

COMMENTARY

Complementary and alternative medicine: the move into mainstream health care

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The use of complementary and alternative medicine (CAM) in Australia is extensive with over 50 per cent of the Australian population using some form of complementary medicine and almost 25 per cent of Australians visiting CAM practitioners. Expenditure on CAM by Australians is significant. The scope of CAM is extremely broad and ranges from complete medical systems such as Chinese medicine to well-known therapies, such as massage and little known therapies, such as pranic healing.

There is a growing focus on CAM in Australia and worldwide by a range of stakeholders including government, the World Health Organization, western medical practitioners and private health insurance companies. CAM practices may offer the potential for substantial public health gains and challenge the way that we view human beings, health and illness. Several issues are emerging that need to be addressed. They include safety and quality control of complementary medicines, issues related to integration of CAM with western medicine and standards of practice.

The evidence base of forms of CAM varies considerably: some forms of CAM have developed systematically over thousands of years while others have developed much more recently and have a less convincing evidence base. Many forms of CAM are now being investigated using scientific research methodology and there are increasing examples of good research. Certain forms of CAM, including Chinese medicine in which ophthalmology is an area of clinical speciality, view the eye in a unique way. It is important to keep an open mind about CAM and give proper scrutiny to new evidence as it emerges.

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The public is voting with its feet when it comes to the use of complementary and alternative medicine (CAM). As primary health care practitioners, optometrists need to know the facts about this increasingly popular and rapidly growing part of the health service industry in Australia and throughout the world. This paper will discuss what CAM is, its use in Australia and overseas, the growing focus on CAM from

different stakeholders and some of the emerging issues about CAM including safety, quality control, integration with western medical practice and standards of practice. A discussion of some of the potentials of CAM, the developing evidence base of CAM, the eye and CAM systems and the implications of CAM to optometrists will conclude the paper.

USE OF AND EXPENDITURE ON CAM IN AUSTRALIA

A South Australian survey conducted in 2000 by MacLennan, Wilson and Taylor¹ found that 52 per cent of those surveyed had used at least one non-medically prescribed CAM (excluding calcium, iron and vitamins) and that 23 per cent had visited at least one CAM practitioner in

the previous 12 months. In the study, use of complementary and alternative medicine was investigated under the following subcategories: non-prescribed vitamins, aromatherapy oils, herbal medicines, mineral supplements (excluding iron and calcium supplements), evening primrose oil, ginseng, homoeopathic medicines, Chinese medicines, menopause products and 'other'.¹ Use of various items had significantly increased from 1993 to 2000, including aromatherapy oils, herbal medicines, ginseng, Chinese medicines and 'other'.¹

Extrapolating to the Australian population, the South Australian study estimated that in 2000, the national Australian expenditure on CAM was \$AUD2.3 billion.¹ Of this figure, \$1,671 million was spent on complementary and alternative medicines and \$616 million was spent on CAM practitioners.¹ This represents an increase of 120 per cent in expenditure on complementary and alternative medicines after accounting for inflation over seven years (from \$621 million in 1993) and an increase of 62 per cent in expenditure on CAM practitioners (from \$309 million in 1993).¹ The study¹ found a median annual cost of \$228 for complementary and alternative medicines and a median annual cost for CAM practitioners of \$175 in 2000.

By way of comparison, as reported by MacLennan and colleagues,¹ the national expenditure under the Pharmaceutical Benefits Scheme (PBS) for the year ending 31 December 2000 was \$4.14 billion, of which government expenditure was \$3.45 billion and \$688 million was patient contributions for pharmaceuticals.² For pharmaceutical items on the PBS that are prescribed by a western medical practitioner, patient contributions are set by the government.

Currently, in 2003, the maximum cost to the patient for a PBS item (that is, the patient contribution) is \$23.10 for general patients and \$3.70 for a concessional patient, though some exceptions may apply, for example, in the case of a brand premium, therapeutic group premium or where a special patient contribution applies.³

USE OF CAM IN OTHER COUNTRIES

In the United States, a 1990 population survey estimated that approximately 34 per cent of respondents had used at least one CAM therapy in the previous 12 months.⁴ A follow-up survey in 1997 found this figure to have increased to 42 per cent.⁵ Over the seven years, there was a 47 per cent increase in total visits to CAM practitioners (427 million in 1990 to 629 million in 1997), exceeding the estimated total number of visits to all primary care physicians.⁵ In terms of expenditure, the 1997 survey found that total out-of-pocket expenditure by the US public relating to CAM therapies was US \$27 billion, similar to the 1997 projected out-of-pocket expenditure on all services by physicians.⁵ Expenditure on CAM professional services was estimated to be approximately \$21 billion in 1997, an increase of 45 per cent from 1990 and 1997.⁵

Elsewhere in the world, there is also evidence of substantial use of CAM or 'traditional medicine'. The term 'traditional medicine' is used here in the context of developing countries and 'CAM' in the context of developed countries. Up to 80 per cent of the African population relies on traditional medicine to help meet health needs and Chinese medicine accounts for 40 per cent of health care in China.⁶ A 1994 report on CAM in Europe reported that proportions of the population using CAM therapies in seven European countries and the US ranged from 20 to 50 per cent.⁷ The World Health Organization (WHO) reports that the proportion of the population that has used CAM at least once is 70 per cent in Canada, 38 per cent in Belgium and 75 per cent in France.⁶ Research suggests that CAM is popular in developed countries and that the popularity of CAM is growing.^{1,5-11}

WHAT IS CAM?

CAM is popular. What is CAM, who is using it and why is it used? There has been disagreement about the most appropriate terminology to use when discussing that which has been referred to in this paper as 'complementary and alternative medi-

cine', a term used by the National Center for Complementary and Alternative Medicines (NCCAM), one of the centres of the National Institutes of Health (NIH) in the USA. Other terms include natural medicine, natural therapy, non-conventional therapies, unorthodox therapies, holistic medicine, integrative medicine, traditional medicine and complementary therapies.^{6,12-14} There are problems with many of these terms. For example, it could be argued that CAM is not always complementary to western medicine: it may be used as an alternative. What is considered 'unorthodox' is a matter of opinion and depends on perspective. In countries such as China, acupuncture and Chinese herbal medicine would be considered orthodox forms of treatment and with at least 15 per cent of Australian GPs practising acupuncture,¹⁵ the 'unorthodox therapies' description does not seem apt.

Moreover, Australia is a multicultural society; many of those who have immigrated here have brought with them forms of medicine that are orthodox in their countries of origin, if not in Australia. Even the use of the word 'therapy' is not appropriate when considering complete medical systems such as Chinese medicine and Ayurvedic medicine (Indian traditional medicine). The term 'integrative medicine' has some popular usage but it is not a comprehensive descriptor as it implies that some aspects of alternative medicine may be worthy of integration into western medical practice rather than standing on their own. Some medical professions such as Chinese medicine may not agree to being grouped together with CAM therapies that arguably have little or no evidence base.

The World Health Organization makes a distinction between the terms 'traditional medicine' and 'CAM'. The WHO Traditional Medicine Strategy 2002-2005 explains that terms such as 'complementary', 'alternative' and 'non-conventional' medicine are often used (instead of 'traditional medicine') in countries where the dominant system of health care is allopathic medicine or where traditional medicine has not been included as part of a national health care system.⁶ Accordingly,

the WHO Traditional Medicine Strategy 2002–2005 uses the word 'CAM' when referring to Europe, North America and Australia, and 'traditional medicine' when referring to Africa, Latin America, South-East Asia and/or the Western Pacific region.⁶

One of the better definitions of CAM has come from the NIH Office of Alternative Medicine, now the National Center for Complementary and Alternative Medicine:

'... a broad domain of healing resources that encompasses all health systems, modalities and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM systems include all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and wellbeing. Boundaries within CAM and between CAM domain and the domain of the dominant system are not always fixed and sharp'.¹³

The scope of CAM is extremely broad and ranges from complete medical systems, such as Chinese and Ayurvedic medicine to well-known therapies, such as aromatherapy, reflexology and massage, and diagnostic modalities, such as iridology, to lesser-known therapies, such as 'pranic healing' (a form of healing using the energy fields of the body) and crystal therapy.¹⁶ Some forms of CAM have developed systematically over thousands of years and have a solid base of experiential evidence, while others have developed much more recently and have a less convincing evidence base.

There are various ways in which CAM practices may be classified. Pietroni¹⁷ developed a classification based on four main groupings:

1. complete systems, for example, herbal medicine, Chinese medicine, homoeopathy
2. diagnostic methods, for example, iridology, kinesiology
3. therapeutic modalities, for example, massage, reflexology
4. self-care approaches, for example, meditation, yoga, dietetics.

	Definition	Examples *
Alternative medical systems	Complete systems of theory and practice that have developed independently and often prior to the Western biomedicine; practised by individual cultures throughout the world ¹⁸	<ul style="list-style-type: none"> • Chinese medicine: includes acupuncture, Chinese herbal medicine, Chinese massage, qi gong, tai chi and diet therapy • Ayurvedic medicine • Tibetan medicine • Aboriginal medicine • Naturopathic medicine: includes Western herbalism, massage, nutrition, nutritional supplementation • Homoeopathy
Mind-body interventions	Techniques that enhance the ability of the mind to affect the body's function and symptoms ¹⁸	<ul style="list-style-type: none"> • Meditation • Prayer • Art therapy
Biologically-based therapies	Therapies that use substances found in nature such as herbs and foods; may overlap with Western medicine's use of dietary supplements; includes as yet scientifically unproven therapies ¹⁸	<ul style="list-style-type: none"> • Orthomolecular therapies: eg. mega-doses of vitamins, use of minerals (Mg, Se) • Special dietary therapies: eg. Pritikin diet • Herbal products • Individual biological therapies: eg. shark cartilage to treat cancer
Manipulative and body-based methods	Methods that involve manipulation and/or movement of one or more parts of the body ¹⁸	<ul style="list-style-type: none"> • Chiropractic • Osteopathy • Massage therapies: remedial massage, Swedish massage, shiatsu, Bowen therapy
Energy therapies	Biofield therapies: therapies that focus on biofields, the purported energy fields surrounding and within the body (the existence of which has not yet been proven scientifically) and bioelectromagnetic-based therapies that involve the unconventional use of electromagnetic fields to treat conditions ¹⁸	<ul style="list-style-type: none"> • Biofield therapies: qi gong, reiki, pranic healing, polarity therapy, therapeutic touch, crystal therapy • Bioelectromagnetic-based therapies: magnetic therapy

Source: NCCAM¹⁸
 * Examples additional to those given by the NCCAM have been added

Table 1. NCCAM major domains of CAM

The NCCAM categorises CAM into five major domains.¹⁸ These are presented in Table 1 together with some examples.

WHO IS USING CAM AND WHY?

Various studies have examined the demographic descriptors and characteristics of users of CAM. Some of the more consistent descriptors identified in the literature

include being female,^{1,19-22} more highly educated,^{1,19,23} wealthier,^{1,19,20,23} employed^{1,19} and having private health insurance.^{20,22} Research suggests that CAM users tend to have an optimistic outlook on life, a holistic orientation to health, a belief in individual responsibility and subscribe to a post-modern philosophy (a value system that supports individual perspectives and opposes scientific rationalism).^{19,23,24}

The reasons for people choosing CAM are varied and include visiting for specific injuries and illnesses,²⁰ recommendation by a general practitioner,²⁰ dissatisfaction with western medicine (including the experience and the medical outcomes),^{20,23} congruency with users' values and beliefs towards health and life²³⁻²⁵ and because it helps or relieves a condition or injury.⁹

CAM use tends to be high in sub-populations suffering from particular diseases such as cancer and HIV-AIDS. It has been reported that between nine per cent and 54 per cent of cancer patients have used some form of CAM.²⁶ A South Australian study found that approximately 46 per cent of children with cancer had used at least one CAM therapy (mostly, in addition to orthodox medical treatment).²⁷ In one Australian study of HIV-positive people, 55.5 per cent were found to use CAM therapies and 48 per cent were found to use vitamins or herbal therapies, usually as an adjunct to anti-retroviral drugs.²⁸

A 1996 report on the practice of Chinese medicine in Australia found that patients were receiving treatment for a wide range of health conditions. Among 14 diagnostic categories, rheumatological disorders constituted the greatest proportion of cases being treated by Chinese medicine practitioners and medical practitioners practising Chinese medicine.²⁹ Further studies are needed to understand for which particular health disorders Australians are using other CAM practices or medicines.

There is a high degree of satisfaction with CAM treatment and practitioners. For example, a 1995 survey²⁶ of cancer patients in Sydney reported that 70 per cent were satisfied with CAM treatment. A 2000 study²⁰ commissioned by the Royal Australian College of General Practitioners reported that 83 per cent of respondents were satisfied with CAM treatment, and a 1995 Sydney survey³⁰ of users of Chinese medicine reported a very high rate of satisfaction (98 per cent) with the effectiveness of Chinese medical treatment.

GROWING FOCUS ON CAM

In Australia and worldwide, there is an increasing awareness and focus on CAM from western medicine and allied health practitioners, insurance companies, regulatory bodies and consumers.

Private health insurance company focus

An increasing number of private health insurance companies offer cover for certain forms of CAM. US surveys found that the primary motivating factor for offering insurance coverage of CAM was consumer demand and that factors that determined whether they would offer coverage for additional forms of CAM included potential cost-effectiveness, consumer interest, evidence of clinical efficacy and state mandates.^{31,32}

Government focus

In Australia, there is an increasing focus by Government on CAM. Until recently, most Australian CAM professions have been self-regulated. In May 2000, Victoria became the first state in a western country to introduce statutory regulation of Chinese medicine. The Victorian Department of Human Services (DHS) responded to the perceived increase in demand for and use of Chinese medicine by Victorians, complaints to the Health Protection Section's Therapeutic Goods Unit of DHS about herbal medicines and advice from the major government body controlling Chinese medicine in China.²⁹ The department commissioned a review of Chinese medicine in 1996 and in May 2000, the Chinese Medicine Registration Act 2000 was passed in the Victorian Parliament. NSW is reviewing the need for regulation of CAM professions and released a discussion paper at the end of 2002.

Chiropractic and osteopathy have been regulated in Victoria since 1978, with the combined Chiropractors and Osteopaths Act 1978 being replaced by the Chiropractors Registration Act 1996 and the Osteopaths Registration Act 1996. Chiropractic and osteopathy are regulated in all other Australian states and territories.

In addition, the Victorian Department of Human Services funded a feasibility study in 2000–2001 into the establishment of a CAM research centre in Victoria.³³ The project received wide support from universities, privately operated schools of CAM, CAM professional associations and practitioners. The Victorian government recently announced support for the establishment of the research centre and implementation is underway. The centre has been named the Australian Research Centre for Complementary and Alternative Medicine.

Several Commonwealth Government departments and committees have a direct interest in complementary and alternative medicines. The Therapeutic Goods Administration (TGA) has an Office of Complementary Medicines and a website that features practitioner alerts, information fact sheets and information on regulation of medicines (see www.health.gov.au/tga/cm/cm.htm). In Australia, the TGA regulates proprietary medicines including complementary and alternative medicines. Proprietary medicines sold in Australia must be listed or registered with the TGA and labelled with an 'Aust L' or 'Aust R' number, respectively. Listed products have been assessed for quality and safety; registered products have been assessed for quality, safety and efficacy.

Under the GST Act, the supply of certain CAM services (set out in Subsection 38-10 [1] of the GST Act) may be GST-free. One of the stipulations for this to occur is that the supplier is a 'recognised professional' in relation to the services provided. Since 30 June 2003, for CAM practitioners to retain or obtain GST-free status for certain services, they need to be recognised professionals. In any state where there is statutory registration, a CAM practitioner needs to be registered to fulfil the definition of 'recognised professional'. This applies only to chiropractic and osteopathy (in all Australian states and territories) and Chinese medicine (in Victoria only) as these are the only CAM professions to have statutory regulation. All other forms of CAM are self-regulated. In the case of other CAM services that may be eligible for GST-free status (including

Chinese medicine outside of Victoria), practitioners need to be members of a recognised professional association that has, among other requirements, uniform national registration to fulfil the definition of recognised professional. In 2002, the Commonwealth Government provided funding of \$500,000 that was split between five professional CAM associations (Australian Natural Therapists Association [ANTA], Australian Traditional Medicine Society [ATMS], National Herbalists Association of Australia [NHAA], Federation of Natural and Traditional Therapists [FNNT] and the Australian Chinese Medicine and Acupuncture Association [AACMA]) to develop professional registration bodies or systems for the purposes of establishing 'uniform national registration' for CAM. The details and logistics of the way in which such registration bodies would work have not yet been finalised.

World Health Organization focus

On the world stage, the WHO has recognised the widespread use of traditional medicines (TM) in developing countries and the increasing use of CAM in developed countries. It has defined its role in TM/CAM and has released a strategy paper entitled 'WHO Traditional Medicine Strategy 2002–2005'.⁶ This document addresses issues in the areas of policy development and implementation, safety, quality and efficacy, access and rational use of TM/CAM.⁶ The WHO has instigated two other initiatives concerned with TM/CAM. The first is a Forum on Harmonisation of Herbal Medicine (FHH), which included input from a small number of countries including China, Japan, Australia and Korea and which is considering ways of harmonising the growth, manufacture and regulation of herbal products across the countries. The second is a WHO Working Group on the harmonisation of traditional and modern medicine, which is concerned primarily with issues of research into TM/CAM.

INTEREST FROM WESTERN MEDICINE PRACTITIONERS

The interest in CAM appears to be increasing among practitioners of western medi-

cine. In Germany, 95 per cent of GPs use some form of CAM at least occasionally,³⁴ in Holland 47 per cent of GPs use CAM (mostly homoeopathy)³⁵ and more than one-third of general medical practitioners in France practise some form of CAM.⁷ In New Zealand,³⁶ 30 per cent of general medical practitioners and in Canada around 16 per cent of GPs use some form of CAM.³⁷ CAM is popular among Australian GPs. In 1996, approximately 50 per cent of Perth GPs surveyed had completed some form of postgraduate training in CAM³⁸ and in 1997, almost 20 per cent of Victorian GPs surveyed practised some form of CAM.³⁹

Western medical schools are incorporating CAM into their curricula. Of 125 medical schools surveyed in the USA, 117 responded and 64 per cent of these offered elective courses in CAM or included CAM topics in compulsory courses.⁴⁰ Several Australian medical and nursing courses are also incorporating CAM topics.

Australian medical practitioners are also referring to CAM practitioners. Ninety three per cent of Victorian GPs have referred at least once per year for CAM therapy³⁹ and a survey³⁸ found 67.8 per cent of Perth GPs were in favour of referring to CAM practitioners.

There are several professional associations representing western medical practitioners with an interest in CAM, including the Australasian Integrative Medicine Association (AIMA) and the Australasian College of Nutritional and Environmental Medicine (ACNEM).

CAM EDUCATION AND WORKFORCE

CAM education has moved into Australian universities with several undergraduate and postgraduate courses offered, including courses in naturopathy, Chinese medicine, osteopathy and chiropractic. The Australian National Training Authority has established competency-based standards for training (Health Training Packages) in massage (including remedial massage and shiatsu), western herbal medicine, homoeopathy and naturopathy (see <http://www.cshta.com.au/htp.htm>).

The CAM workforce is substantial and

growing. There was a 12-fold increase in the size of the CAM workforce between 1970 and 1986.⁴¹ Figures from the Australian Bureau of Statistics suggest that in 1999–2000, there were 3,700 practitioners employed as natural therapy professionals in Australia but this is likely to substantially underestimate the real number.³³ Combining the national membership numbers of two of the largest professional associations in Australia in 2001 (the Australian Natural Therapies Association and the Australian Traditional Medicine Society) suggests a figure in excess of 11,000 practitioners.³³ The degree of overlap in membership is not known, as membership is not compulsory, although it is an advantage for those who wish to be providers of CAM services for the purposes of private health insurance.

EMERGING CAM ISSUES

Several issues need to be addressed, including safety and quality control. Integration of CAM into western medicine is not necessarily straightforward.

Safety of CAM practices and medicines

The safety of CAM practices and medicines is of concern to health practitioners and governments. Although generally perceived as safe, many herbs are not safe and adverse effects can include allergic reactions, toxic reactions (including renal and hepatic toxicity), mutagenic effects, herb-drug interactions and idiosyncratic reactions, some of which can result in death.^{29,42}

There are known interactions that can occur between certain herbs and pharmaceuticals, for example, an adverse interaction can occur between the Chinese herb Dan-shen (*Radix Salviae miltiorrhizae*) and warfarin.⁴³ Practices such as acupuncture clearly have the potential to cause injury if not practised correctly. This underscores the need for practitioners of CAM to be adequately trained and for western medical practitioners to be adequately informed about commonly-used CAM treatments.

Some interesting patterns have emerged about consumer behaviour and usage of

CAM. In the USA, surveys in 1990⁴ and 1997⁵ found high proportions of people (51 per cent and 46 per cent, respectively) were using CAM therapy without advice from either a CAM practitioner or a medical practitioner; the 1990 survey⁴ also found that two-thirds of respondents who had used at least one CAM therapy during the previous 12 months had done so without visiting a CAM practitioner. A South Australian study¹ found that 28 per cent of complementary and alternative medicines are self-prescribed, 28 per cent are doctor-prescribed and 13.4 per cent are used on the advice of a CAM practitioner. A 1999 survey⁴⁴ in Australia found that CAM practitioners play only a small role in distribution of herbal products with about six per cent of consumers purchasing products from a CAM practitioner compared with 34 per cent in supermarkets, 32 per cent in pharmacies and 45 per cent in health food outlets.

Significant numbers of people are using CAM therapies and western medical intervention. A 1997 US study⁵ found that approximately 32 per cent of patients visiting a medical practitioner for a principal medical condition also used a CAM therapy and that 13.7 per cent of patients who visited a medical practitioner also visited a CAM practitioner. There is concurrent use of western pharmaceuticals and herbal medicines and/or high dose vitamins: a 1997 US study⁵ found that almost 20 per cent of persons on prescription drugs were also taking herbs and/or high dose vitamins and two Australian studies^{30,45} on the use of Chinese medicine found that 49 per cent³⁰ and 35 per cent of patients⁴⁵ were taking herbal medicines in combination with pharmaceutical medication.

Disturbingly, a US study⁴ in 1990 found that of patients who visit CAM practitioners, 72 per cent do not inform their western medicinal practitioner that they have done so. Australians seem equally reticent to inform their GPs. In Sydney, 32 per cent of users of Chinese medicine had not informed their GPs³⁰ and 40 per cent of cancer patients did not admit using CAM,²⁶ while in South Australia, 57 per cent of parents of children with cancer²⁷ and 57

per cent of those who had used CAM in the preceding 12 months¹ did not inform their medical practitioners. Self-medication and failure to inform medical practitioners about the concurrent use of complementary and alternative medicines has the potential for adverse reactions and/or herb-drug interactions.

There is limited information on adverse events associated with CAM in Australia. There are approximately 150 to 200 reported cases of adverse reactions to complementary medicines per year recorded by the Australian Commonwealth Government's Adverse Drug Reactions Advisory Committee (ADRAC).⁴⁶ Given the widespread use of CAM in Australia, this suggests either under-reporting of adverse events related to CAM or that CAM is associated with a relatively low risk of adverse events.³³

A report on hospital admissions to the Prince of Wales Hospital in Hong Kong found that 0.2 per cent of general admissions were for adverse reactions to Chinese herbal medicines compared with 4.4 per cent of admissions due to western pharmaceuticals.⁴⁷ An Australian study²⁹ found that practitioners of Chinese medicine experienced 1.1 ± 1.9 (SD) adverse events per year of full-time practice and medical practitioners (practising Chinese medicine) experienced 2.5 ± 3.6 per year of full-time Chinese medical practice.

Another Australian study⁴⁸ found that 5.7 per cent of hospital admissions were related to western drugs. However, any comparison between complementary medicines and western pharmaceutical medications in terms of risk needs to keep in mind the purposes or clinical disorders for which the medicines are used and needs to consider an assessment of the risks and benefits of the individual medicines. For example, many western medications that have side-effects are extremely effective in treating serious diseases and the benefits may far outweigh the risks.

Quality control of complementary and alternative medicines

Quality control is an important issue in complementary medicines. Problems with herbal medicines can include adulteration

of herbal preparations with western pharmaceuticals, substitutions (of other herbs) and contamination of herbs (for example, with heavy metals or pesticides). In Australia, a stringent form of quality control exists for proprietary medicines including proprietary complementary and alternative medicines. Proprietary medicines are regulated by the Therapeutic Goods Administration and Good Manufacturing Practice (GMP) standards and Good Agricultural Practice (GAP) standards apply to manufacturers of proprietary medicines that seek to list or register their product with the Australian Register of Therapeutic Goods (ARTG). The recent recall by the TGA of more than 1,500 CAM products manufactured by Pan Pharmaceuticals Limited due to TGA concerns over safety and quality of products produced by the company, highlights the necessity of quality control mechanisms for CAM products and the benefits of having a regulatory watchdog like the TGA. Consumers have a right to safe and efficacious medicines.

The Australian TGA does not regulate raw herbs and the quality control over raw herbs is loose. The Australian Quarantine Inspection Services (AQIS) and Australian Customs are the government bodies responsible for ensuring that endangered, prohibited and/or contaminated substances are not imported into Australia. The Victorian Government is examining the issue of safety with respect to potentially toxic raw Chinese herbs following amendments made to the Victorian Drugs Poisons and Controlled Substances (DPCS) Act 1981 by the Chinese Medicine Registration (CMR) Act 2000. In essence, the CMR Act 2000 renamed Schedule 1 of the Victorian Poisons List: 'Poisons of plant, animal or mineral origin that in the public interest should be available only from a person registered under the Chinese Medicine Registration Act 2000 or authorised under another act'.⁴⁹ It also gave the Victorian Minister for Health power to 'a. specify the substances to be included in Schedule 1 in the Poisons List; and b. amend, revoke, substitute or insert substances in Schedule 1 in the Poisons List'.⁴⁹ The Chinese Medicine Registration

Board of Victoria and the Department of Human Services are preparing a list of potentially toxic Chinese herbs to be considered by the Victorian Minister for Health for inclusion on Schedule 1 of the Victorian Poisons List. A discussion document on the scheduling of potentially toxic raw Chinese herbs in Victoria was due for release by the CMR Board in 2004 and addresses the issues of quality control of Chinese herbs (see www.cmr.vic.gov.au).

Integration of CAM and standards of practice

There are potential problems concerning the integration of CAM into western medical practice. In particular, there is the risk that the essence of the CAM therapy will be altered, diluted or delivered in the wrong context. Whereas therapies belonging to a traditional medical system are taken out of the traditional context and practice, results of treatment may be different. For example, medical acupuncture practised by western medical practitioners is different from traditional Chinese acupuncture (in which the choice of acupuncture points and needling techniques is guided strictly by traditional Chinese medical theory). Conclusions drawn (from clinical trials or otherwise) about the efficacy of acupuncture where the treatment has not been guided by traditional theory (for example, in terms of Chinese medical diagnosis, treatment strategy, acupuncture points chosen and/or needling technique) may not reflect the efficacy of acupuncture that is guided by traditional theory.

Obviously, standards of practice of CAM modalities will impact on the efficacy and safety of treatment. For many forms of CAM, standards of practice and training vary widely. It could be argued that standards of training may be more important for complete medical systems such as Chinese medicine or Ayurvedic medicine than for modalities such as reiki.¹⁶ Not all CAM practices are easily added to standard medical training.¹⁶ For example, the training for Chinese medicine (that includes acupuncture and Chinese herbal medicine) in China is a five-year degree and four- and five-year degree courses in

Chinese medicine are offered at a number of universities within Australia.

It is important that practitioners of particular forms of CAM are adequately trained to protect the public. For example, not all herbal medicines are safe, some can interact with pharmaceuticals, and serious adverse events can occur in practices such as acupuncture. Adequate standards of training are essential.

Safety issues of CAM aside, there are the ethical implications to consider in the use of CAM: for example, the time and monetary costs to the patient of forms of CAM that are not efficacious.

The potentials of CAM

CAM practices may offer the potential for substantial public health gains, particularly in prevention of ill health, treatment of chronic diseases that do not respond well to western medical treatment and optimisation of health.³³ There is also the potential for long-term cost savings from CAM for insurance companies and governments. For example, an 11-year population study by an insurance company in the USA compared 2,000 people who practise meditation with 600,000 non-meditators and found a 63 per cent reduction in health care expenditure, 11.4 times fewer hospital admissions for cardiovascular disease, 3.3 times fewer for cancer and 6.7 times fewer for mental disorders and substance abuse in those who practised meditation.^{50,51} Another US study found that the use of a lifestyle program that included meditation, yoga and a vegetarian diet in conjunction with standard medical care in patients with coronary heart disease (CHD), compared with a control group receiving standard medical care, was associated with a reversal of CHD angiographically, an increase in quality of life and a cost-saving of US\$58,000 per person.^{52,53} Five years later, the control group (standard medical care) had 2.5 times the number of ongoing major cardiac events in comparison with the lifestyle intervention group that had further improved their CHD.⁵⁴

When we think of health, we tend to think of the absence of disease but the WHO gives us a more encompassing defi-

nition of health as not simply the absence of disease but a positive state of mental, physical and social wellbeing.⁵⁵ Many forms of CAM have the potential to optimise health in these dimensions.

From an economic perspective alone, our health care system is expensive and largely focuses on the illness end of the health-illness spectrum. The potential for many forms of CAM to reduce expenditure on health care is yet to be fully investigated.

One of the major potentials of CAM is to challenge the way that we view humans, health, illness and wellness. Most CAM practices recognise humans as multidimensional, having physical, emotional, mental and spiritual dimensions and are underpinned by an understanding of the connection of mind and body.¹⁶ It could be argued that Chinese medicine and Ayurvedic medicine, in particular, are well-developed systems of mind-body medicine. The developing western medical field of psychoneuroimmunology that studies the way in which the mind-emotions influence the immune system is making inroads into understanding mind-body interaction.

In contrast to more mechanistic biochemical models of the body, there are emerging paradigms of mind-body medicine that describe the human in terms of complex, multidimensional subtle energy systems and use holographic principles (each piece of a hologram contains the whole) to understand the nature of human: these are described in the book *Vibrational Medicine* by Gerber⁵⁶ and may hold some of the keys to future development of medicine and understanding of how many forms of CAM are effective.

Each system has its own strengths and weaknesses. Many forms of CAM have their own language that may not be viewed as scientific and this can be a barrier to exchange of knowledge. For example, the concepts of heat and dampness in the body in Chinese medicine can describe pathological states within the body. Heat can manifest in numerous ways, such as fever, pharyngitis, red face, bulbar conjunctival hyperaemia, irritability and various infections and inflammations. Damp-

ness may manifest as sticky discharges (nasal, vaginal et cetera) or oedema. Through the manifestations, described in western terms, a basic understanding of some of the Chinese medical terminology can be formed but a bridge in terms of language is only part of the solution.

Forms of CAM like Chinese medicine are based on fundamentally unique paradigms. Understanding these paradigms, particularly when schooled in western medical thought, is more difficult for the western mind. This is only the beginning, if one is to attempt to bridge the understanding of western medicine and of other forms of medicine like Chinese medicine and develop a new understanding of human beings and life.

Evidence base of CAM

The immense value of experiential evidence that has formed the basis for some of the oldest medical systems such as Chinese medicine, Tibetan medicine and Ayurvedic medicine should not be understated. In more recent times, there has been a shift within western medicine towards an evidence-based approach that demands that a practice or medicine be investigated according to scientific research methodology, from which develop best-practice guidelines. This must occur in the CAM professions, if they are to be accepted by western medicine and integrated into the western health care system. This is occurring.

Some CAMs have been and continue to be investigated using scientific research methodology and the evidence base for many forms of CAM is increasing. A glance at the Cochrane Collaboration's *Cochrane Database of Systematic Reviews (CDSR)* (<http://www.nicsl.com.au/cochrane/index.asp>) indicates that for many CAM practices, the research has not been sufficient to draw solid conclusions. Problems with CAM research have included inadequate sample size, failure to use an adequate placebo and inappropriate research design but there are examples of good CAM research in the literature.

There are significant complexities that need to be taken into account in the research of CAM. Researchers need to

understand and take into account the philosophies and theories that underpin the particular CAM practice, otherwise there is a risk that research results will produce erroneous conclusions. For example, in Chinese medicine, a disorder or disease is generally differentiated into three to five subcategories called syndromes. Each syndrome is characterised by particular symptoms and signs and represents the pathology of the disease at that time, as understood according to Chinese medicine theory. The treatment principle and the Chinese herbal medicinal formula developed will be specific for each syndrome. If the efficacy of a particular Chinese herbal medicine that is specific for a particular syndrome is tested in a population that contains a mixture of syndromes of the disease and if the trial does not demonstrate efficacy of the medicine, a conclusion may be drawn that the medicine was not efficacious in treating the disease. In fact, it may have been effective in subjects subcategorized into the syndrome for which the herbal formula was appropriate. Alternatively, it may not have been successful for this sub-group and that is also useful information. Arguably, Chinese herbal medicinal formulae are different from western pharmaceuticals.

Complementary and alternative medicines are often individualised. It is possible that the efficacy of a proprietary form of a herbal medicine (in which the constituents and dosage of individual herbs are fixed) may be different from the efficacy of a raw herbal medicine prescription, in which the herbs chosen and herb dosages are tailored to the patient. Clinical studies may choose to test the practice rather than a particular medicine.

The issue of individualised versus standardised herbal treatment (in which the herbs and dosage are fixed) was addressed in a well-designed Australian clinical study of Chinese herbal medical management of symptoms related to irritable bowel syndrome (IBS).⁵⁷ The study compared treatment with a standardised herbal formula, Chinese herbal prescriptions individualised to each patient and a placebo. Both Chinese herbal treatments were significantly more effective than the placebo in

the management of symptoms related to IBS.⁵⁷ Herbal prescriptions individually tailored to the patient were no more effective than treatment with a standardised herbal formula in terms of management of symptoms, however, 14 weeks after completion of the treatment, only the individualised treatment group maintained improvement.⁵⁷

There are other examples of well-designed studies of CAM. For example, an Australian study⁵⁸ into the efficacy of acupuncture in the treatment of seasonal allergic rhinitis used a two-phase cross-over single-blind methodology and found that the treatment group experienced a significant improvement in nasal and non-nasal symptoms.

Jonas, Kaptchuk and Linde⁵⁹ summarised a number of reviews of clinical trials in homoeopathy and reported that three independent reviews of placebo-controlled studies concluded that the effects of homoeopathy seemed to be greater than placebo and that one review reported that the effects were similar to placebo. Linde and colleagues⁶⁰ summarised the available systematic reviews of clinical trials in acupuncture and found that the limited evidence available suggests that acupuncture may be useful in the treatment of some conditions including fibromyalgia, post-operative nausea, post-operative pain following dental procedures and temporomandibular joint dysfunction. They also found that the evidence did not support its effectiveness in treating smoking addiction and was inconclusive regarding acupuncture to treat back and neck pain.⁶⁰

It is beyond the scope of this paper to summarise the evidence base of CAM given its extremely broad scope and the reader is directed to literature available through sources such as MEDLINE and the Cochrane website. There is substantial CAM research activity within Australian universities and increasingly, complementary medicines and practices are being investigated with rigorous scientific research methodology.

A significant problem is the lack of funding for CAM research. This has been traditional in Australia in comparison to

western medical research. In 2001, total funding by the National Health and Medical Research Centre (NHMRC) for all new and continuing grants was \$216,249,026, of which \$104,328 was allocated to CAM research projects.⁶¹ In comparison, the National Center for Complementary and Alternative Medicine in the USA is strongly supported by government and had a budget of US\$113.1 million (fiscal year enacted level) in 2003.⁶²

Recent developments in Victoria may facilitate CAM research activity. As mentioned previously, the Victorian Government recently announced that it would support and fund the establishment of a CAM research centre (the Australian Research Centre for Complementary and Alternative Medicine). There are also university-based (and other) research centres actively investigating CAM in other Australian states.

OPHTHALMOLOGY AND CAM

Ophthalmology is an area of clinical speciality in Chinese medicine, in which the health and spirit of the person are reflected in the eye. The major organ systems of the body are associated with particular parts of the eye but not in the same way as in iridology. In Chinese medicine, the eye is particularly associated with the liver organ system, being connected to it via energy pathways called meridians. The liver meridian passes through the liver and travels up to the eye and acupuncture points on the liver meridian are often used to treat eye disorders. Like all of the organs in Chinese medicine, the liver's function does not correlate directly with the understanding of its function in western medical terms and is better thought of as a functional system. In Chinese medicine, the liver system is concerned with the 'free-flowing' of the subtle energy or Qi of the body and plays a role in the harmonisation of the emotions, promotion of digestion, blood circulation and fluid metabolism.⁶³ The liver regulates the circulating blood volume as well as the functioning of the tendons and the condition of the nails.⁶³ In Chinese medicine, deficiency of 'liver blood' may result in dry eyes. In such

cases, herbal treatment would include herbs that strengthen the liver and nourish the blood. Chinese medicine aims to treat the root cause of the disease as well as secondary manifestations. In China, herbal medicine and acupuncture are used to treat a wide range of eye disorders including dry eye, macular haemorrhage, glaucoma and age-related maculopathy. It is practised predominantly in hospitals where the two systems are well integrated. Within Chinese medical hospitals, western medical diagnostic tests, medicines and surgical techniques may be utilised, if appropriate.

Iridology or iris diagnosis has been much maligned in western medical circles, yet remains a major diagnostic practice used by naturopaths. In Germany, 80 per cent of *Heilpraktiker*, non-medically qualified health practitioners, practise iridology.⁶⁴ It is based on the premise that the body structures and organs are mapped out on the surface of the iris and that dysfunction in the body is reflected in changes in the iris.⁶⁵ A review of published literature on iridology by Ernst⁶⁵ found that of 77 papers, 17 attempted to validate iridology as a diagnostic technique and of these, the majority were flawed methodologically: either they were uncontrolled or the evaluator was not masked, adding a potential source of bias. Ernst⁶⁵ reported that while all of the uncontrolled studies and several of the unmasked studies supported the validity of iridology, the only four controlled, blind studies did not support the validity of iridology as a diagnostic tool.

CAM AND OPTOMETRISTS

CAM is very much a part of Australian health care and optometrists need to be informed about it. In taking a case history, optometrists should question their patients not only about general health and the use of western medications but also about CAM therapy. Given the relatively high percentage of patients who do not talk to their general medical practitioners about CAM use and the proportion of patients self-medicating with complementary and alternative medicines, the optometrist

is in a unique position to detect potential problems that could be associated with CAM use and/or drug-CAM interactions simply by questioning the patient. It is not the role of the optometrist to diagnose problems associated with CAM use but optometrists are in a position to advise patients to seek further advice and/or to initiate dialogue with the patient's medical practitioner. There are obviously barriers to patients talking to their GPs about CAM use, so it is important that optometrists keep their own personal biases and judgements about CAM out of the conversation so that patients will feel comfortable discussing CAM use.

The process of integration of aspects of CAM therapy with western medicine has begun and will continue. CAM is popular among Australians and this is unlikely to change. Based on scientific research, the evidence base of CAM is developing. It is important to keep an open mind about CAM and to give proper scrutiny to new evidence as it emerges.

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