and increasing use of CAM by patients. The general public perceives that CAM is safe and effective. As responsible physicians, it is incumbent on us to resolve this vital public health issue, and we clearly cannot do this in a largely research-free zone with no research infrastructure.

Competing interests.

None identified.

References

- 1 MacLennan AH, Wilson DH, Taylor AW. The escalating cost and prevalence of alternative medicine. *Prev Med* 2002; 35: 166-173.
- 2 Bensoussan A, Myers SP, Wu SM, O'Connor K. Naturopathic and western herbal medicine practice in Australia — a workforce survey. *Complement Ther Med* 2004; 12: 17-27.
- 3 Ernst E. Prevalence of use of complementary/alternative medicine: a systematic review. *Bull World Health Organ* 2000; 78: 252-257.
- 4 Bensoussan A. Complementary medicine — where lies its appeal? *Med J Aust* 1999; 170: 247-248.
- 5 Coulter I, Willis E. The rise and rise of complementary and alternative medicine: a sociological perspective. *Med J Aust* 2004; 180: 587-589.
- 6 World Health Organization. Fact sheet No. 271. Traditional and alternative medicine. Facts and figures. Available at: www.who.int/medicines/organization/trm/factsheet271.doc (accessed Aug 2004).
- 7 Coghlan A. Chinese herbs hits malaria where it hurts. *New Scientist* 2003; 23 August: 16.
- 8 Bensoussan A. Complementary medicine: searching for the evidence. *Aust Family Physician* 2000; 29: 1129-1133.
- 9 Coon JT, Ernst E. Complementary and alternative therapies in the treatment of chronic hepatitis C: a systematic review. *J Hepatol* 2004; 40: 491-500.
- 10 Ernst E. Complementary and alternative medicine in rheumatology. *Baillieres Best Pract Res Clin Rheumatol* 2000; 14: 731-749.
- 11 Huntley AL, Ernst E. Soy for the treatment of perimenopausal symptoms — a systematic review. *Maturitas* 2004; 47: 1-9.
- 12 Pittler MH, Schmidt S, Ernst E. Hawthorn extract for treating chronic heart failure: meta-analysis of randomised trials. *Am J Med* 2003; 114: 665-674.
- 13 Expert Committee report. Complementary medicines in the Australian health system. Report to the Parliamentary Secretary to the Minister for Health and Ageing, 2003. Available at: www.tga.gov.au/docs/html/cmreport1.htm (accessed May 2004). Department of Education, Science and Training. The National Research Priorities and their Associated Priority Goals. An environmentally sustainable Australia. Available at: www.dest.gov.au/priorities/goals_summary.htm (accessed Aug 2004).
- 14 Ernst E. Obstacles to research in complementary and alternative medicine. *Med J Aust* 2003; 179: 279-280.
- 15 House of Lords. Science and technology — sixth report www.parliament.the-stationery-office.co.uk/pa/ld199900/ldselect/ldsctech/123/12301.htm (accessed Aug 2004).
- 16 Wider B, Ernst E. CAM research funding in the UK: surveys of medical charities in 1999 and 2002. *Complement Ther Med* 2003; 11: 165-167.
- 17 US White House Commission on Complementary and Alternative Medicine Policy. Available at: www.whccamp.hhs.gov/finalreport.html (accessed Aug 2004).
- 18 Chesney MA, Straus SE. Complementary and alternative medicine: the convergence of public interest and science in the United States. *Med J Aust* 2004; 181: 335-336.
- 19 Hentschel C. Profiling "centres of excellence" in CAM research. *Complement Ther Med* 2002; 10: 46-48.
- 20 Invest Victoria. Investor's guide to Victoria. New research centre to focus on traditional medicines [media release]. November 24, 2003. Available at: <http://invest.vic.gov.au/Press+Room/News/New+research+centre+to+focus+on+traditional+medicines.htm> (accessed May 2004).
- 21 Nahin RL, Straus SE. Research into complementary and alternative medicine: problems and potential. *BMJ* 2001; 322: 161-164.
- 22 Podell RN. Understanding the transition from alternative medicine to mainstream science: the homocysteine theory of heart disease and the crucial role of effective mentoring. *Med Hypothesis* 2003; 61: 340-345.

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