Review of Complementary Medicine in NSW

REPORT to the Ministry for Science and Medical Research

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Executive Summary

In 2003 the NSW Minister for Science and Medical Research, the Hon Frank Sartor, commissioned a review of health and medical research in NSW. The review, *A Prescription for Health*, was released in 2004 and informs the development of the health and medical research plan for NSW. This report aims to supplement the health and medical research plan by providing an analysis of the way in which complementary medicine practices are used in NSW and Australia, the size and scope of the industry and the nature of relevant research activities in NSW. It describes the current major funding mechanisms and quantum of research funds available to complementary medicine researchers, describes the nature of this research and provides strategic direction on enhancing research opportunities in complementary medicine with a view to strengthening the industry and ensuring the provision of quality services. It is envisaged that this report will contribute to the ongoing development of the NSW health and medical research plan.

The complementary medicine landscape

Complementary medicine usage now represents a substantial proportion of activity in the Australian health care sector. Each year between 50-75% of the Australian adult population use at least one complementary medicine product and one in four Australians use complementary medicine services. There are in excess of fifteen million consultations nationwide each year in herbal medicine, naturopathy, acupuncture, chiropractic and osteopathy alone. Various government responses to this marked activity have occurred, including the development of new legislation to regulate complementary medicines, the introduction of practitioner registration and the establishment of key expert committees to review approaches to management of the industry.

A conservative estimate of the industry turnover of complementary medicine products in Australia sits at $1-2 billion per annum. Provision of complementary medicine services accounts for an additional $600 million per annum, putting the total industry value (products and services) conservatively at about $1.5 to $2.5 billion per annum, excluding insurance, research and investment in infrastructure. The industry continues to grow steadily at approximately 10% per annum with increasing uptake by consumers and there is no sign of abatement in the near future. Overseas studies have also showed a steady growth in the industry and, coupled with an aging population and a tradition of complementary medicine use in chronic disease management, the demand for complementary medicine products and services is likely to increase.

Scientific literature exists demonstrating that some complementary medicine interventions have high level evidence for their effectiveness. For example, nutritional supplements have been shown to significantly decrease the risk of fatal myocardial infarctions, decrease the risk of antibiotic associated diarrhoea, treat insomnia in the elderly, benefit osteoarthritis and rheumatoid arthritis, increase bone density in postmenopausal osteoporosis and reduce pre-eclampsia. Herbal medicine has been shown to reduce hyperlipidemia, act as an effective adjunct treatment in congestive cardiac failure, improve chronic venous insufficiency, treat functional dyspepsia, treat mild to moderate depression, improve cognitive impairment in dementia, decrease anxiety, benefit osteoarthritis and benign prostatic hyperplasia and prevent urinary tract infections. Acupuncture appears to have benefits for the relief of pain and nausea. Spinal manipulative therapy may be beneficial for the relief of episodic attacks of tension headache. There is clearly potential for

complementary medicine in the management of chronic illness, preventative care and aged care, which are identified as national research priorities. However, it is important to note that given the potential therapeutic range of complementary medicine and the economic activity associated with it, there is a substantial gap between the level of usage and the scientific evidence that supports it.

There are broader social implications in the widespread community use of complementary medicine. For example, a small degree of clinical improvement or delayed onset of dementia that may be proffered by complementary medicine would represent substantial savings to the community both in terms of quality of life years and financial cost (through reduced institutionalisation). Whilst there are noted health benefits to complementary medicine intervention, the relative cost-benefit of complementary medicine treatments are poorly studied. There is nevertheless, a clear perception by consumers and some data that suggest complementary medicine might have fewer side effects than orthodox medicine and a potential to save health costs. Preliminary evidence suggests that some complementary medicine products and services may provide a cost effective alternative to conventional treatment, particularly in key national health priority areas.

Complementary medicine research

Health research has been demonstrated to be of significant value to national growth and development in both human and financial terms by optimising Australia's capacity to address the burden of disease. Over the last five years more than $26 million has been invested in complementary medicine research in Australia. Industry contributed approximately 40% of total funds, with a further 29% from commonwealth sources and 21% from universities. A total of $2.35 million was provided for complementary medicine research by the National Health and Medical Research Council (NHMRC) - 0.1% of the $1.68 billion research funds available to the NHMRC and no funding was allocated to new complementary medicine research projects in 2004 or 2005. The Australian Research Council (ARC) contributed $1.9 million over the same period. Complementary medicine research is clearly under-funded by government in relation to the high level at which it is utilised, the size of the industry and the urgent need for evidence-based practice guidelines.

By all measures (number of grants received, degree of funding, number of complementary medicine research active staff, key complementary medicine research centres, postgraduate research students), approximately 50% of Australian complementary medicine research activity occurs in NSW. Three of the larger university designated complementary medicine research centres (albeit still moderate in size when compared to orthodox medical research centres) are located in NSW with four smaller research concentrations and numerous individual researchers. Many of the complementary medicine and related pharmaceutical companies are situated within NSW making it easier to develop the necessary links between industry, practice and research in order to foster exchange, good manufacturing practice and investment and marketing of new products. There is increasing collaboration between complementary medicine and conventional medical researchers but this needs to be strengthened. There exists a clear foundation for further capacity development - the opportunity exists for NSW to capitalise on the current situation and foster complementary medicine research as a NSW medical and health research strength.

Several factors have contributed to low levels of complementary medicine research in Australia. These include the lack of capacity and infrastructure, inadequate government funding, competition for limited resources, lack of systematic collaborative linkages between researchers and the lack of research training and expertise.

Under the current minimal funding arrangements and dispersed complementary medicine research efforts it is extremely difficult for researchers to undertake even a small fraction of the research required to strengthen the evidence for complementary medicine. Neither corporate nor competitive funding agencies have yet developed the vision or mechanism to adequately fund complementary medicine research. An appropriate solution to fund and build capacity in complementary medicine research is required.

Funding models for complementary medicine research are well established in some overseas jurisdictions. Both the UK and the US approaches, whilst on their own do not ideally lend themselves for adoption in NSW, provide some direction in the design of a NSW complementary medicine research plan.

Strategies and recommendations for NSW

We propose a complementary medicine research plan which will integrate well with the MSMR strategic medical research plan and will:

- Create a needed concentration and direction of complementary medicine research effort,
- Strengthen NSW's role as a national and regional leader in complementary medicine research,
- Create increased efficiencies through greater collaboration, economies of scale, and shared resources,
- Provide greater appeal for active participation by industry, and
- Assist to address key public health issues.

Specific recommendations to strengthen the NSW base of complementary medicine research and to assist in the development of an appropriate evidence-based complementary medicine industry include:

1. *The NSW government should provide infrastructure support to a strategic hub for NSW complementary medicine research.*

Coordination of complementary medicine research activities is the first step required to enable potential benefits in the field to be pursued and realised. Opportunities exist to improve the coordination of the research effort between complementary medicine researchers, to better identify complementary medicine research priorities, to strengthen the pathways for complementary medicine research funding, and improve success with national competitive grants.

The principal mechanism to facilitate the above is to establish a Committee for Complementary Medicine Research to oversee its development in NSW. This NSW Committee would assist to establish research platforms, encourage excellence and foster good governance in complementary medicine research. This can be initiated without the requirement of substantial infrastructure in terms of facilities, but rather represents the development of a coordinated approach. A central co-ordination or 'hub' will help optimise use of current facilities and concentrate activities that exist.

2. *The NSW government, through the newly established NSW Committee for Complementary Medicine Research, should establish collaborative teams and complementary medicine research platforms to build excellence and critical mass in NSW complementary medicine research.*

Effective applied clinical research requires strong collaborations to be developed and supported between complementary medicine clinicians and medical researchers. It requires a deliberate policy that supports a collegiate approach. The complementary medicine centres do not have the resources to develop the required networks nor have the infrastructure capacity to maintain a significant research focus or platform. A NSW based expert committee with government support would have

the capacity to build on existing networks established by the research centres in NSW, and drive and co-ordinate further collaborations. There is a need to develop mechanisms to identify and prioritise key research areas in complementary medicine, and to provide infrastructure support to stabilise capacity in complementary medicine research centres (such as post-doctoral research fellows, some physical infrastructure and/or arrangements for shared access). As part of supporting collaborations it would be appropriate to facilitate through seed funding the development of collaborative complementary medicine research proposals to be submitted for national competitive funding.

3. *Relevant departments and agencies within the NSW government (such as the MSMR, Department of Health and NSW Department of State and Regional Development) should liaise further with relevant Commonwealth agencies (such as NHMRC, ARC and Department of Industry, Tourism & Resources) to provide an ongoing quantum of research funding for complementary medicine.*

Government funding for complementary medicine research needs to be increased in order to build an effective complementary medicine research capacity in NSW and Australia, to capitalise on significant commercial opportunities and to assist in fulfilling national research priorities. Seed funding and funding for small and large grants, particularly in identified research priority areas, is necessary to address the relative lack of evidence related to complementary medicine. Fundamental mechanisms need to be facilitated and promoted within national competitive granting authorities (NHMRC, ARC) that address concerns with regards to the lack of funding opportunities to research high use complementary medicine interventions. The NSW government should advocate improving complementary medicine research funding within national and state funding bodies.

4. *Relevant NSW government agencies (such as the NSW Department of State and Regional Development) should continue to strengthen vehicles for public private partnerships in NSW complementary medicine research by leveraging Commonwealth and industry funding and requiring funding input from hub partners.*

Whilst the complementary medicine industry has provided significant research funds, additional funding from local industry should be promoted. Industry and government partnerships can be strengthened by enhancing existing programs such as the *BioFirst* and *BioBusiness* programs to support commercialisation of complementary medicine research discoveries. Further support schemes could be developed, for example, where industry jointly with government funds a research position (for example, post-doctoral research fellow) rather than a specific research project (currently required for '*Proof of Concept*' funding).

5. *The NSW government, through the newly established NSW Complementary Medicine Research Committee, should work with relevant stakeholders (government, industry and researchers) to establish priorities for complementary medicine research in Australia.*

The public health questions regarding complementary medicine can only be addressed through a well defined research agenda. It is expected this would include supporting relevant public health and health services research in priority areas such as patient safety, health economics, management of chronic disease and ageing. A key role of the Committee would be to hold an annual conference to assist in the establishment of complementary medicine research priorities (aligned with state and national research priorities) and ensure the participation and co-ordination of all relevant stakeholders including researchers, clinicians, consumer representatives and industry.

6. *The NSW government, through the newly established NSW Committee for Complementary Medicine Research, should develop mechanisms to strengthen networking and dissemination of information on complementary medicine research.*

There is a need to develop a register of researchers interested and active in the field and their areas of expertise. There is also a need to link with international, national and state centres for clinical

trials and other forms of collaboration and exchange. A website and database for Australian complementary medicine research should be developed and linked with databases available overseas. There is a need to develop minimum datasets and databases, and link with national and state health services to collect information on complementary medicine research, in addition to facilitating implementation of complementary medicine research into practice guidelines. Infrastructure and funding are required to develop and support such linkages and dissemination of information.

Initial investment

In establishing the NSW Committee for Complementary Medicine Research investment is needed to:

- Support the coordinator's role, basic administration and the annual conference,
- Provide seed funding to support priority area programs (such as preparing background evidence reviews) and research platforms (ensuring appropriate teams and infrastructure are in place), and
- Actively promote new public private partnerships (for example, by way of university based post-doctoral fellowships and research scholarships).

We recommend that a quantum of funds be allocated over the next five years to initiate and support a NSW complementary medicine research strategy. This quantum should be proportional to the size of the industry and we recommend it be set at between $500,000 and $1.5 million per annum, approximately 2-5% of the Goods and Services Tax collected from the NSW component of the complementary medicine industry. Furthermore, there is a need to facilitate and promote mechanisms within national competitive granting authorities (NHMRC, ARC) for increased and adequate funding by commonwealth agencies for the investigation of complementary medicine practice.

Australia, and NSW in particular, has enormous potential to be an international leader in evidence-based complementary medicine products and services. Australia enjoys a strong international reputation in medical research and has an internationally well respected regulatory approach to complementary medicine products. Australian medical research expertise is high and clinical trial costs are relatively low, contributing to the appeal of Australia as an important research environment particularly for Asian complementary medicine products. We see significant merit in value adding through high quality complementary medicine research undertaken in NSW. Unless a deliberate strategic approach to complementary medicine research is established in the next five years this is likely to represent a lost opportunity for NSW and Australia. There is an opportunity cost if NSW fails to participate sufficiently in complementary medicine research in lost intellectual property and commercialisation opportunities, particularly in the context of the Asian market.

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CHAPTER 1 SIZE AND VALUE OF THE COMPLEMENTARY MEDICINE INDUSTRY

1.1 Introduction

In 2003 the NSW Minister for Science and Medical Research, the Hon Frank Sartor, commissioned a review of health and medical research in NSW. This review provided an understanding of the research landscape, including an overview of NSW performance and generated recommendations for the future. The resulting report, *A Prescription for Health*, was released in 2004 and informs the development of the health and medical research plan for NSW. However, this report provided no analysis of the utilisation of complementary medicine in NSW or of its current research status. Hence, as a supplement to that report the Minister has sought to gain an understanding of the way in which complementary medicine practices are used in NSW and Australia, the current evidence base for their practice, the size and scope of the industry and the nature of relevant research activities in NSW and Australia. It is envisaged that this report will further contribute to the development of the health and medical research plan for NSW.

Complementary medicines and associated therapies have been widely used by Australians for over two decades. Complementary medicines themselves (including vitamin supplements) are now used regularly by more than 70% of the population, whilst one in four Australians use complementary medicine services each year. Growth in usage appears to be continuing. Various government responses have occurred in response to this growth, including the development of new legislation to regulate complementary medicines, the review and introduction of practitioner registration, and the establishment of key expert committees to review approaches to the management of this industry.

This report describes the size and value of the complementary medicine industry, outlines the potential role it may play in Australian healthcare, summaries the current major funding mechanisms and quantum of research funds available to complementary medicine researchers, describes the nature of this research and provides some strategic direction on strengthening the research opportunities in complementary medicine with a view to strengthening the industry and ensuring the provision of quality services.

1.2 Complementary Medicine: Scope and Definition

Complementary medicine (CM) refers to a diverse range of therapies that include chiropractic medicine, osteopathic medicine, naturopathic medicine (deriving its roots from traditional European medicine), traditional Chinese medicine, Ayurvedic medicine (the traditional medicine of the Indian sub-continent), Unandi medicine (traditional Islamic medicine) and numerous other indigenous medical systems. Within these broad discipline areas are distinct therapeutic modalities such as acupuncture, herbal medicine, massage, dietary therapy and life-style interventions.

The term *complementary medicine* is a broad term pertaining to the field in general. The term *complementary medicines* refer to the therapeutic products prescribed by CM practitioners and used by the general public. In Australia, complementary medicines are regulated by the Commonwealth Government and are defined in the *Therapeutic Goods Act 1989* (Table 1). The states and territories, as with other health professionals, regulate complementary medicine practitioners. Currently, only chiropractic and osteopathic medicine practice are regulated Australia wide and Chinese medicine practice is regulated in Victoria.

Item	Ingredient or kind of ingredient
1	an amino acid
2	charcoal
3	a choline salt
4	an essential oil
5	plant or herbal material (or a synthetically produced substitute for material of that kind), including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll
6	a homeopathic preparation
7	a micro-organism, whole or extracted, except a vaccine
8	a mineral including a mineral salt and a naturally occurring mineral
9	a mucopolysaccharide
10	non-human animal material (or a synthetically produced substitute for material of that kind) including dried material, bone and cartilage, fats and oils and other extracts of concentrates
11	a lipid, including an essential fatty acid or phospholipid
12	a substance produced by or obtained from bees, including royal jelly, bee pollen and propolis
13	a sugar, polysaccharide or carbohydrate
14	a vitamin or provitamin

Table 1.1: Complementary medicines are defined under Schedule 14 of the Commonwealth *Therapeutic Goods Act 1989* through a list of designated active ingredients that constitutes the range of complementary medicines available in Australia.

In contrast to the clear definition of complementary medicine products under the *Therapeutic Goods Act (1989)*, there is controversy over the appropriate terminology to use when defining the general field of CM. There is no precise definition and CM is usually defined in terms of what it is not, that is, CM therapies are not orthodox or conventional medicine. Terms such as natural medicine, non-conventional medicine or therapies, holistic medicine, complementary therapies, alternative medicine, unorthodox therapies, integrative medicine and traditional medicine have been used.

The National Institutes for Health (NIH) defines CM as health care practices that are not an integral part of conventional medicine. That is, "*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.*[3] 'Complementary medicine' may refer to when such health practices are used in conjunction with the dominant health system. The term 'alternative medicine' may be used to refer to health practices used in lieu of the dominant health system. Importantly, CM is a cluster term, inclusive of established public health systems (such as herbal medicine in China), ancient esoteric skills (such as meditation for health) and fashionable new modalities (such as rebirthing and biofeedback).

The boundaries between the CM domain and the dominant medical domain are not always fixed or sharp.[4] What constitutes CM varies of over time, place and culture. With time and changes in knowledge, cultural profile and activity, CM is increasingly being integrated within mainstream health. This soft definition of the CM boundary can make measurements of the use of CM over time problematic. Furthermore, as CM is heterogeneous in nature and encompasses diverse forms of therapy and belief systems, the use of some CM modalities can be increasing while others are decreasing and the overall rate of CM use will not provide a clear picture of this phenomenon.

There are currently a large number of sectors and stakeholders relevant to the CM industry including consumers, production and sale of goods, service and therapy provision, workforce and professional organizations, education and training, integration of CM in pharmaceutical and conventional health services, health insurance, and research. Each of these sectors contributes to the size and value of the industry.

Data for this report were obtained from MEDLINE and Pubmed searches; a review of relevant reports in Australia, United States, United Kingdom and the World Health Organization; and an internet search for grey literature including market research reports and annual reports from relevant organizations and professional Registration Boards. Where possible Australian data has been used but overseas literature was also accessed to identify comparative trends.

1.3 Prevalence and incidence of complementary medicine use

1.3.1 Australia

The use of complementary medicines in the Australian community is widespread and has risen significantly over the past three decades.[5,6] In 2000 it was estimated that almost one in four Australians visited a CM practitioner every year.[6] The Australian Longitudinal Survey of Women's Health, a large population based national survey of women conducted in 2002, indicated that 15-28% of women had attended a complementary medicine therapist in the last year and that rates varied with age.[7]

The 2001 National Health Survey revealed 3.5% of the population (661,400) had consulted a complementary or alternative health professional in the two weeks prior to the survey - 4.1% of females (388,700) and 2.9% of males (272,700). The majority of consultations (423,800) were for persons aged between 25 and 54 years. About 2.0% (387,900) of Australians consulted a chiropractor, 1.0% (129,800) consulted a naturopath and about 1.5% (177,300) consulted an acupuncturist, herbalist, hypnotherapist or osteopath.[8]

In 1996 it was estimated that there were 2.8 million consultations per year in traditional Chinese medicine in Australia.[5] In 2003 it was estimated that there were 1.9 million consultations per year in naturopathy and western herbal medicine in Australia.[9] Extrapolating from these figures, it is estimated that in 2005 consultations in these three CM disciplines alone will approximate 5 million visits. Furthermore, an additional 10 million consultations are estimated to occur each year in chiropractic and osteopathy.[10] Combined with other CM practices, it can be seen that this sector provides a substantial volume of health care services. In comparison there are approximately 220 million Medicare claims per year for conventional medicine.[11]

Use of CM products is even higher. In 2001, it was estimated that 70% of Australians take a CM product each year. Many of these are herbals, minerals, vitamins or dietary supplements resulting from self treatment by consumers through purchase of over the counter products without prescription from a therapist.[12] These estimates were confirmed by a national survey conducted by Cardinal Health in 2004 (n=813) which found that 74% of the population had taken one or more vitamin, mineral or nutritional supplements in the previous 12 months.[13] Both figures are higher than estimates provided by a South Australia population survey in 2000, where it was estimated that 52% of Australians used at least one non-medically prescribed complementary medicine.[6] By 2000 it was estimated Australians were spending $1.7 billion per annum, nearly four times the public contribution to all pharmaceuticals.[6] This expenditure proportional to contributions to pharmaceuticals had almost doubled since 1993.[14]

A consumer survey conducted by Mayne Health in Sydney, Melbourne and Brisbane found that between 34-50% were using multivitamins, 60% had been taking the vitamins daily and on average consumers had been taking the vitamins for 8.6 years with people in Sydney being the most frequent users.[15]

1.3.1.1 New South Wales

In 1998, 44% of a small convenience sample on the north coast of NSW reported that they visited complementary medicine practitioners.[16]

1.3.1.2 Queensland

In 2003, a survey of 171 adults in Queensland found that 36% regularly used alternative health practitioners with the most common being a naturopath.[17]

1.3.1.3 South Australia

In 1993 and 2000, two large population based surveys with samples between 1500-3000 individuals were conducted using the South Australian Health Omnibus Survey.[6, 14] These surveys made a clear distinction between self-prescribed complementary medicines and attending CM therapists. The use of at least one non-medically prescribed CM in the previous year increased from 48% to 52% between 1993 and 2000. Self treatment with vitamins was the most common CM reported. The use of complementary therapists increased from 20% to 23%, with the use of chiropractors the most frequently used therapist in both surveys. This data was extrapolated to the Australian population and is generally reported as reflective of nationwide activity.

1.3.2 Overseas

In 2002, The World Health Organization (WHO)[18-20] estimated that 80% of the world's population depends on CM, including traditional indigenous medicines, for primary health care. Populations throughout Africa, Asia and Latin America use traditional medicine and it has been fully integrated into the public health systems of China, North and South Korea and Vietnam.[20] The World Health Organization has provided estimates of CM use for the following countries: France 49%, Chile 71%, India 70%, and Colombia 40% and up to 80% in African Countries. A separate study of CM utilisation in Japan indicates it is as high as 76%.[21]

1.3.2.1 United States

In the US, nationally representative telephone surveys in 1990 (n=1539) and in 1997 (n=2055) indicated the use of at least one CM in the previous year increased from 34% in 1990 to 42% in 1997.[22] During this period the most rapidly growing therapy was herbal medicine. There was a 380% increase in herbal remedies and a 130% increase in high dose vitamins.[22] In the United States there are now more CM than conventional medical consultations in primary care, while demand for, and expenditure on, CM has doubled over the decade of the 90s.[22]

An estimate of CM use by US consumers, from a secondary analysis of the 2001 National Health survey of 30,801 adults, reports CM use to be 30%.[23] This national survey found that spiritual healing to be the most frequently used CM, followed closely by herbal medicines [23]. Another large population based survey was also conducted as part of the National Health Interview data in 2002 (n=31,044). This survey identified that 62% of adults used some form of CM in the previous 12 months. The most common of which was prayer, specifically for health reasons.[24] If prayer and the use of megavitamins are excluded then 36% are using some form of CM each year. A smaller sample of 113 Oregon family practice patients in 1996 indicated that 50% are using some form of CM.[25]

Kessler et al (2001)[26] investigated the long-term trends in conventional medicine use for three age cohorts in the US. The results demonstrated that the lifetime use of CM steadily increased with age

across the three age cohorts and concluded that the trend was likely to continue for the foreseeable future.

1.3.2.2 Canada

The Canadian national population health survey (1994-5) with a sample of 17,626 individuals found that an estimated 15% of Canadians aged 15 and over (3.3 million people) used some form of alternative health care. Chiropractic was the most common therapy used.[27] It has also been estimated that 70% of Canadians have used CM at some stage.[28]

1.3.2.3 United Kingdom

In 1999, a representative survey of 1,204 British adults reported that 20% of the sample had used a CM therapist in the previous year, with herbal medicine being the most common form of CM used.[29] A second study published in 2001 reported usage at 28%,[30] and a large consumer survey of 25,000 conducted in 2003 found that 50% of Britons had visited an alternative health practitioner such as an osteopath or acupuncturist.[31] It was estimated that 5 million people in Britain use CM each year.

1.3.2.4 Italy

A representative sample of 30,000 Italian families indicated 15.6% of the sample used CM between 1997 and 1999. It was estimated that the usage of CM has doubled since 1991. Homeopathy was the most commonly used CM by Italians.[32]

1.3.3 CM use by groups with specific chronic diseases

The use of CM by specific disease groups appears to be higher than in the general population. In the US it has been estimated that 78% of patients living with AIDs use CM compared to 40% in the general population.[3] Similar high rates of use were demonstrated in a recent study of 1,675 HIV positive men and women which found that that 63% of participants had used CM in the previous year.[33] Results of a national survey of 925 Australian HIV/AIDS patients supported this trend.[34]

CM use is also reported to be high in cancer sufferers in Australia.[35] In the United States sixty-three percent of cancer centre patients have been found to use at least one form of CM other than spiritual healing and physical therapies.[36] Another survey of a random selection of 2000 tumour registry patients found 75% had used at least one CM modality in the last 12 months.[37] Furthermore, 63% of cancer patients enrolled in pharmaceutical trials for the US National Institutes for Health had also used at least one form of CM therapy. An earlier survey conducted in 1994 in South Australia indicated 46% of children with cancer had used at least one form of complementary medicine therapy.[38] In 2001, 87% of children admitted to a major hospital in South Australia had been exposed to one alternative therapy and, extraordinarily, 17% had used six or more different CM therapies.[39]

1.4 Summary of use of CM products and therapists

Clearly a large proportion of the population, both in Australia and overseas, use CM each year. Between 50-75% of the Australian adult population use at least one CM product each year and between 15-30% visit a CM practitioner. Variations in the data are primarily due to differences in methods of data gathering, the researchers' definitions of CM, the time frame for recall, whether providers and self care therapies were included and the year of the survey. The representative South Australian surveys in 1993 and 2000 indicate an increase in use of both complementary medicines and therapists has occurred during this period. This growth trend over time is reflected in similar surveys conducted in the US by Eisenberg and other smaller studies.

1.5 Size and value of the complementary medicine industry

Precise information on the size of the complementary medicines market is not currently available. The Australia Bureau of Statistics (ABS) does not recognize a separate CM sector when compiling market data, with information dispersed among a number of ABS sectors, including food, grocery, pharmaceuticals and cosmetics. One particular difficulty is that complementary medicines are available over the counter as well as from a variety of therapists. Furthermore, because of the diversity in CM modalities, there is no one representative body that collects industry data.[40] For the purposes of this report estimates of the value of the CM industry have been calculated using sales of products obtained from manufacturers and distributors, and extrapolations from consumer surveys.

1.5.1 The Australian market for CM products

By 2000 it was estimated that Australians were spending $1,671 million on CM products and $616 million for CM therapists (extrapolated from a South Australian survey). This represents a 120% increase in expenditure for CM products and a 62% increase in expenditure for CM therapists over 7 years, accounting for inflation.[6] The overall expenditure on CM had more than doubled to $2.3 billion by 2000. This compares to $3.45 billion of government expenditure for the Australian Pharmaceutical Benefits Scheme of which $688 million was patient contributions. From this data, it was calculated that in 2000, the public paid almost four times as much on CM therapies as its contribution to pharmaceuticals.

Estimates of the size of the market and sale trends can also be obtained from pharmacy sales. The growth in pharmacy sales of dietary supplements including herbal, vitamins and minerals and other supplements such has fish oils have steadily increased since 2000.[41] Whilst there was a slight drop in the sales of herbal medicines and dietary supplements after the Pan Pharmaceuticals recall, other items such as vitamins, minerals and other supplements were maintained or increased slightly.[41] Most argue that setbacks in CM production (such as the collapse of Pan Pharmaceuticals) are likely to have a minimal impact on the trend of increasing sales of such products.[42] Pharmacy sales of dietary supplements were estimated to have increased by 10.4% in the 12 months to December 2002.[40, 43] Confirming these rises, sales by Blackmores Ltd were reported as having increased by 6.5% in 2002 compared with the previous 12 months[44] and by 15.1% in the first quarter of 2005[45] Mayne Groups' nutraceuticals sales for July-December 2002 rose by 13.3% compared to the corresponding period in 2001, and AZTEC information services estimate there was an overall increase in nutraceuticals of 8.5% in 2002.[15, 46] Finally, Blackmores' estimate of the total market size, excluding practitioner sales of CM products and sales of raw herbal medicines (which includes the whole Chinese medicine sales area) sits at approximately $1 billion per annum with a growth rate of 10%.[47]

CM products are also sold through grocery stores. In 2004, $350 million was spent on vitamins, minerals, dietary supplements and herbals in grocery stores. Mayne[15] estimated a 25% growth in grocery sales and 7% rise in pharmacy sales of vitamins, despite pharmacy having a 64% market share for these products and grocery having a 36% share.

The majority of CM producers are small to medium scale organizations with only three organizations turning over more than $50 million per year and most are not listed on the stock exchange.[12] There are nine sizable companies which primarily market CM products listed on the stock exchange. Six of these companies are recent additions and several are in the top 100 performing companies listed on the stock exchange. Only three of these companies produce solely CM products. Major distributors of pharmaceuticals in Australia who also distribute CM products are not included. An estimated 20% of Australian CM production is exported.[48]

1.5.2 Size of the CM workforce in Australia

The total CM workforce includes therapists such as naturopaths, chiropractors, osteopaths, TCM practitioners, herbalists, as well as practitioners of conventional medicine such as nurses and medical practitioners who use CM in conjunction with orthodox therapy.

In 1996 the Census of Population and Housing, recorded 1,909 naturopaths, 1,710 chiropractors, 464 acupuncturists, 259 osteopaths, and 352 natural therapists. In 1999-2000, the Australian Bureau of Statistics (ABS) estimated that 3,700 individuals were employed as 'natural therapists'. This does not include conventional medical and health therapists who use CM as an adjunct to their practices. Professional associations suggest these figures under-represent the workforce.

There are over 100 professional associations representing CM practitioners.[9, 40] Not all CM practitioners belong to professional associations however, since the 2001 Goods and Services Tax Regulation, practitioners must prove professional status through government practitioner Registration or membership with recognized professional associations. The Therapeutic Goods Administration lists 41 representative practitioner associations related to Schedule 1 of the TGA Regulations.[40] Over one third of practitioners belong to more than one professional association making it more difficult to accurately estimate the CM workforce.[5, 49] For example, in 1996 there were 23 associations representing the traditional Chinese medicine (TCM) profession in Australia with no one association covering the entire profession. Membership numbers varied from 24 to 764, with half the associations having less than 150 members.[5] At the time it was estimated there were approximately 2,500 TCM practitioners in Australia.[5] A similar survey of naturopathic and western herbal medicine associations estimated 3,117 practitioners.[9, 50] The Australian Traditional Medicine Society currently claim 9,989 financial members including massage therapists (http://www.atms.com.au/).

It has been estimated that 22% of CM practitioners were educated in CM between 1980 and 1989.[49, 51] A further 50% of practitioners were educated in the following decade from 1990 to 1999, indicating that the number of practitioners more than doubled over that period. Since 2000 an additional 23% of practitioners have completed CM education. This reflects a strong growth in the CM workforce and compares to the overall growth in the health workforce in Australia where between 1996-7 and 2000-1 the number of health professionals increased by 8.2%.[52]

Data from professional Registration Boards represent another approach to estimation of CM practitioners. In Australia, chiropractors and osteopaths must be registered in all States and Territories. TCM practitioners are required to be registered only in Victoria since 2002. There are no regulations requiring naturopaths or homeopaths to be registered. Not all registered practitioners will necessarily be in practice. Also, practitioners who practise CM but are registered in other disciplines, such as medicine and nursing, do not have to register as CM practitioners. There are 3,492 chiropractors registered in Australia and approximately 825 osteopaths.[53] Since registration for TCM practitioners commenced in 2002 in Victoria there have been 984 applications, with 685 practitioners registered in 2002.[54] These data compare with the 1996 census which found there were 1,710 chiropractors, 464 acupuncturists, 259 osteopaths in Australia.

Overall, the data suggest that the CM workforce consists of at least 5-8,000 active clinicians who provide a small but significant service within the healthcare system and that the number of CM practitioners is continuing to increase.

1.5.3 Cost of Australian CM therapy services

The South Australian survey conducted in 2000 indicated 23% of the population visited a CM practitioner at least once in the previous 12 months with increasing use in acupuncture, reflexology,

aromatherapy and herbal therapists since 1993.[6, 14] The standardized expenditure for therapists increased by 62% from $309 million to $616 million between 1993 and 2000, primarily due to increase in the frequency of use rather than cost of therapy.[6, 14]

In 1996 it was estimated that traditional Chinese medicine practice in Australia resulted in approximately 2.8 million consultations annually with an estimated turnover of $84 million.[5] A similar survey in 2003 of naturopathic and western herbal medicine practitioners estimated there were 1.9 million consultations per year representing a turnover of $85 million.[9]

In Australia, since the introduction of the Medicare rebate for acupuncture in 1984, the use of acupuncture by medical practitioners has increased greatly. Reimbursements to doctors rose from $7.7 million the financial year 1984/85 to $17.7 million in the financial year 1996/7.[55] However, it is estimated that non-medical traditional Chinese medicine practitioners conduct twice as many consultations. Medicare claims cannot be made by non-medical acupuncture practitioners.[5]

Surveys indicate that the majority of CM therapists earn between $30-50,000 per year[5, 9, 49] and many work part time. Approximately 25% earn over $50,000 per year.[49]

1.5.4 Summary of the size and value of the Australian CM Industry

An accurate estimate of the total Australian market size is difficult to calculate, nevertheless, it would appear from a variety of sources that the Australian CM product market is worth between $1 and $2 billion per year. This figure excludes the cost of visits to CM practitioners. Practitioner consultation costs represent an additional $0.6 billion. Hence, a conservative estimate of the value of the Australian CM industry is $1.5-2.5 billion per annum. The market trend suggests a steady, small to moderate increase in value of the CM sector in both sales of products and practitioner services.

The Australian conventional health market as a whole has been estimated in 2002 to be worth $50 billion. This estimate includes: 44 health funds, 15,000 hospital and day surgeries, 36,000 clinicians plus the manufacturers of health products.[56] In contrast, our estimate of the worth of the Australian CM market is between $2-4.5 billion (annual turnover). This estimate is however, limited to the markets for manufacture and sale and does not take into account the full range of service facilities, education, research and insurance costs.[48]

1.5.5 The global market

It is difficult to differentiate the sale of CM products from orthodox medicine and functional confectionery (for example sweets for sore throats, energy bars and food for people with allergies). There is evidence that the global market for the manufacture and sales of CM products is large but almost impossible to accurately quantify because of the diverse range of products and marketing sectors which handle these products. The following examples are provided to give some perspective of the scale of the global market.

In 1996 the international market for CM products was estimated to be worth $US20 billion at retail level and to be expanding at 15% per year.[57] Reviewed estimates in 2000 placed the size of the global market for CM at $US31.7 billion and growing by 11% annually.[58] Other estimates for the same period are higher but base their calculations on different assumptions, definitions and methods. For example in 2001, it was estimated that worldwide value of 'over the counter' health products was worth $AUD135 billion, with vitamins worth $AUD49 billion, Chinese supplements $AUD1.2 billion and natural supplements $AUD0.8 billion.[59, 60] In 2002 the Hong Kong Trade Development Council however, estimated the world market for Chinese medicine doubled in the previous 10 years to about $US23 billion and the market for Chinese medicines to be growing by 25% each year.[61] The US market for nutritional products was also estimated in 2002 to be well over $US60

billion annually, with the sale of supplements and functional foods accounting for one third each of this market.[61] The production of raw materials for making herbal products has been recently estimated to be $US24 billion per year.[48]

In 1997 the UK expenditure for CM based on extrapolations from consumer surveys was estimated to be £1.6 billion.[62, 63] In the UK, the market for homeopathic remedies is believed to have grown by 10-15% per year throughout much of the 1990s, although the rate of increase fell to 7.3% in 2002. The rate of increase is predicted to stabilize between 6-7% in 2006-07. It is argued that the predicted dip in the rate of increase is largely the result of regulatory activity in herbal products, and of certain reports regarding safety and efficacy of the products.[64]

1.5.6 International estimates of therapist costs

Few overseas studies separate therapist costs from overall spending on CM. Extrapolations from the US national representative telephone surveys indicated a 47% increase in the number of visits to CM practitioners between the years 1990-97.[22] The number of visits increased from 427 million to 629 million visits, exceeding the total number of visits to US primary care physicians.[22] Expenditures for CM professional services were conservatively estimated at $US21.2 billion in 1997 with $US12.2 billion being paid out of pocket. This exceeds the 1997 out of pocket expenditures for all US hospitalizations. Increases in expenditure have been due to the increased proportion of people seeking CM rather than to an increase in the number of visits per person.[22]

CHAPTER 2 CRITICAL FACTORS AFFECTING COMPLEMENTARY MEDICINE UTILISATION

There are a number of critical factors affecting CM utilisation by the community and its uptake into mainstream healthcare. The most important of these is the developing scientific evidence base for CM. There is no doubt that evidence has now become a major driver of healthcare. As the evidence base mounts in favour of CM there is increased pressure by consumers and health professionals for broader recognition of CM and its integration into public health services.

A number of other factors also play an important role in the popularity and growth of CM and are key considerations in any analysis of CM utilisation. These include:

- Demographic considerations
- Beliefs and reasons associated with CM use
- CM education and training
- Regulation of CM practitioners
- Australian regulation of CM products
- Health insurance
- Degree of integration of CM.

Many of these factors contribute significantly to CM related expenditure.[48]

2.1 The scientific evidence base for complementary medicine

Evidence based medicine (EBM) is a phenomenon that has found resonance in all fields of healthcare. It advocates the case that scientific knowledge should drive practice, rather than the force of tradition. In many ways it could be described as an 'idea whose time has come'. Specifically, if an intervention does not work it should be discarded no matter how long it has been used. The first evidence based review was undertaken by Chalmers, Enkin and Keirse in 1989 and its findings led to extensive changes in the clinical practices used in pregnancy and child birth.[65] This review stimulated a wider discussion about the role of evidence in other sectors of medicine. The term EBM was coined in the 1990s and has been described by Sackett as the "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients".[66] As a foundational concept on how clinical practice should be fashioned, EBM is shaping the future of healthcare, including CM.

In considering evidence-based complementary medicine (EBCM) a number of issues are immediately apparent. Firstly, the ease of adoption of an EBCM approach may vary between CM disciplines depending on their basis in modern bioscience. The greater the role that bioscience has played in the foundational concepts of a discipline, the simpler it may be for that discipline to develop a scientific evidence base. In CM disciplines, such as traditional Chinese medicine and Ayuvedic medicine, which depend on foundational concepts that are not directly related to bioscience the development of a scientific evidence base will be a more complex undertaking. In these disciplines their core foundational concepts will also need to be tested. In contrast, nutritional supplementation which was developed in the twentieth century and relies solely on science for its foundational concepts may have an easier path to an evidence-based approach.

Secondly, it is important to recognise that the traditional knowledge in CM disciplines is not simply 'anecdotal', but a form of empirical knowledge, as it is the collective accumulation of individual observations by generations of practitioners, in some cases over hundreds of years. The empirical

body of CM knowledge has been systematically structured by practitioners working to understand cause and effect, and is quite different from anecdotal knowledge. Specific theories relating symptoms, signs, causes, interventions and outcomes are constructed based on cycles of empirical observation and refinement of theory. In sharp contrast, a collection of anecdotes is fragmented and lacks unification, experiment or the value of repeated experience. To consider the body of traditional knowledge in CM to be a collection of anecdotes is to dismiss the science of systematic observations tested by experiment.[67] To illustrate this point more rigorously, the US pharmacognosist Professor Norman Farnsworth noted in 1985 that of the 119 drugs of known structure used globally that have been derived from plants, 75% have the same use in conventional medicine as they do according to folklore claims.[68] Acceptance that CM traditional knowledge is a form of evidence is an appropriate, respectful starting point in developing a more rigorous approach to assessing the validity of this evidence. As such it can be seen that EBCM is a process of increasing the value of the traditional evidence by a systematic approach aimed at eliminating bias from the observations.

Thirdly, to date a large component of research that has been undertaken in CM has been the pharmacological investigations of specific complementary medicines. This appears on the whole to be an exploitative research approach, without an over-arching policy about the research priorities in CM. Such an approach to research risks reducing traditional systems of medicine with thousands of years of history to a few medications of potential value to conventional medicine. Such an outcome does not fulfil the promise that CM aroused within the community for a more holistic approach to healthcare. For example, St. John's Wort (*Hypericum perforatum*) has become more widely known as an antidepressant. Over thirty randomised controlled trials have been undertaken to assess this association.[69] While this plant has been used for centuries as an anxiolytic and research on its role in depression is based on its traditional use, it has also been used as a respiratory medicine, a gastrointestinal medicine and a wound healer. While these other uses have not been the subject of rigorous systematic investigation it is essential that they are not overlooked. To do so would be to dismiss the complexity of plant medicines and to fail to understand their full therapeutic potential (on different physiological aspects of the body) which is part of traditional CM practice.[70] The CM field should not be seen simply as a blue sky opportunity for new pharmaceutical drugs. There is concern that this represents what one author has referred to as "bio-medical cherry picking from the complementary field".[71] Research is required on the whole practice of CM disciplines in their community context, specifically where traditional holistic practice has meant the combination of various tools of intervention, such as herbal medicines, dietary changes and acupuncture.

2.1.1 Scientific evidence of efficacy, safety and cost effectiveness

2.1.1.1 Efficacy of complementary medicine

It is clear that increased evidence in support of the benefits of CM interventions contributes to their increased usage. A recent survey of general practitioners reported that 85% would recommend a CM product if the product claims were evidence based.[72]

There is increasing evidence that CM interventions and products provide therapeutic benefits to users. In order to assess the state of this evidence a review was undertaken for this report which is presented in full in Appendix 1 and summarised below. This review of the benefits of CM was primarily limited to an evaluation of the specific tools of practice as this currently represents the principal body of evidence. This project was constrained to an analysis of the systematic reviews of randomised controlled trials. There is a substantive body of scientific literature on the efficacy of various CM interventions. This review demonstrates that a number of the therapeutic interventions have strong evidence for their effectiveness. It is important to note that the data presented in this

review must be seen as a segment of the evidence supporting CM and is not considered to be the totality of evidence available.

The review found that there is considerable evidence that demonstrates nutritional supplements decrease the risk of fatal myocardial infarctions, decrease the risk of antibiotic induced diarrhoea, treat insomnia in the elderly, benefit osteoarthritis and rheumatoid arthritis, increase bone density in postmenopausal osteoporosis and reduce pre-eclampsia.

Western herbal medicine has shown promise in treating hyperlipidemia and as an effective adjunct treatment in congestive cardiac failure. It may improve chronic venous insufficiency, reduce functional dyspepsia, treat mild to moderate depression, improve cognitive impairment in dementia, decrease anxiety, assist in osteoarthritis and benign prostatic hyperplasia and may reduce the incidence of urinary tract infections.

Systematic reviews indicate acupuncture to be effective in the reduction of dental pain and nausea and vomiting associated with chemotherapy. Other reviews signal promising evidence in the management of lateral epicondylar pain, back pain, chronic pain, recurrent and idiopathic headaches, joint pain in osteoarthritis, fibromyalgia, treating temporomandibular joint dysfunction and Bell's palsy.

Reviews of chiropractic and osteopathy provide some evidence that spinal manipulation contributes to short-term benefit in the treatment of chronic headache and migraine and in acute uncomplicated low back pain. It appears to improve mechanical neck disorders and may assist in the treatment of non-specific back pain of less than three months duration.

It is important to recognise that these CM interventions are generally prescribed as part of an individualized whole person approach to therapy. This review evaluates mainly the individual tools of the practice of the CM professions and does not represent an evaluation of the effectiveness of these practices in totality. In addition, as per conventional medicine there is a recognised need to improve the methodological quality of clinical trials in most areas of CM research.

However, it is also clear from these reviews that CM addresses a number of national research priorities including aged care (dementia, arthritis, cardiovascular risk) and preventative health. For example, the total financial cost of dementia in Australia in 2002 was estimated at $6.6 billion – over $40,000pa per person with dementia.[73] A 2005 update of this data suggests that by 2050 the number of dementia patients will be 25% higher than projected in the 2003.[74] It is currently estimated that 1,000 new dementia patients will be diagnosed each year in Australia.[74] Severe dementia carries the highest disability weight for all illnesses, equal with severe rheumatoid arthritis and higher than that of final stage terminal cancer.[73] The burden of dementia to the Australian community is clearly substantial. No simple pharmacological options are currently available for this condition. However, preliminary clinical and strong preclinical evidence is available that supports the use of specific herbal medicines in dementia. The Cochrane Systematic Review on the use of *Ginkgo biloba* for dementia concludes that whilst there exists promising positive evidence in support of the use of *Ginkgo biloba* "…there is need for a large trial using modern methodology and permitting an intention-to-treat analysis to provide robust estimate of the size and mechanism of any treatment effects." [75]

Even a small degree of clinical improvement or delayed onset of dementia that may be proffered by CM would represent substantial savings to the community both in terms of quality of life years and financial cost (through reduced institutionalisation). Given the existence of preliminary evidence in support of the benefit of CM in dementia, and its recognition as a national research priority, it is

surprising that greater precedence has not been allocated to further research to clearly evaluate its potential benefit, if any.

2.1.1.2 Safety of complementary medicine

Assessing risks to patients is an inherently difficult problem for many reasons. In principle, exposure to any therapeutic intervention or chemical agent (natural or synthetic) exposes an individual to risk. It is axiomatic, then, that any such risk needs to be weighed by the individual against the perceived benefit of the intervention or agent.[42] This also involves the assessment of the risk of failing to perform the activity or use the agent in question. This leads to a concept of a risk-benefit ratio, in which the individual may be seen as seeking to minimize risks where possible, while gaining the maximum benefit. To our knowledge there have been no studies which have looked at the risk-benefit of CM therapy by itself or in conjunction with conventional therapy.[42]

The Australian Adverse Drug Reaction Advisory Committee received 165 reported cases of adverse reactions to complementary medicines in Australia in 2004, compared with 9,461 cases of adverse reactions to pharmaceutical medications in the same year.[76] However, it is considered that the adverse reactions to CM therapies are poorly collected and are likely to be underestimated by these ADRAC figures.[77] The Australian workforce data for western herbal medicine suggests that practitioners will experience one adverse event every 11 months of full time practice with 2.3 adverse events every 1000 consultations.[9] Adverse events for non-medical TCM practitioners in Australia are estimated to occur at a rate of 1.1 per year and for medical TCM practitioners the rate is 2.5 per year. It is calculated that there are 4.2 adverse events per every 1000 TCM consultations.[5, 77] Another survey of 1,500 western herbal and traditional Chinese medical therapists conducted in 2002 found 243 adverse reactions since 1979.[49] Fourteen percent reported adverse reactions which required a subsequent consultation with a GP for skin reactions, allergies, intestinal pain, headaches, vomiting and diarrhoea.

An Australian general practitioner survey suggests there is one adverse event arising from CM for every 125 consultations or about one per week.[50] The therapies responsible for the greatest number of adverse events were chiropractic (17.8%), herbal medicine (15.6%) naturopathy and vitamin/mineral therapy (13.2% each) and Chinese herbal medicine (7.4%). GPs attributed the adverse reactions to a number of causes including ineffective treatment, wrong diagnosis, allergic reaction and drug interactions. However, in an analysis of malpractice in the US between 1990-1996, claims against chiropractors, massage therapists and acupuncturists were generally found to occur less frequently and usually involved less severe injury than against allopathic practitioners.[78]

2.1.1.3 Cost effectiveness of complementary medicine

Only a few studies have estimated the cost-benefit of using CM therapy. For example, it has been estimated that vitamin supplementation can reduce hospital costs in the United States by almost $US20 billion.[79] Another study in Peru compared the results of patients from clinics and hospitals in Peru's National Programs in Complementary Medicine and Pan American Health organizations. Treatments were compared for selected pathologies with the same degree of severity including: moderate osteoarthritis, back pain, anxiety neuroses, asthma, migraine headache and obesity.[18] CM in general had higher efficacy and fewer side effects, greater user satisfaction and risk reduction. The overall cost effectiveness of CM was 56-63% higher than that of conventional treatments for the pathologies examined.[18]

Comprehensive lifestyle changes have also been used successfully as an alternative to coronary artery bypass. Lifestyle intervention has been found to delay surgery for three years without increased risk of heart attack, stroke or death and the savings were estimated to be $US29,500 per patient. A meta-analysis of this type of intervention concluded that a comprehensive lifestyle

program including exercise, diet, stress management and group support, is highly likely to be cost saving and extremely unlikely to be cost increasing.[3] Similar cost saving results have been found for mind body self management techniques for arthritis and chronic pain.[3, 80] Acupuncture has also been shown to reduce pain, medication and even need for surgery in osteoarthritic patients waiting for knee replacement.[81] Segal and colleagues (2004) recently estimated the cost effectiveness of glucosamine sulphate treatment for osteoarthritis to be less than 10% of the cost associated with the use of pharmacological approaches to osteoarthritis treatment.[80]

One population study by an insurance company of 2,000 people who practised meditation compared to 600,000 who did not, showed a 63% reduction in health costs over that time with 11.4 fewer hospital admissions for cardiac disease, 3.3% less for cancer and 6.7% less for mental health illness compared to non-meditators.[82] Health insurance payments decreased by up 12% in the medication group with a cost saving of $US300 million per year compared to the non-meditation group.

2.2 Other factors affecting complementary medicine utilisation

2.2.1 Demographic characteristics associated with CM use

Middle-aged individuals are currently more frequent users of CM.[22,27,29,83-85] However, an aging population with more disposable income may increase the demand for CM products and services, which are already more frequently used for chronic disease. Women of child-bearing age are currently the most frequent users of complementary medicines.[14,17,22-24,27,29,83,84,86-88] It is probable that women will transfer this behaviour to their children making the next generation greater CM users.

CM use is positively associated with increased education[14,22,23,27,29,84,87-89] and wealth.[14,86, 88] However, the reverse is true in developing countries. Although the majority of CM users pay for it out of their own pocket, individuals with health insurance are more likely to use CM than those without.[23, 86, 87, 89] There does not however, appear to be a difference in CM use between those who have a health insurance policy that reimburses for CM use and those who have insurance which does not reimburse CM.[3]

2.2.2 Beliefs and reasons associated with CM use

Several authors argue that CM use is primarily due to a pragmatic desire to improve health and treat disease, particularly when conventional medicine is perceived to be less successful.[42, 90] One Australian study found that 75% of users of traditional Chinese Medicine (TCM) were being treated for chronic complaints which had lasted longer than three months and for which the majority of users had already sought conventional medical help.[5] Their reasons for using Chinese medicine were that it was more accessible 83%, provided faster pain relief 73%, resulted in fewer side effects 62%, provided better long term assistance 43%, and was more affordable 41%. An Italian population based survey also found that 71% used CM for the treatment of pain and to improve the quality of life.[32]

Individuals with chronic diseases more frequently use CM than those without.[27, 83] It appears that these individuals are more likely to use CM in conjunction with orthodox medicine rather than replace it. For example, a secondary analysis of medical expenditure panel survey with 16,000 respondents found that high users of conventional medicine were twice as likely to use CM as lower users.[91] Similar results have been found by others.[23,86,89] The Australian Women's Longitudinal Health survey also found that users compared to non-users of CM tend to report poorer health and more symptoms and illness. Again, participants did not necessarily use CM to replace conventional medicine but in a complementary fashion.[7]

Surveys indicate that CM is used for a very broad range of conditions, with a focus on chronic diseases rather than acute care.[5, 22, 24, 25, 84, 89, 92-96] Kronenberg (2004) using a mixed race US sample found that depression, heart disease and cancer were the top three disorders for which CM was used.[96] Other research has reported that people with mental, metabolic or musculoskeletal problems were three times more likely to see CM therapist than people with other ailments.[91, 97] Similarly, an Australian study of TCM users reported that 58% of people used TCM for rheumatologic or neurological complaints.[5]

Many CM therapies are also perceived to be natural and have fewer side effects. The green movement has promoted an increasing preference for organic, natural and non-chemical treatments.[98, 99] Furthermore, CM therapy is believed to accommodate holistic values where the mind and body are seen as one,[89, 99] and increasing individualism means that more people are not prepared to accept the traditional authority of doctors.[86, 99, 100] Surveys indicate that many participants believe they will receive greater attention from CM therapists. In general, CM therapies are in keeping with self-management and notions of empowerment and control over one's own health.[89, 99] It allows the selection of health therapies in keeping with one's own belief systems.[42]

2.2.3 Complementary medicine education and training

Over the last ten years CM has become increasingly established as a core university activity both in terms of teaching and research. There are currently three universities in Australia that offer chiropractic degree programs (Macquarie University, RMIT, Murdoch University), three with osteopathic education (University of Western Sydney, RMIT, Victoria University of Technology), four that offer traditional Chinese medicine education (University of Western Sydney, University of Technology Sydney, RMIT, Victoria University of Technology) and four which offer naturopathy or herbal medicine degrees (University of Western Sydney, Southern Cross University, Newcastle University, University of South Australia). Many private colleges also deliver CM training programs, some at bachelor degree level. Some conventional medicine courses also now incorporate CM into lectures and the curriculum.[5,40,85]

A recent survey of western herbal education facilities found there were 47 institutions in Australia that train practitioners in western herbal medicine. Most of these institutions are located in the eastern states with 12 in NSW, 11 in Victoria and 10 in Queensland. Eleven universities, 4 TAFE colleges and 32 private collages offer over 104 different courses in western herbal medicine. However, the courses are taught primarily by sessional and guest lecturers with only 4.5% of staff employed full time by the institutions. This type of workforce would limit the review and improvement of courses and the opportunities to participate in research activities. Only eight staff from these courses had published in peer-reviewed journals. Three universities and one private college had participated in research activities for western herbal medicine.[101]

2.2.4 Regulation of complementary medicine practitioners

In Australia, with the exception of chiropractors and osteopaths, and TCM practitioners in Victoria, CM practitioners are largely self-regulated. For the self-regulated CM professions professional associations define practice standards. However, given the large number of professional associations in CM (see Section 1.5.2) with differing accreditation, professional standards and standards of education, the result is little consistency and potentially lack of transparency in investigations of allegations of unprofessional conduct.

It is argued that statutory regulation of CM practitioners is warranted on the basis that

- There is a level of risk comparable to other regulated professions
- There is a particular risk related to the interaction of herbal medicine and orthodox medicine

and the need for appropriate prescribing frameworks
- Existing regulatory frameworks are insufficient to protect against professional misconduct
- There are divergent professional practice standards between professional associations and an inability for associations to come to a common agreement
- There are divergent standards in education and training and a lack of movement towards common standards.

The Victorian Department of Human Services has led with the review of TCM practice and subsequent introduction of statutory regulation.[5, 102] This has been followed by current reviews of TCM practice by NSW Health, and naturopathy and western herbal medicine by the Victorian Department of Human Services.

Overseas there is a trend towards increased statutory regulation of CM practitioners and products. In the United Kingdom acupuncturists and herbal medicine practitioners are preparing for statutory regulation. That is, there are plans to establish a single herbal council to register practitioners and develop a single regulatory framework and standards. Currently osteopaths and chiropractors are regulated under statute in the UK. Other CM professionals function under a system of voluntary regulation with no legal protection of title or function and no state recognition of educational standards, but they can practice 'medicine' based on common law principles of a commitment to giving people choice about health care.

Statutory regulations in European Union member states are complex with specific legislation required to enable practitioners who are not registered medical practitioners to practice CM. However, the laws vary between member states with three general approaches – monopolizing, tolerant and mixed. *Monopolizing* systems only allow medical practitioners to deliver therapeutic healthcare. This has been adopted by countries such as Austria, Belgium, Greece, Ireland, Italy, Spain and France. For example, homeopathy and acupuncture are recognized in France but may only be practiced by medical practitioners. A *tolerant* system of regulation is found in Germany. In Germany there is no legal monopoly over medicine. Thus licensed, non-allopathic practitioners can practice healthcare and all licensed medical practitioners are allowed to use CM. There are however restrictions to medical acts, eg preparing death certificates, ordering radiology, etc. A *mixed* system occurs when only health care professionals are allowed to perform specific medical acts and violation of this is an offence. For the remaining acts individuals not qualified as a physician are tolerated, eg Denmark.

In the United States individual states are responsible for regulating health care disciplines and few health care activities are permitted without authorization. Regulation occurs through licensing, certification and registration of approved administrative bodies eg American Herbalist Guild and Botanical Medicine Academy. The four major licensed professions in the US are chiropractic, traditional Chinese medicine, naturopathy and massage.

The New Zealand laws are particularly important to Australia because of future changes relevant to the Trans Tasman acts. The New Zealand Health Practitioners' Competence Assurance Act 2003 enables practitioners unregulated prior to the commencement of the act, such as CM professionals, to apply to become registered. The act allows exclusive scope of practice, restricted activities, right to practice and an overarching framework to regulate health practitioners including a single disciplinary tribunal.

In many developed countries CM practitioners face strong opposition from the powerful orthodox medical organizations in relation to licensing and regulation.[3] Despite this, CM practitioners have fought and won battles against conventional care professional organizations due to the support of

consumers.[3] Such support has increased the funding for licensing, regulation and research for CM and increasingly legitimizes the use of CM. Although improving practice standards may make CM services more expensive initially they will also improve the credibility of complementary therapists and provide greater competition within the health care industry.

2.2.5 Australian regulation of complementary medicine products

CM products are primarily regulated by the Commonwealth government under the Australian Therapeutic Goods Act 1989. Australian CM regulations are considered to be the most well developed in the world and ensure that complementary medicines are regulated as therapeutic goods alongside pharmaceutical medicines. The Therapeutic Goods Administration (TGA) has developed a two-tiered risk-based framework for the classification of medicines on the Australian Register of Therapeutic Goods (ARTG). Complementary medicines can be either *Listed* medicines (Aust L classification) or be *Registered* medicines (Aust R classification) on the ARTG. *Listed* medicines must be composed of ingredients that have been assessed by the TGA as suitable for availability to the general public. *Listed* medicines are assessed by the TGA for quality and safety, but not for efficacy. Sponsors however, are expected to hold scientific or traditional use evidence of efficacy. *Registered* medicines are assessed by the TGA for quality, safety and efficacy and can make higher level therapeutic claims. Most complementary medicines are *Listed* medicines.[40] The Therapeutic Goods Administration has a policy of 100% cost recovery from the industry.

Complementary medicines, unlike pharmaceutical medicines, are also subject to the Goods and Services Tax. Whilst the government subsidizes pharmaceutical costs to consumers by $5 billion per year no such subsidies are available to the costs of CM products.[12]

2.2.6 Health insurance

Health insurers have embraced CM in last 30 years as a method of enticing consumers to join their funds. In Australia, CM is one of the few ways the funds can distinguish themselves from each other. As consumer demand grew for CM, so did the provisions from the health care insurers. In 1974, only one fund offered to reimburse CM use in Australia. In 2005, all funds recognise at least some CM practices. However, assessment of practitioner applications for recognition by health funds is made difficult by lack of standards in education and training, the large number of professional associations and their diverse approaches to accreditation, the lack of a coherent regulatory system or central registration or licensing body.

With the increased adoption of acupuncture by general practitioners, acupuncture also became a claimable item for general medical practitioners through government funded Medicare. Medicare claims have risen from $655,000 in 1984-85 to $960,000 in 1996-97 and 0.7% of all Medicare claims and 1.2% of patients.[55]

Similar increases in insurance coverage have occurred in the US. In 1995, 35% of employee funds offered chiropractic coverage. In 1996, 60% of health insurance organizations were planning coverage for CM. The growth in CM has been attributed to competitive pressures.[103] By 2000, 70% of employee sponsored health programs in the US covered chiropractic, 17% covered acupuncture and 12% covered massage.[3] Most insurers offer coverage in nutritional counselling, biofeedback, psychotherapy, acupuncture, preventative medicine, chiropractic, osteopathy and physical therapy. The primary motivator for covering CM was market demand. Factors which may influence insurers offering additional coverage were potential cost effectiveness, consumer interest and demonstrable clinical efficacy. The most common obstacles for incorporating CM into mainstream medicine were lack of evidence of clinical effectiveness, economics, ignorance of CM, provider competition and lack of standards.[104] There is some evidence that insurance coverage impacts on CM use.[105, 106]

2.2.7 Degree of integration of complementary medicine

The increasing importance of the CM industry to the global health system can be identified in the increase in regulation, and the increase in economic and political discourses about integration of CM with conventional medicine. The World Health Organization recommends that countries develop a national policy and regulation for the recognition, integration, equitable distribution and rational use, resource allocation and capacity building for CM. Thirteen percent of WHO member states had CM policies in 2002 and the number of countries with regulations for herbal medicines increased from 52 countries in 1994 to 64 in 2002.[18-20]

Although there are ongoing political debates between the main stakeholders of CM therapy and conventional medicine there is also growing acceptance and integration of at least some of the CM therapies within the conventional health system. This has been to some degree economically driven but it also affected by the beliefs and experience of individual medical practitioners and the sometimes reluctant acceptance of medical professional organizations of the extent of use of CM. The international Cochrane Collaboration, which evaluates medical evidence, incorporates a CM node and CM research in many systematic reviews.

There is growing evidence that patients themselves are integrating CM with orthodox medicine. Surveys indicate one half to two thirds of CM users have consulted a medical practitioner or specialist for the same condition.[9] One third indicated that consultations with medical practitioners were continuing. However, the model of integration was not optimal as communication between practitioners occurred in only 27% of cases increasing the potential for over-treating and harmful interactions.

The Australian Medical Association and Australian Medical Council acknowledge increasing use of CM and recommend a basic understanding in CM therapies by the medical profession.[107] The Australian Royal College of Nursing supports the use of CM by nurses within limits of their skill and knowledge and supports the attempt of the profession to integrate CM.[108] Postgraduate courses for medical practitioners and other health practitioners are increasingly available in tertiary institutions. There also appears to be increasing demand for such courses, with 62% of a sample of general practitioners in Western Australia reporting they would like further training in CM.[109] Eighty five percent of pharmacists also believed that further training and information on CM is required for pharmacists.[40]

There is growing acceptance of CM by medical practitioners in Australia and overseas. Studies have indicated that 30-40% of general practitioners subscribe, administer and use CM.[42, 110, 111] Fifty-nine percent of general practitioners report an increasing patient demand for CM therapies.[110] Fifty percent of general practitioners in one study had completed some form of CM training.[109] Ninety-three percent of Victorian GPs reported referring clients to CM practitioners at least once.[110, 112]

Other evidence of the growing integration includes integrated CM clinical research facilities, such as the Chinese Medicine Clinical Research Centre at Liverpool Hospital collaboratively established in 2002 between the University of Western Sydney and the South Western Sydney Area Health Service, the Natural Therapies Unit at the Royal Women's Hospital in Sydney and the ACCMER clinical research facilities in the Mater Hospital in Brisbane

There are ethical and legal issues related to the interface of complementary and conventional medicine. One of the more contentious but central concerns is that conventional medical practitioners may risk legal liability by ignoring patient use of CM. Given the widespread use of CM, frequently in conjunction with prescribed medicines, it can be argued that doctors should ask patients about their use of CM and advise patients about the efficacy and risks if such information is

available. This can however, prove difficult with the lack of standardization and regulation in the CM industry. Literature from the US suggests that most doctors have limited knowledge of CM and this is primarily determined by their beliefs about the legitimacy of such therapies.[113] Integration may also have a significant impact on the CM profession. Integration may actually mean subjugation, disintegration and marginalization of CM therapists and may fail to take into account difference and the individual nature of many CM therapies and so fundamentally alter CM practice.

Between 59-90% of general practitioners in UK, US, New Zealand, Israel, Canada and Holland refer patients to CM practitioners.[55, 83, 114-116] A review of 25 surveys of physician practices found about half believed in the efficacy of the five common CM modalities ie acupuncture, chiropractic, herbal, homeopathy and massage.[117]

In the US over 10% of hospitals and 65% of clinics offer both CM and orthodox modalities.[48] Respected organizations such as the Arthritis Foundation and American Cancer Society provide information about CM to patients and health care clinicians.[118] In 1995-96 36% of US medical schools included CM topics in curriculum this increased to 66% by 1999-2000, with most providing CM training by stand-alone courses and electives.[118] Similar increases are described in the UK with a growing trend for National Health to pay for services of CM.[62] There are also increased opportunities for CM training in the UK where the proportion of medical schools offering CM courses increased from 10% in 1995 to 40% in 1997.[18, 62]

The World Health Organization provides evidence of integration in other countries:[19, 20]

- Traditional medicine is fully integrated into the health systems of China, North and South Korea and Vietnam. For example, 95% of Chinese hospitals have units for traditional medicine and it accounts for 30-50% of total health consumption.
- In Germany, 77% of pain clinics use acupuncture
- In 2000, 72% of Japanese western style doctors used Kampo medicine (an adaptation of Chinese medicine)
- In 1993, Thailand established the National Institute of Traditional Medicines and in 1999 traditional medicine was integrated into 1,120 health centres

2.3 Summary of factors affecting the complementary medicine market

Surveys indicate that CM is used for a very broad range of conditions, with a focus on chronic disease management rather than acute care. Individuals are more likely to use CM in conjunction with conventional medicine rather than replace it. Middle-aged individuals with higher education background are currently more frequent users of CM. Furthermore, an aging population with more disposable income may increase the demand for CM products and services. Many CM therapies are also perceived to be natural and have fewer side effects.

Over the last ten years CM has become increasingly established as a core university activity both in terms of teaching and research. However, with the exception of chiropractors and osteopaths, and TCM practitioners in Victoria, CM practitioners are largely self-regulated. It is argued that statutory regulation of CM practitioners is warranted on the basis of the increasing risk exposure to the public and the inadequate existing regulatory frameworks. There is a trend overseas towards increased statutory regulation of CM practitioners and products.

With the increased adoption of acupuncture by general practitioners, acupuncture also became a claimable item for general medical practitioners through government funded Medicare. However, whilst the government subsidizes pharmaceutical costs to consumers by $5 billion per year no such subsidies are available to the costs of CM products. Health insurers have embraced CM in the last 30

years as a method of enticing consumers to join their funds. Similar expansion of insurance coverage has occurred in the US. The most common obstacles for incorporating CM into mainstream were lack of research into clinical effectiveness, economics, ignorance of CM, provider competition and lack of standards.

There is growing evidence that patients themselves are integrating CM with orthodox medicine. Surveys indicate one half to two thirds of CM users have consulted a medical practitioner or specialist for the same condition. The Australian Medical Association and Australian Medical Council acknowledge increasing use of CM and recommend a basic understanding in CM therapies by the medical profession. Eighty five percent of pharmacists also believed that further training and information on CM is required for pharmacists. Ninety-three percent of Victorian GPs reported referring clients to CM practitioners at least once. In the US over 10% of hospitals and 65% of clinics offer both CM and orthodox modalities. Similar increases are described in the UK with a growing trend for the National Health Service to pay for CM services.

Only a few studies have estimated the cost-benefit of using CM therapy. However these studies have indicated a potential for cost savings in healthcare. To our knowledge there have been no studies which have looked at the risk-benefit of CM therapy by itself or in conjunction with conventional therapy.

As the movement for evidence based medicine builds, CM will be under increasing pressure to demonstrate scientific evidence of efficacy and safety. There is increasing evidence that CM interventions and products provide some therapeutic benefits to users. As the cost effectiveness of these interventions and products is determined, there will be an increasing call on the institutions governing public health policy to integrate those interventions and products with clear evidence of efficacy, reduced side effects and significant cost benefit into mainstream healthcare delivery.

CHAPTER 3 RESEARCH CAPACITY, INFRASTRUCTURE AND FUNDING

While many forms of complementary medicine have had a long tradition of use, in some cases dating back thousands of years, formal scientific research into complementary medicine is still in its infancy. In Australia, dedicated researchers in complementary medicine only began to appear in the mid-1990s and the field has grown and developed rapidly over the past ten years. The field has come a long way over a short time. The Complementary Health Care Council of Australia (2003) suggests that Australia has enormous potential to be an international leader in CM research.[12] However, it has been argued that Australian research infrastructure for CM is not well developed in comparison with the United States and the United Kingdom.[40] Many believe that CM research funding received from the public and private sectors in Australia is limited compared to that received by orthodox medicine, with claims that government funding bodies such as the NHMRC and ARC are hesitant to fund research into CM.[12, 112] This chapter systematically examines the infrastructure and funding available for CM in Australia and, in particular, NSW for the period 2000-2005, including:

- The research funding programs and estimated level of funding for CM research available from Commonwealth departments and NSW State departments, and
- The infrastructure, research activity and research funding obtained by organizations that conduct CM research in NSW and other states, including a description of the major CM research centres in NSW and the nature and quantum of industry funding.

To date, there has been no clear estimation of the level of funding from both industry and government bodies available to CM research in Australia.[1]

3.1 Methodology

Three approaches were used to collect data on the CM infrastructure and research funding:

1. Relevant government bodies were asked to identify funding programs most relevant to CM research and identify the level of funding from each of these programs which has been allocated to CM projects over the last five years.
2. A survey was conducted of organizations that were most likely to conduct CM research, including relevant university research centres, individual researchers, private CM education facilities, relevant professional associations and 12 prominent Australian CM companies (as identified by the industry peak body and an advisory group).
3. An infrastructure review of the main university CM research centres in NSW based on website information.

Ethics approval was sought and granted through the University of Western Sydney.

3.1.1 Government agencies

The Ministry of Science and Medical Research contacted the directors of the relevant government agencies by letter to request they assist in this review. All agencies were asked to identify the number of research applications by year, the number of successful grants by year, the name of the projects, chief investigators, their research organizations, and the level of funding. Government agencies differed in their ability to systematically identify specific CM research projects, hence different search methods were used by each agency. Data were collected from the following government agencies:

- *National Health and Medical Research Council* [2]. They completed a systematic search of NHMRC databases from 1999-2004 (inclusive) using keywords: alternat*, complementary, (plus

naturopath, acupuncture, oriental, herbal) and RFCD codes: preventative medicine, nutrition and the 321300 RFCD series for complementary and alternative medicine.

- *Australian Research Council (ARC).* The ARC conducted a search of ARC databases from 1999-2004 (inclusive) using RFCD codes as per the NHMRC. The ARC databases were unable to be searched by keyword. Information on the total level of funding for health and medical research was also collated from ARC annual reports, which were available from 2002.
- *AusIndustry, Commonwealth Department of Industry, Tourism & Resources.* AusIndustry was contacted to identify potential and actual sources for funding for CM research and development activity over the last five years.
- *Department of Education Science and Training*. DEST was contacted for relevant information. Data from public reports were also reviewed.
- *NSW Department for State and Regional Development*. The DSRD was asked to identify funding and resources that have been provided to the CM industry in the last five years. A review of annual reports from 2000-2004 was also conducted.
- *NSW Health and Area Health Services*. All Area Health Services (AHS) chief executive officers in NSW were contacted to identify whether any CM research was being conducted in their area or had occurred in the last five years.

3.1.2 Researchers and research organizations

Potential Australian CM researchers were identified through a variety of strategies, including directly contacting known researchers and centres which publish in CM, contacting university faculties and schools likely to be conducting such research, contacting professional associations and private CM education organizations. Some respondents to the survey identified additional researchers working in the area. A selection of 12 prominent CM industry organisations was also contacted to determine the level of research conducted. A total sample of 104 individual researchers, centres and organisations were both faxed and emailed the survey. Non-respondents were contacted by phone or email after one week as a reminder.

The survey requested information about the:

- number of staff and students working in CM research in the centre or department in which the respondent worked
- area of expertise of staff
- number of competitive funding grants submitted over the last five years
- number of research projects which had been funded in the centre or department in the last five years
- amount of CM research funding in dollars
- funding sources
- level and type of research collaboration.

Respondents were also asked open ended questions about the:

- best strategies to capitalize and promote CM research within existing research structures,
- strategies for attracting international funding for CM research,
- improving the capacity for CM research, and
- potential for supporting future collaborative research.

A copy of the survey instrument is attached as Appendix C.

3.1.3 Infrastructure of principal NSW-based CM research centres

Research centres that had received over $1.5 million of funding from a variety of sources or had carried out more than ten research projects in the last 5 years were classified as major centres and detailed information about their infrastructure and research activities was collected from their

websites. Centres that had received at least $0.5 million were categorized as smaller centres and a summary of their research areas was obtained from their websites.

3.2 Results

3.2.1 National Health and Medical Research Council

The NHMRC specifically funds health and medical research through competitive grants and has several types of funding frameworks to which CM researchers can apply. These include:

- Development (Industry) grants: These support the development of health or medical research that has commercial potential.
- Enabling grants: Funding is available for capacity building including partnership grants to develop collaboration and research programs that build research capacity and expertise in identified priority research areas.
- Project grants: This is the NHMRC's main avenue of support for individuals and small teams of researchers undertaking biomedical, clinical, public health or health services research in Australian universities, medical schools, hospitals or other research institutions.
- People support: Provides funding to researchers at various stages of their career from novice (scholarships, new investigator grants, career development awards) to the more experienced researchers (fellowships).
- Program grants: Provides support for teams of researchers, to pursue and develop broadly based collaborative research activity and programs. Successful applicant teams have a very high record of achievement in research, and a strong case to make regarding their team record.

The NHMRC provided total funding data on medical research in general and a list of CM research applications. The abstracts of funded CM projects were examined to ensure they were correctly categorized as CM projects. Project titles were also used to determine whether non-funded CM projects were in fact relevant to CM. Projects within preventative medicine and nutrition were only included if they were directly relevant to CM.

Since 1999, the NHMRC has received 9,710 research applications of which 62 (0.6%) CM research applications were identified in the NHMRC search (see Table 3.1). The NHMRC report a total of eight CM projects had been funded during this period. This represents a success rate of 13%, significantly lower than the 25% success rate for NHMRC applications in general. Between 2000-2004 a total of $2.35 million NHMRC funding was allocated to CM research, which represents 0.1% of the estimated $1.68 billion research funds available during this period. Furthermore, no funding has been allocated to CM research by the NHMRC in either 2004 or 2005.

Year funded	2000	2001	2002	2003	2004	2005	Total
Total # of applications	823	1,793	1,650	1,754	1,798	1,892	9,710
Total # of CM applications (received in the prior year)	5	9	13	12	9	14	62
Total successful CM applications	2	1	1	4	0	0	8
Total NHMRC funding ($millions)	82.0	82.1	204.8	271.6	300.7	Not available	1,677.4
Total CM funding ($millions)	0.5	0.2	0.7	0.9	0.0	0	2.35 (2000-2005)
% of NHMRC funding allocated to CM research	0.6	0.2	0.3	0.3	0	Not available	0.1 (based on 2000-2004)

Table 3.1: NHMRC research applications and funding by year, 2000-2005

CM grant applications were examined to determine which topic areas were of most interest to NHMRC applicants. Table 3.2 provides the frequency of applications by topic area. The three most frequently researched CM areas and the most successful for receiving funding were nutritional supplements, acupuncture and western herbal medicine.

Area of research	Applications	Successful
Western and herbal medicine	13	1
Acupuncture	12	2
Nutritional supplements	10	3
General complementary medicine	10	1
Chinese herbal medicine	7	0
Socio-cultural factors in CM	4	1
Chiropractic	2	0
Hypnosis	1	0
Yoga	1	0
Massage/reiki	1	0

Table 3.2: Research area of NHMRC applications, 2000-2005

The NHMRC has recently allocated priority research funds to CM research. In response to the Expert Committee on Complementary Medicines in the Health System review,[40] the NHMRC, in collaboration with the Health Services Improvement Division (HSID) of the Department of Health and Ageing, has called for applications for a targeted research program to determine the efficacy and cost effectiveness of glucosamine sulphate (a natural therapy used to treat pain and disease progression associated with osteoarthritis) compared with other treatments. The HSID has provided $450,000 from the "Better Arthritis Care" budget to fund this research, and the NHRMC is responsible for managing the peer review process.[119]

3.2.2 Australian Research Council

The ARC fund research related to Australian research priorities, one of which is promoting and maintaining good health. Health and medical researchers can apply for ARC funding as long as the project is not clinically related in which case they are directed towards NHMRC funding programs. The ARC offers the following funding programs:

- Federation Fellowships: Up to 125 Federation Fellowships with a standard tenure of five years are available. The aim of the fellowships is to attract and retain leading Australian and international researchers to undertake research which will expand Australia's knowledge base and research capability and is of national benefit to Australia.
- Discovery Program: This program, consisting of project grants and fellowships, emphasizes the need for collaboration, and the development of capacity-building partnerships to work on a cohesive research program that will make a major contribution to generating knowledge.
- Linkage Program: This consists of project grants, fellowships and infrastructure grants to support research and development projects that aim to encourage and develop long-term strategic research alliances between higher education institutions and industry. Proposals must contain an industry contribution and therefore be linked with actual or potential users of research outcomes.
- Centres & Networks Funding: The ARC has established the Centres of Excellence program to create the scale and focus necessary to maintain and develop Australia's international standing in Australia's areas of research priority.
- Special Research Initiatives: The ARC in consultation with a range of relevant stakeholders may identify Special Research Initiatives.

The ARC provided a list of projects with relevant RFCD codes that had been funded since 2000 (application year 1999). The list was reviewed and any project not related to CM was deleted. It was not possible to estimate the success rate of CM research applications to the ARC as the total number of unsuccessful applications related to CM could not be estimated. According to the ARC only one CM research project received ARC funding during the period 2000-2004, representing $227,967 of funding. This equates to 0.04% of total ARC funding or 0.65% of ARC health related funding in 2004 alone (see Table 3.3).[1]

[1] However, CM researchers reported substantially more grants received from the ARC than those identified through the ARC database searches (see Section 3.3.3).

Year funded	2000	2001	2002	2003	2004	TOTAL
Total # of applications	4,655	5,220	5,326	6,122	5,547	32,190
Total # of health research applications	322	182	170	174	229	1,077
Total # of successful health research applications	73	44	52	47	65	281
% successful ARC health applications	22	24	31	27	28	26
Total # of successful CM applications	0	0	0	0	1	1
Total ARC funding ($millions)	228	117.5	393	442.7	639.3	1,820.5
Total ARC funding for health research ($millions)	Not available	Not available	15.6	10.7	35.1	61.4
Total funding for CM research ($millions)	0	0	0	0	0.2	0.2
% of ARC health funding allocated to CM research	-	-	0	0	0.04%	-

Table 3.3: ARC research applications and funding for 2000-2004

3.2.3 CM funding success for ARC and NHMRC funds by State

According to the NHMRC and ARC data NSW received 26% of the $2.6 million of funding allocated to CM research by the ARC and NHMRC (see Table 3.4). This compares with South Australia, which received 59% of the funding and WA which received 15% of the funding.

STATE		NHMRC	ARC	TOTAL	% CM funding received by States
NSW	# successful	1	1	2	
	Funding	$440,250	$227,967	$668,217	26%
VIC	# successful	0	0	0	
	Funding	0	0	0	0
QLD	# successful	0	0	0	
	Funding	0	0	0	0
SA	# successful	6	0	5	
	Funding	$1,516,830	0	$1,516,822	59%
WA	# successful	1	0	1	
	Funding	$391,365	0	$391,365	15%
TAS	# successful	0	0	0	
	Funding	0	0	0	0
TOTAL		$2,348,445	$227,967	$2,576,412	

Table 3.4: CM research funding by state and funding source 2000-2004

3.2.4 AusIndustry

AusIndustry provides a range of programs that are designed to assist Australian businesses to conduct research and development. These include:

- Biotechnology Innovation Fund (BIF). This $40 million scheme helps biotechnology companies move projects beyond the research stage to early commercialization. It builds upon the Commercial Ready program and links to the R & D Tax Concession and COMET programs, as well as relevant development programs at a state level. BIF can fund up to $250,000 or 50% of the project's expenditure.
- Commercial Ready. This program aims to stimulate greater innovation and productivity growth in the private sector by providing around $200 million each year in competitive grants to small and medium-sized businesses. Grants range from $50,000 up to a limit of $5 million over three years.
- Commercializing Emerging Technologies (COMET). This assistance is given to early growth stage companies and spin off companies from private or public research institutions. The grant value is $56-64,000 and up to 80% of eligible expenditure. It provides financial assistance for businesses and advice such as business planning, export strategies, management skills, intellectual property, and establishing markets.
- Pharmaceuticals Partnerships Program. This program aims to increase high quality pharmaceutical R&D activity in Australia. Participating companies will receive thirty cents for each additional dollar they spend on eligible R&D in Australia up to a maximum grant amount of $10 million.
- R&D Tax Concession. This is a broad-based tax concession that allows companies to deduct up to 125% of qualifying expenditure incurred on R&D activities when lodging their corporate tax return. It can only be claimed for systematic, investigative and experimental activities. A 175% Incremental (Premium) Tax Concession and R&D Tax Offset are also available in certain circumstances.
- Innovation Investment Fund. Pooled development funds are designed to promote the commercialization of Australian research and development through the injection of venture capital.

AusIndustry was unable to provide specific data. However, publications available on the web provided project titles of successful applications for the most relevant Biotechnology Innovation Fund (BIF) programs. This permitted an analysis of the level of funding for CM in this program only. Eleven CM projects were funded through the BIF program, with an average level of funding for each project of $250,000 (see Table 3.5). Over the last five years a total of $2.7 million has been allocated to CM through the BIF program, representing approximately 8% of total BIF funding.

	2001	**2002**	**2003**	**2004**	**Total**
Total BIF expenditure ($millions)	6.7	5.5	9.1	11.8	33.1
Number of CM projects	1	0	5	5	11
BIF funding for CM ($millions)	0.2	0	1.2	1.25	2.7
% BIF funding available to CM	4	0	13	11	8

Table 3.5: BIF funding for CM research, 2001-2004

It is unclear how much funding has been allocated to CM through the Commercial Ready and COMET programs. These programs have been available since 2003 and at least one company developing CM products from seaweed was identified as having received $894,237 through the COMET program. Information on the number of CM companies that request R & D Tax Concessions was not available nor could it be determined whether any CM companies had received funding from the Pharmaceutical Partnerships Program. No venture capital funds were allocated to CM industries through AusIndustry programs.

3.2.5 Department of Education Science and Training

The Department of Education, Science and Training (DEST) provides funding to research though a number of funding frameworks including block grants to universities and competitive grant programs such as the Cooperative Research Centres program and International Science Linkages program. None of these programs are specific to health or medicine and there is a broad base of research competition for these programs. The DEST funded programs include:

- Research Infrastructure Block Grants (RIBG), Institutional Grants Scheme (IGS), Research Training Scheme (RTS). DEST allocates grants to publicly funded universities on the basis of an index which measures institutional success in obtaining competitively awarded research funding and in research training and performance. Allocation of these funds is then up to individual institutions. It is presumed some of these funds are allocated to CM research where universities have relevant designated research concentrations.
- Cooperative Research Centres. This program emphasizes the importance of collaborative arrangements to maximize the benefits of research through an enhanced process of utilization, commercialization and technology transfer. The CRC program currently contributes approximately $145 million a year to Centres. Over the past 12 years, participants have committed more than $7 billion (cash and in-kind) to CRCs. There are 69 CRCs operating in 6 sectors: environment, agriculture, information and communications technology, mining, medical science and technology and manufacturing.
- International Science Linkages (ISL). This program aims to assist Australian researchers to increase their participation in international scientific research. The ISL comprises three components: Competitive Grants, Australia-China Special Fund for S&T Cooperation, French Australian Science and Technology Program.

DEST were unable to provide detailed information about the level of funding provided to support CM research. DEST could not identify any research grants directly related to CM in the last five years. However, DEST has funded two CRCs that are marginally related to CM research in the last five years, the CRC for Bioproducts and the Grain Foods CRC.

The Cooperative Research Centre for Bioproducts had a focus on developing commercially valuable materials produced by plants and other living organisms, such as natural colours, complementary medicines, nutraceuticals, pharmaceutical intermediates and biopolymers. Its objective was to establish new industries based on these novel bioproducts and bioprocesses, and to improve the efficiency and profitability of existing industries involved in the production and use of bioproducts. The CRC for Bioproducts was funded for 7 years in 1999 for a total amount of $48.8 million.

The Grain Foods CRC aims to develop and commercialise high value grains and grain food products, new ingredients, nutraceutical products and innovative processing and manufacturing technologies. The Grain Foods CRC was funded for 7 years in 2003 with $24 million in DEST funds or a total of $94 million including industry funds.[120]

The Australian Centre for Complementary Medicine Education and Research (ACCMER) has been involved with the Grain Foods CRC through its core partner Southern Cross University (see Section 3.3.8.3). ACCMER has worked on one project involving grain allergy however, to date has not worked with the CRC on nutraceutical development.

Information on successful grants within the International Science Linkages (ISL) program was unavailable, although Australia-China Special Fund for S&T Cooperation may be particularly relevant to traditional Chinese medicine research and the Centre for Complementary Medicine Research (CompleMED) at the University or Western Sydney (see Section 3.3.8.1) obtained similar

funding through a one-off DEST initiative in 2003 – the China Higher Education Strategic Initiative (CHESI) scheme.

The Commonwealth Scientific and Industrial Research Organization (CSIRO) is Australia's national science agency. It carries out research and development in focused, leading edge, international scientific research and technology; and increased strategic alliances between Australian and overseas researchers. Several areas in the CSIRO have potential to contribute to CM research. The CSIRO was contacted to determine whether CM related research was being conducted. The CSIRO has several departments which have the potential to be relevant to CM research, including Health Sciences and Nutrition, Preventative Health and Molecular Science. Health Sciences and Nutrition did not perceive they were working in the area of CM, although much of their work related to functional foods, including dietary and lifestyle strategies for the control of obesity and obesity related conditions. The Preventative Health department was unable to respond within the time frame provided. The Molecular Science department is collaborating on a project for medicinal herbs related to cardiovascular disease.

3.2.6 NSW Department of State and Regional Development

The NSW Department of State and Regional Development (DSRD) has several development programs:

- BioFirst awards are designed to enhance biotechnology research in NSW by attracting leading biotechnology researchers to NSW.
- The BioBusiness program aims to close the gap between basic research and commercialization. The DSRD funds businesses that meet the BioBusiness program participation criteria on a dollar-for-dollar basis. It provides financial assistance for Non-Research Establishment costs and the High Growth Business support to a maximum combined total of $75,000.
- The Proof of Concept program is designed to complement the Commonwealth Government's Biotechnology Innovation Fund (BIF) which aims to increase the rate of commercialization by reducing the cost of demonstrating 'proof of concept' for new biotech initiatives. The NSW grant offers up to 15% of the BIF recipient's total eligible project expenditure to a maximum of $50,000 over the project period.
- The Professional Leadership and Development program is working with third party providers to deliver professional development programs that focus on both start-ups and established biotech businesses.
- The Australian Technology Showcase (ATS) program promotes leading-edge Australian technologies, and supports and companies behind them. Export grants up to $20,000 are available to undertake market visits, participate in trade fairs and related activities, protect IP, develop export-related promotional material and for export/business improvement planning.
- The New Export Opportunities Program assists trade missions and market visits overseas, targets high potential and emerging markets for NSW goods and services. Assistance is provided with business matching, appointments and other in-market services, preparation of pre-approved, specialized marketing materials, freight on non-commercial quantities of samples, and interpreter services.

The DSRD were only able to provide some of the relevant information on CM funded projects. Two CM projects for Proof of Concept were awarded a total of $200,000 in the five years since 2000. The DSRD also supported a trade mission and market visit between NSW CM researchers and Taiwanese traditional Chinese medicine industries to explore new linkages, including opportunities for clinical trials in NSW CM centres and new CM export markets. Several CM industries have been marketed through the Australian Technology Showcase including Novogen Ltd, Ultraceuticals, Sunscreen technologies, and VRI Biomedical Ltd, which have developed new natural based products. Data related to CM funding were not available for the remaining DSRD programs.

3.2.7 NSW Department of Health and Area Health Services

The NSW Area Health Services (AHS) are undergoing restructuring and the majority were unable to respond to the request for information within the timeframe for this report. The few that did respond reported that no systematic information was available on CM research that is conducted within the area health service. Other sources of information on AHS research funding in NSW were sought from the literature available on health research funding in NSW.[121]

Three AHS's responded to the review and each identified between one and three researchers that might be working in CM. However, they were unable to provide details of the research topic or funding source. The researchers identified by the AHS were sent a survey to detail their work in CM. Personal communication with the researchers indicated that research funding was not provided by the AHS, although AHS's provided in kind support, such as the facilities in which the research was conducted.

NSW Health provide research infrastructure funding of approximately $20 million per annum. However, none of this has gone to any CM organization.[122] NSW Health also administers a Research and Training program through the AHS. It includes in-kind support (infrastructure, staff and services) and limited funds for the purchase of research equipment. No funds were known to be allocated to CM research.

3.3 Survey of CM researchers and centres

The survey instrument (see Appendix C) was sent out 104 potential CM researchers or/and research centres. It is possible that some CM researchers were not included in the survey as they work alone or have poor networks and links with the remainder of the Australian CM research community. Furthermore, the time frame (due to Ministerial constraints) for responding to the survey was extremely brief and fell during a period when the majority of Australian academics take annual leave. This may have limited the numbers of CM researchers who were able to respond to the survey in time.

Individuals and centres were asked to record all research projects that had been funded and all research related staff in their unit over the last five years. An inability to collect this information in the specified time frame may have resulted in incomplete responses for a small number of organizations. It is, however, unlikely that major grants were missed. Some CM researchers were reticent about reporting current research projects because of commercial and intellectual property issues and therefore provided only limited information about the area of research.

Where possible the number of research staff, number of students, number of projects and level of research funding was calculated for the each State. Research themes, comments about infrastructure, current funding programs, capacity in CM research, research priorities, research collaboration and industry participation in research were obtained from the responses to the open ended questions.

3.3.1 Infrastructure for CM research

In response to the survey twenty-seven centres and individuals (referred to hereafter as 'units') identified they performed CM research. All major groups with a reputation for CM research in Australia known to the investigators responded to the survey. No private education organization reported any significant research activities, although several stated they were interested in getting involved in such activities in the future. Only one of the professional associations had provided

small amounts of funding to support research ($2,000 per year), but none reported having collaborated on research projects.

Of the 27 units that had conducted CM research, 48% (13) were NSW-based, 8 in Victoria, with 1-3 units in each of the remaining States (see Table 3.6). This suggests that there is greater level of infrastructure for CM research in NSW and Victoria compared to other States.

The respondents reported that funding from competitive applications was generally not successful and more research funding came from non-competitive sources, most notably industry (see Table 3.6). NSW researchers have the highest rate of submissions for competitive funding over the last five years, with 56% of the CM research applications for competitive grants. Victoria and SA have been increasing the number of competitive research applications over the period examined. In 2005, Victoria submitted 17 applications for competitive funding, 50% of all applications.

According to CM researchers NSW has the greatest number of funded projects with 104 (50%) in total, followed by Victoria with 55 projects (26%). NSW had the highest level of funding at $11.8 million or 51% of the total funding. Victoria had the second highest level of funding during this period ($7.5 million, 33%) (see Table 3.6 and Figure 3.1).

Category	NSW	QLD	SA	VIC	WA	Total	% NSW
CM units	13	3	2	8	1	27	48
CM researchers	86	10	9	32	4	141	61
Research student	81	5	9	36	4	135	60
Student scholarships	20	2	1	14	0	37	54
Research submissions for competitive funding							
2000	11	1	2	6	9	29	38
2001	21	0	1	7	0	29	68
2002	21	1	1	8	0	31	68
2003	21	2	2	9	3	37	57
2004	25	1	4	13	0	43	58
2005	11	1	5	17	0	34	32
Total	**118**	**6**	**15**	**60**	**12**	**211**	**56**
Funded research projects							
2000	9	1	2	9	10	31	29
2001	7	0	0	12	0	19	37
2002	25	5	0	9	0	39	64
2003	20	3	2	12	3	40	50
2004	29	13	5	12	0	59	49
2005	14	2	4	1	0	21	67
Total	**104**	**24**	**13**	**55**	**13**	**209**	**50**
Total funding ($millions)	**11.8**	**1.7**	**0.7**	**7.5**	**1.3**	**23**	**51**

Table 3.6: Infrastructure and research activity by State as reported by CM researchers

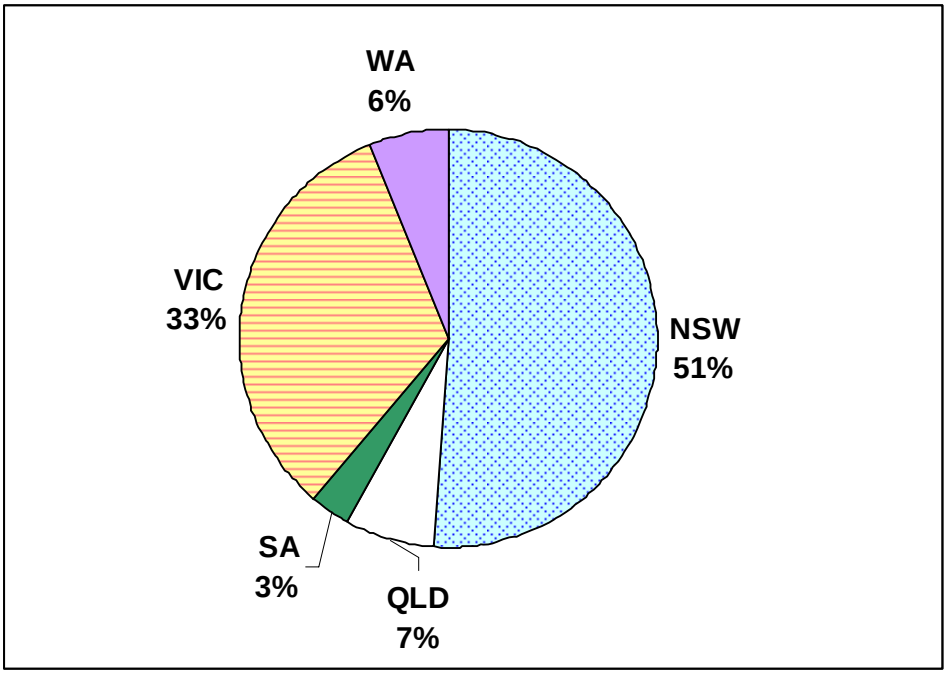

Figure 3.1: Research quantum received by State, 2000-2005

Sixteen units reported having specific laboratories and equipment related to their research in CM. NSW is well placed with specialist facilities and equipment for CM research (Table 3.7). However, one NSW participant reported that research was not being carried out because of absence of funding for required equipment and facilities.

State	Units with CM laboratories	Type of laboratories
NSW	8 (1 shared with unit in QLD)	Toxicology, biochemistry lab capable of biochemical, microbiological and cell culture, human nutrition laboratory, clinical trials, analytical chemistry, microbiology lab.
Victoria	5	Psychophysiology laboratory, vascular and hormone laboratory for tissue culture, animal research facilities, toxicology, biochemical lab, herbal identification lab, herbal plantation sites, DNA fingerprinting and tissue culture, clinical trials.
QLD	1 shared with unit in NSW	Toxicology, biochemistry lab capable of biochemical, microbiological and cell culture
SA	1	Facilities for studying herb drug interactions
WA	1	Microbiology lab for antiviral, antifungal, antibacterial testing

Table 3.7: CM research facilities by State

3.3.2 Research expertise and capacity

NSW units reported having a total of 86 researchers working in the area of CM research representing an estimated 61% of the CM research staff in Australia. Victoria had 32 research staff (see Table 3.6, Fig 3.2). These figures suggest that NSW has the greatest capacity for CM research in the future.

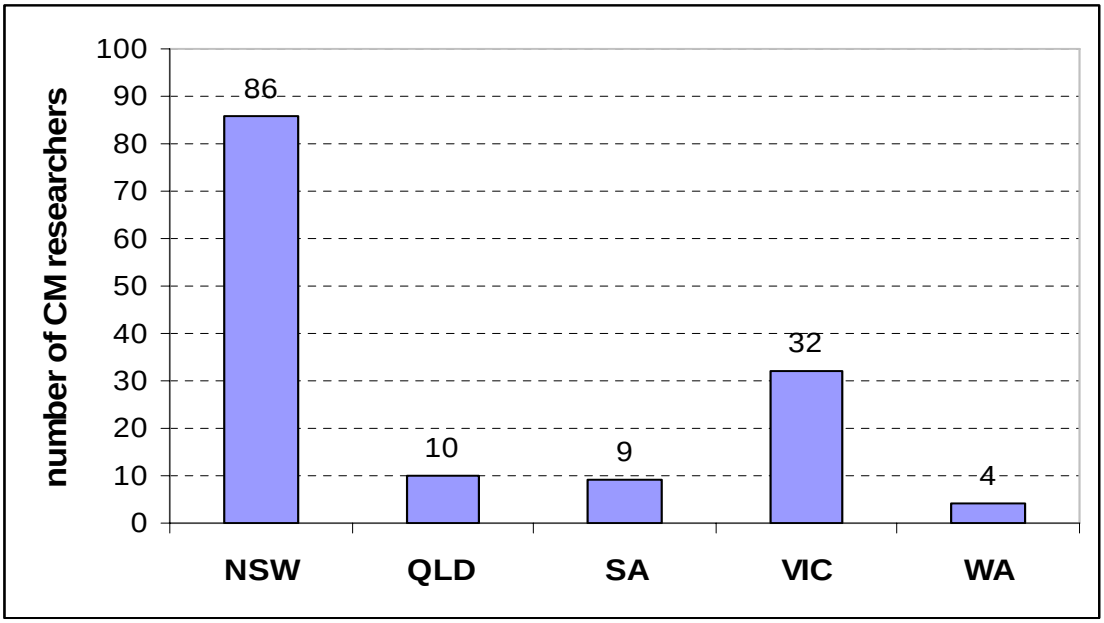

Figure 3.2: CM researchers by State

The number of research staff in CM research units ranged between 1 and 11 with most having two to three researchers. Centres with larger numbers of research staff, reported having researchers who worked on a part time basis or only contributed a small proportion of their time to CM research (5-50%). This suggests that there is the expertise available to expand capacity in the near future. Many of the units reported having research staff with expertise other than CM, for example, in medicine, neuroscience, pharmacology, physiology, microbiology, biochemistry, engineering and chemistry.

The responding units reported having 135 research students, of which 98 (72%) are at PhD level. NSW units have 81 postgraduate research students representing an estimated 60% of CM research students in Australia (see Table 3.6, Figure 3.3). Approximately 27% of students have scholarships. Of the 37 student scholarships 15 (40%) were Australian government postgraduate scholarships, 13 (35%) were university scholarships, 7 (19%) were from industry and 2 (5%) were funded by the NHMRC.

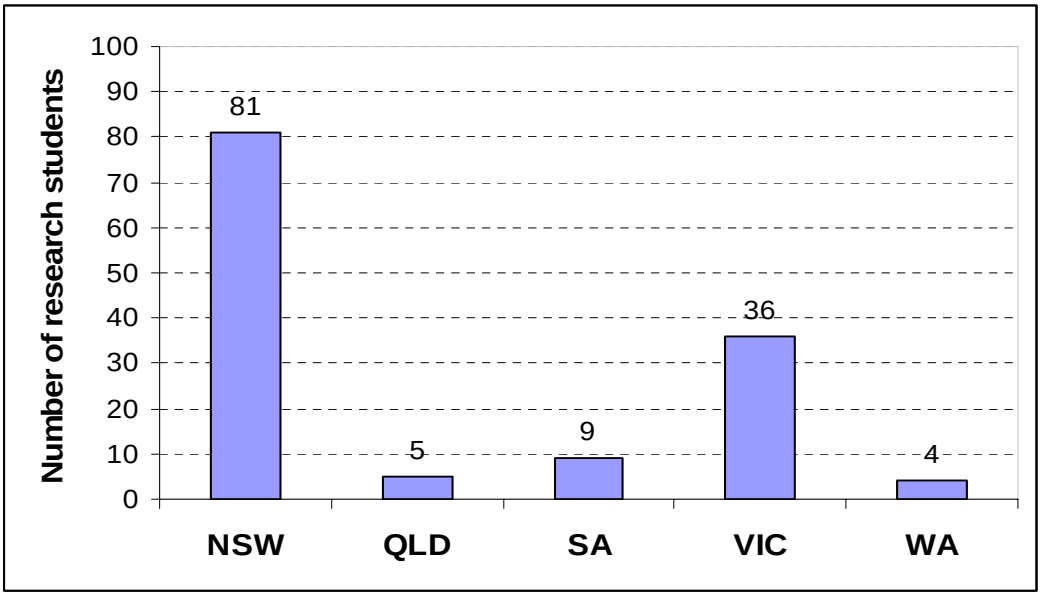

Figure 3.3: CM postgraduate research students by State

Survey respondents believed Australia had significant potential to expand its activities in the area of CM research. Comments by respondents suggest that:

"Australia has a clear advantage over Europe and the US in terms of value for the dollar and concentration of expertise that should be attractive to overseas companies interested in having CM products researched. (Australia also has) a relatively active field of CM researchers. There is good potential for developing links with China and other developed countries."

While respondents in general believed the demand for CM research was increasing, their capacity to respond to this demand was limited due to the shortage of funding, resources and skills readily available to them. Some participants reported having to reject research projects from industry because of the one-off nature of such projects and staff already being committed to other projects.

"We currently have 12 research students with more coming all the time. We are running into the problem of not having enough supervisors for the projects. Our department would benefit greatly from some facilitated access to funding, other research academics and mentoring and exchange programs."

Barriers to increasing research capacity were also identified in the responses to open ended questions on the survey. Several respondents argued that there was a need for stronger regulatory frameworks in both CM marketing and the education of practitioners to promote the need for and use of research. It was argued that increased regulation of CM products both in Australia and overseas will increase the demand for research into the standardization, quality, efficacy and safety of products. Such regulation and evidence is required because of the large numbers of CM users and possible risks associated with the product itself or the combined use with other medicines.

Training in research methods and the development of research methodologies appropriate for CM research was perceived to be particularly important for capacity building by some respondents. It was recommended that workshops to develop advanced research skills be implemented particularly in the area of research design and proposal development. The development of leadership skills in more experienced researchers was also necessary to provide a good foundation for the development of CM research capacity.

Respondents also suggested research subjects be incorporated in the CM undergraduate curriculum as a standard for practitioner registration. This would increase not only research skills and appreciation and knowledge of research evidence but also increase the use of evidence-based practice. It was recommended that CM subjects and evidence be part of the medical curriculum to increase the acceptance and knowledge of effective CM treatments but also to promote a greater willingness to collaborate in CM research.

3.3.3 Industry involvement in CM research

Of the twelve major CM companies to whom the survey was sent, six indicated that they had contributed to research but one was unable to provide details of the funding within the time constraint for the report. These companies estimated that they had contributed a total of $2.8 million to research funding and infrastructure in the last five years. Companies varied significantly in the level and type of funding, with larger companies conducting more in-house research, commissioning more external research and funding research positions in university research units. Smaller companies tended to partially fund projects or provide in-kind support by supplying products to be tested. Many of the industry organizations reported that they primarily synthesize research that is currently available in Australia and overseas and conduct market research. Nevertheless, several industry respondents described a willingness to participate in and contribute to CM research in Australia. Three companies had received grants from state and Commonwealth government to support research - one company was a partner in an ARC industry grant and one a co-investigator on an NHMRC grant.

Many of the industry respondents reported a lack of knowledge about the NHMRC and ARC process and typically sought funds from DSRD and AusIndustry. It was recommended that the NHMRC, TGA, state health departments and DEST be lobbied to provide adequate funding for CM research and development. One researcher suggested that biotechnology forums would be an important strategy to get more international industry involvement but that such forums are expensive when the major targets are the US and Europe.

While several respondents reported that there was a need for increased private funding for *in vitro* studies and clinical trials, the difficulties confronting industry groups who contribute to research was also identified. For example, "*any intellectual property advantage is short term and the costs of research are large relative to potential profits gained by industry*". Many of the smaller CM industry organizations who responded to the survey did not have the resources to fund full-scale trials although they were willing to contribute smaller amounts of funding and in kind assistance.

Another comment described the frustration of industry *"Industry is seen by some researchers as cash cows and there appears to be different rates for work undertaken for industry versus that for other academics. This will lead to a lot of one off work. NHMRC funding is notoriously difficult to access and ARC funding is based purely on scientific benefit rather than benefit to industry. AusIndustry funding is difficult to obtain as our industry is small in comparison to other industries and as such the commercial benefits are difficult to justify. In summary the existing grant structure does not work."*

3.3.4 Total research activity and research funding

It is estimated that academic and industry researchers have carried out 252 CM research projects during 2000-2004 with a combined total funding of $26.35 million (see Table 3.8). Industry contributed the greatest proportion of funding to CM research at $10.4 million or approximately 40% of funds. CM researchers commented that a significant proportion of industry funding came from overseas (see Figure 3.4). Approximately 33% of funding came from competitive funding bodies and government departments. The next highest category of research funders were universities (21%) followed by philanthropic and non-government organizations (6.5%) (see Table

3.8). At present CM research is carried out primarily in universities with a very small amount carried out in privately owned schools, or by national professional bodies representing practitioners and industry.

All respondents believed that current funding for CM was insufficient given the degree of use by the Australian population and increased regulatory pressures to demonstrate efficacy and safety. They recommended that increased funding be allocated to CM research. They believed that inadequate funding was provided by the NHMRC. *"Most work is currently commercial and confidential for specific clients. The pool of funds (state and federal) is small for infrastructure and generic research for CM."*

Source	Number of projects	Research quantum ($millions)	Percentage of total quantum
NHMRC	7	2.35*	8.9
ARC	8	1.9*	7.2
Other federal eg DEST, AusIndustry	20	3.4	12.9
State Govt bodies	15	1.0	3.8
Industry	132	10.4	39.5
NGO/charity	17	1.7	6.5
University/private college	53	5.6	21.2
Total	**252**	**26.35**	**100**

Table 3.8: Funding reported by CM researchers, government agencies and industry from all sources, 2000-2004. (*CM researchers reported only $1.8 million of the $2.35 million CM research funds identified by the NHMRC. CM researchers reported $1.9 million compared to $0.2 million CM research funds identified by the ARC. The higher figure has been used for calculations in each case.)

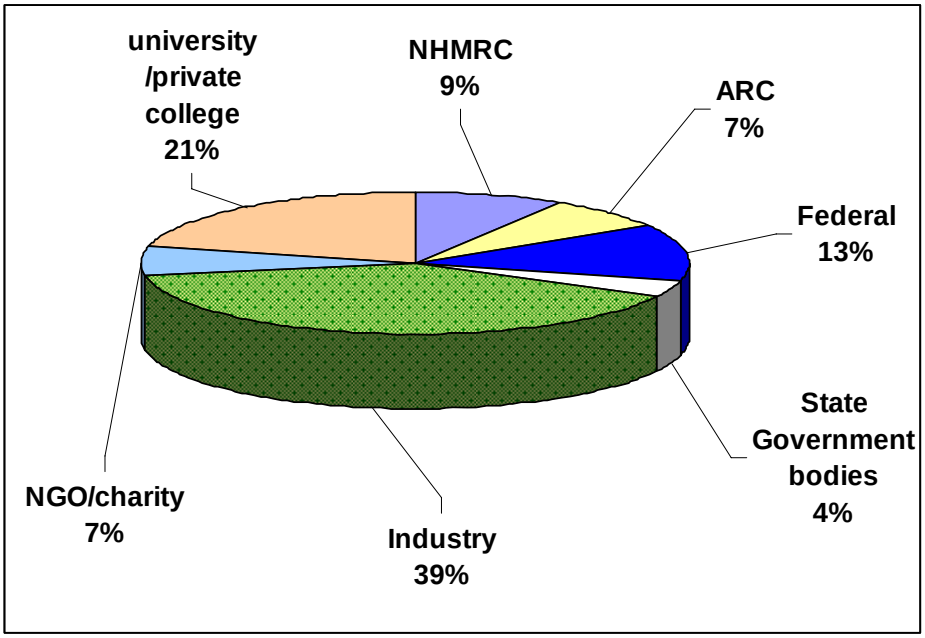

Figure 3.4: Total research quantum by funding source, 2000-2004

Eight CM research projects were identified as having received ARC grants - seven more than the ARC RFCD code search identified. Of the research projects that were successful in gaining ARC funding (from the researcher survey data), five related to traditional Chinese medicine, one to research on nutritional supplements, one to western herbal medicine and one was not specified. Most of the projects that received ARC funding were linkage grants requiring industry contributions.

3.3.5 Research priorities

Researchers were asked to specify the fields of research for funded research projects. Of the 252 projects that identified research topics in the survey, 39% of research quantum was related to western herbal medicine, 23% to traditional Chinese medicine and 19% to nutritional supplements (see Table 3.9, Figure 3.5).

While current research topics were clearly identified in the survey, respondents also described the need to develop future priorities for CM research. **"***There needs to be a meeting of key research players in CM to discern and collaborate on key priorities*". There was concern about relevant CM research methodology. For example, *"While the reductionist product testing approach has its benefits there is a need to focus on the evaluation of natural medicine as it is practiced as a wholistic treatment of the individual. Time and energy needs to be directed into the development of relevant outcome measures that reflect the way in which natural medicine is used."*

One area of priority identified by both industry and respondents was the lack of standardized studies of the benefits and safety concerns of many herbal and other natural medicines. The urgent need for clinical trials, health services research and socio-cultural research was identified by respondents.

Specific CM therapy under research	Percentage of research quantum	Number of projects
Western herbal medicine	39.1	88
TCM	23.3	45
Nutritional supplements	18.5	68
Non specific CM	11.7	16
Acupuncture	3.5	6
Chiropractic	1.3	16
Mind body therapies	1.0	6
Homeopathy	1.0	4
Yoga and Exercise	0.3	2
Massage	0.1	1
Total	**100**	**252**

Table 3.9: Research quantum and number of projects by field of research (2000-2004)

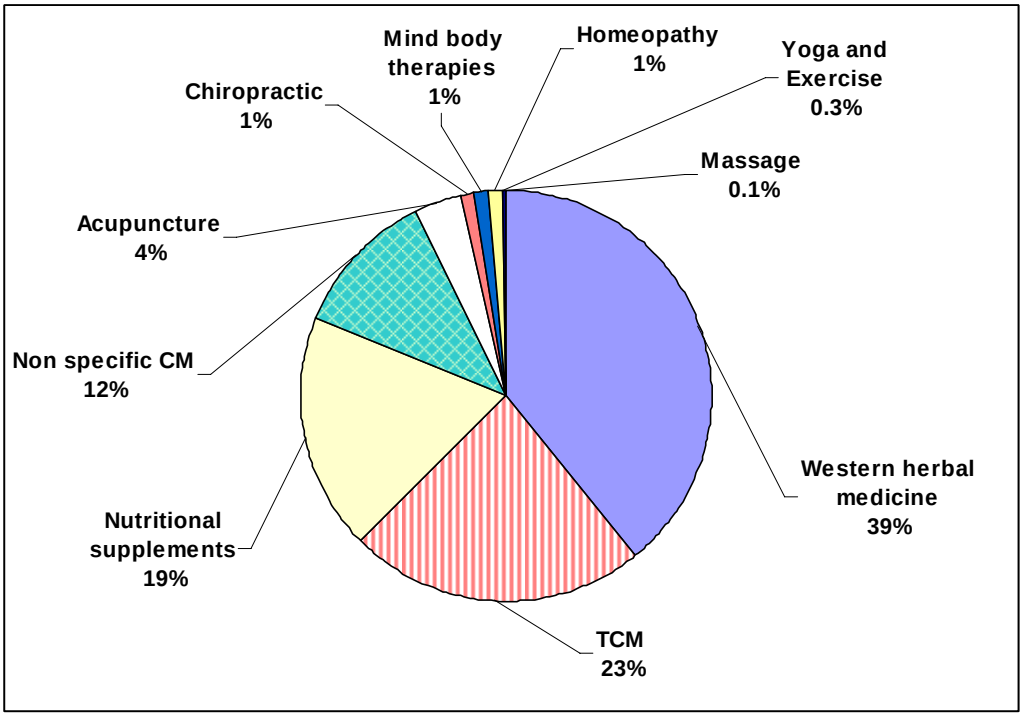

Figure 3.5: Research quantum by field of research (2000-2004)

There is concern that the lack of government research funding and the focus on funding from industry is leading to an emphasis on the pharmaceutical research based on the western bio-medical paradigm, a specific agent for a given disease. It was noted that this approach is not consistent with the philosophical base of many of the traditional CM disciplines that do not treat disease as we know it and believe in a whole person approach to healthcare. The lack of funding for whole practice based research is considered to be a problem of the current funding focus.

3.3.6 Views on access to competitive funding

CM researchers were asked about the best strategies to capitalize on existing research structures, such as the NHMRC and ARC. Their responses indicated an overwhelming dissatisfaction with current funding processes. The perception of many respondents was "*there is a strong bias against complementary medicine research within the peer review funding bodies*" because *"they are exclusively reviewed by those not involved with CM and those that do not share the CM paradigm*".

There is a general perception among respondents that NHMRC and ARC funding is too difficult to obtain. Applications required a lot of resources with little likelihood of success. Respondents reported having positive feedback for their applications from the review panels however, few were actually successful. Respondents identified a need for funding to be earmarked specifically for CM as the current government funding mechanisms were not working for CM researchers or industry. As one respondent replied, "*The national research funding bodies are inherently conservative. Applications are evaluated on collaboration, track record and methodology. There is a need to improve track record to improve the success rate in CM. Different models and methods are often needed to examine CM making it difficult for such projects to be successful unless they are seen as a priority. Similar examples are research in injury and public health and health services where traditional experimental research methods are often not appropriate and where priority funding has been allocated."*

Participants suggested that a valid and reputable peer review process was required to ensure that only CM research of the highest quality be funded. They believed similar standards should be employed for CM research as other types of medical research. Poor quality research would be harmful to the industry and the profession and decrease the standing of CM research as a whole in the research community. *"Research which is not of a high standard will decrease the motivation for non-CM researchers to collaborate on CM research".* Nevertheless, several respondents suggested the need for relevant peer review panels that include non-medical CM researchers to review CM research.

Respondents also identified that intergovernmental cooperation between Australia and other countries could foster collaborative research between countries. However, a track record for high quality research through publication and presentations was required to build an international profile and reputation for excellence in the field of CM over time.

3.3.7 Research collaboration

Data were requested about the collaboration between CM researchers and other research units, overseas researchers or industry, and western medical scientists for each of the funded projects. A summary of the responses is provided in the Table 3.10.

Approximately 41% of projects involved collaboration with other research units, 10% involved overseas collaboration and 51% involved research with western medical scientists. More CM research projects in NSW involved collaboration compared to other states and at least 47% of research projects in NSW involved collaboration with other research units and western medical researchers. This suggests there is a good foundation to build networks and increase collaboration in the future.

While there was strong evidence of collaboration between researchers, respondents also reported that current systems of funding and quantum within universities and the financial challenges of joint funding often provided an environment of competition rather than collaboration. One participant stated "*the low level of funding for CM research and the number of researchers working in this field has perhaps contributed to the lack of collaboration as everyone fights for their share of the funding pot*." Respondents generally implied *"a more coordinated effort from CM researchers would reap excellent rewards*."

Many respondents described the need for development of a research hub, network or council, specifically to deal with to CM issues and to bring researchers together, both CM and medical researchers interested in CM. The role of this organization would be to identify research priorities, provide advocacy, develop CM research methodology, share research infrastructure, share expertise, knowledge and resources, and provide research seeding to create a critical mass of researchers required to develop capacity. Respondents believed a united and visible face for Australian CM research is required to promote and build Australian CM research capacity and increase the public and industry profile of CM research. As one respondent reported "*Research is not coordinated in Australia and there is no independent (ie non commercial) platform for regular meetings of researchers. International forums exist but are expensive. Australia has great capacity for CM research but needs coordination to pool multidisciplinary fields together and minimize duplication."*

		NSW	Vic	SA	QLD	WA	Total
Total # of CM research projects		103	54	13	26	13	209
Collaboration with other units	# of projects	48	6	3	23	6	86
	%	47	11	23	88	46	
Collaboration overseas	# of projects	12	7	0	1	1	21
	%	12	13	0	4	8	
Collaboration with western medical scientists	# of projects	66	7	8	26	0	107
	%	64	13	62	100	0	

Table 3.10: Collaborative research projects by State and type of collaboration (as reported by CM researchers)

With exception of some notable centres, CM researchers are generally isolated. While this can be an advantage in some ways it does weaken links between CM researchers when there is not a central hub for them to link to. For example *"Ninety percent of my research productivity is CM based but I work in a multidisciplinary research centres. It would be advantageous for a CM research centre such as in Queensland and Melbourne to perhaps help develop close links with CM researchers who are located elsewhere".* Also *"I am alone in my research interest in CM issues. Support to enable meetings with other CM researchers to develop research questions and collaborative applications would facilitate quality CM trials in Australia*."

It was generally acknowledged that collaboration between western medical scientists and CM researchers is beneficial. "*We need to promote multidisciplinary research teams to investigate key basic science, clinical public health and health services research of significance to both Australian and overseas markets".* A few participants commented on the challenges of such collaboration including a lack of understanding of the critical elements of CM and the possibility of domination by the western science paradigm. Another challenge in such collaborations is bringing together diverse therapies that sometimes have little in common with each other.

The lack of significant funding for CM research currently places many of the CM centres in competition with each other for limited funds available from industry. Competition between research groups is considered to be a valuable incentive to innovation and as a means of rewarding excellence, however, in an environment of scarcity, competition creates a fragmentation that is undesirable.

3.3.8 Research centres for CM

The main CM research centres in Australia exist in NSW, Victoria and Queensland.

The Victorian government has provided a $500,000 grant to develop a centre for CM research bringing together the main CM units in Victoria. However, despite this initiative commencing two years ago this centre still remains a concept proposal only. There has been commitment for collaboration between six universities, seven privately operated schools and three professional associations.[112] It is projected that this 'Australian' CM research centre will bring investments to Victoria from manufacturers and generate new intellectual property, export earnings and new knowledge for improving public health.[112]

Two NSW centres earned $1.5 million or more (from 2000-2004) in research funding and were categorised as major centres for CM research. These organizations were:

- CompleMED, The Centre for Complementary Medicine Research at the University of Western Sydney, and
- The Herbal Medicines Research and Education Centre at the University of Sydney.

A third, larger centre, located in both NSW and Queensland, also earned over $1.5 million (2000-2004):

- The Australian Centre for Complementary Medicine Education & Research (ACCMER), a collaboration between the University of Queensland and Southern Cross University.

A brief description of the infrastructure and research activities of these three centres is provided below.

3.3.8.1 CompleMED, The Cente for Complementary Medicine Research, University of Western Sydney

CompleMED is a designated Centre of Research Excellence within the University of Western Sydney. CompleMED develops evidence based approaches to the use of complementary medicines within a wide range of healthcare applications. The Centre enjoys a niche position, having world class expertise in research in traditional Chinese medicine. CompleMED runs collaborative research with key teaching hospitals in NSW and, with its focus on Chinese medicine, has been developing strong collaborations with key hospitals and universities in China and Hong Kong. There are three core research streams undertaken by CompleMED:

- *Clinical Research*. CompleMED has completed several clinical trials published in high impact international medical journals (including the *Journal of the American Medical Association*). CompleMED has established the *Chinese Medicine Clinical Research Centre* at Liverpool Hospital (launched by the NSW Health Minister in 2002) with a focus on women's health (dysmenorrhea, endometriosis, menopause, osteoporosis), and is actively working with Bankstown Hospital (dementia studies within Aged Care and Rehabilitation) and Nepean Hospital (irritable bowel syndrome in gastroenterology). Other clinical trial linkages exist with the Australian Institute of Sports (Canberra), John Hunter Hospital (Newcastle) and the Cardiac Health Institute (metabolic syndrome).
- *Laboratory Research*. CompleMED focuses on the development of analytical methods for the active constituents of herbal extracts and the establishment of quality assurance standards for complex herbal medicines. The CompleMED Herbal Analysis Laboratory is extensively equipped to undertake a range of analytical studies and collaborates with local and overseas partners.
- *Health Policy Research*. CompleMED has worked for many years with Commonwealth and state health departments and the World Health Organisation (Western Pacific Region) on public

health and policy issues pertaining to CM in Australia, including safety and usage, industry and practitioner regulation. The Centre director serves as the Chinese medicine expert panel member on the Complementary Medicines Evaluation Committee of the Australia TGA, and serves as one of Australia's two representatives on the Forum for Harmonisation of Herbal Medicine (a WHO Western Pacific Region initiative).

CompleMED enjoys healthy collaborative relationships with Australian and international industry partners and other research institutions.

3.3.8.2 Herbal Medicines Research and Education Centre

The Herbal Medicines Research and Education Centre (HMREC) was established at the University of Sydney in 1997 within the Faculty of Pharmacy. Its objective is to carry out high quality research and education on herbal and complementary medicines. The Centre is a focal point for research and education of value to health care professionals, industry, government and the community on the quality, safety and efficacy of herbal and complementary medicines. The specific objectives are:

- To meet the demands for expertise in herbal and complementary medicines from industry and the community, and health-care professionals in pharmacy, medicine and related areas.
- To develop programs in education and basic and applied research on herbal and complementary medicines, particularly in the area of safety, quality and efficacy of such products.
- To promote cooperation and links between the pharmaceutical and herbal and complementary medicines industries, user groups and the University, and to obtain support from these bodies for the work of the Centre.

Activities of HMREC include characterisation and development of herbal medicines in Australia, drug discovery from traditional Chinese and other herbs and Australian flora, laboratory analyses of herbal medicine, and exploring mechanisms of action of herbal and natural medicines. The Centre also runs education programs in herbal medicine and provides information services. HMREC has established international and industry linkages and collaboration in herbal medicines research and education. Recent research has focused on capsaicin receptor and pain mechanisms, the treatment of arthritis, the cultivation and development of herbal products from plants introduced from China, potential anticancer drugs from medicinal plants, pharmacological activity and stability of ginger extract constituents, anti-inflammatory activity of medicinal plants, cardiovascular activity of phenolic components from Australian native plants.

3.3.8.3 The Australian Centre for Complementary Medicine Education & Research (ACCMER)

ACCMER is a joint venture between Southern Cross University and University of Queensland to establish a unique collaborative research and education centre, with the objective of providing an independent reference point built on substantial strengths in research, innovation and teaching. The Centre offers a Graduate Certificate in Evidence-based Complementary Medicine for pharmacists, doctors, nurses, allied health professionals and trained natural therapists in Australia and internationally. Three branches of research activity are undertaken:

- *Clinical Trials.* The Centre's clinical trial capabilities are multidisciplinary, combining medical, scientific, nursing and administrative expertise. The Brisbane and Lismore nodes of ACCMER have established expertise in all aspects of clinical trials. Trial protocols are developed in close collaboration with relevant medical specialists who are intimately involved in all aspects relating to the health of study subjects, from initial screening to study completion. ACCMER reports clinical trial expertise in osteoarthritis, asthma, hyperlipidemia, haemostasis, obesity, premenstrual syndrome, acne, physiological and psychological effects of essential oils, smoking

cessation, irritable bowel syndrome, interactions between herbal extracts and pharmaceutical drugs, premenstrual syndrome, diabetes, myalgia, dermatitis and psoriasis.

- *Laboratory science.* The Centre for Phytochemistry and Pharmacology at Southern Cross University is a core ACCMER partner and undertakes traditional academic, commercial and speculative research in the field of plant chemistry and bioactivity. ACCMER operates four state-of-the-art research laboratories (two in Lismore and two in Brisbane) and employs more than 20 scientists, technicians, research students and support staff. In addition it works closely with the Centre for Plant Conservation Genetics at Southern Cross University. ACCMER facilities and expertise permit the assessment of the following: anti-microbial activity, anti-inflammatory activity, anti-oxidant activity, fibrinolytic activity (in vivo and in vitro), anti-coagulant activity (in vivo and in vitro), cytotoxicity, immune function (in vivo and in vitro) and gene polymorphisms.
- *Social health science and public policy research.* A major role of ACCMER is to research the use and understanding of CM by the Australian population in general and by health professionals in particular. Projects include risks assessments, educational needs analysis of health professions and socio-cultural mapping of the CM professions.

ACCMER is an integral component of the Cellulose Valley Institute at Southern Cross University. The Institute, which is unique in the world unites seven synergistic research groups in plant genetics, phytochemistry, health sciences, and environmental and resource science. This allows projects in medicinal plants to be developed from the plant genetics through to clinical confirmation. Within the University of Queensland, ACCMER has collaborations with the National Research Centre for Environmental Toxicology, the School of Pharmacy and the School of Population Health.

Since 1996 there has been close ongoing research collaboration between the Faculty of Health Sciences at University of Queensland and the School of Natural and Complementary Medicine at Southern Cross University and with CompleMED at the University of Western Sydney. This collaborative network has obtained a series of research contracts with a focus in public policy research.

3.3.9 Small CM research units

Four units were identified as having received around $0.5 million in CM research funding over the last five years and were categorised as smaller active research centres. These were

- Natural Therapies Unit, Royal Hospital for Women, Sydney
- University New England, Division of Human Biology
- University Technology Sydney (UTS), College of Traditional Chinese Medicine
- Charles Sturt University, Faculty of Health Studies

3.3.9.1 Natural Therapies Unit, Royal Hospital for Women, Sydney

The Natural Therapies Unit has very broad research interests. Over the recent past the Unit has been involved in pharmacological studies of novel types of Hormone Replacement Therapy including an international multi-centred randomized trial of osteoporosis treatments. A number of randomized trials have been performed in the health benefits and safety profile of soy protein. Also a number of herbal products have been investigated in the Unit including ginger for morning sickness, serenoa for prostate problems, shark cartilage for arthritis and a number of trials of meditation (e.g. for headache and hot flushes).

3.3.9.2 University New England, Division of Human Biology

Staff in the division are actively engaged in research on the impact of native Australian plant extracts as bioactive modulators.

3.3.9.3 University Technology Sydney (UTS), College of Traditional Chinese Medicine

Current research projects at the UTS College of Traditional Chinese Medicine include acupuncture clinical trials on stress, acupuncture clinical trial methodology, acupuncture mechanisms in the treatment of inflammatory conditions, acupuncture point location, pharmacognosy of Chinese herbs, and history and development of TCM.

3.3.9.4 Charles Sturt University, Faculty of Health Studies

The Faculty of Health Studies conducts research in a wide range of health related areas. The School of Biomedical Sciences is involved in many natural products and CM research including biological activities of essential oils, use of and attitudes towards complementary therapies, use of complementary therapies and various herbs for reproductive purposes and wound healing properties of honey.

CHAPTER 4 LOOKING AHEAD: CM RESEARCH INITIATIVES FOR NSW

4.1 The CM landscape

Complementary medicine represents a substantial proportion of activity in the Australian health care sector with a high level of use by the Australian public. Between 50-75% of the Australian adult population use at least one CM product each year. Between 15-30% visit a CM practitioner each year. There are in excess of fifteen million consultations nationwide each year in herbal medicine, naturopathy, acupuncture, chiropractic and osteopathy alone. A conservative estimate of the industry turnover of products and services in Australia sits at $1.5-2.5 billion per annum. The industry continues to grow steadily with increasing uptake by consumers and there is no sign abatement in the near future. Overseas studies arrive at similar conclusions.

CM is a rapidly expanding industry with all the hallmarks of significant economic activity (company mergers and acquisitions and venture capital investment. There is significant potential for CM in management of chronic illness, preventative care and aged care, which are identified as national research priorities.[123] Cardiovascular disease, cancers, mental health, injury, respiratory disease, diabetes, arthritis and other musculoskeletal problems cause a significant human and economic burden for the Australian population. Consumers use CM products and services in an attempt to assist mange or treat most of these disease states.

Given the therapeutic range of CM and the economic activity associated with it, there is a substantial gap between level of activity and the scientific evidence that supports this activity. Whilst there are noted health benefits to CM intervention, the relative cost-benefit of CM treatments are poorly studied. There is nevertheless, a clear perception by consumers and some data that suggest that CM might have fewer side effects than orthodox medicine and a potential to save health costs. There is some preliminary evidence which suggests that some complementary medicine products and services may provide a cost effective alternative to conventional treatment, particularly in key national health priority areas. CM may offer substantial financial savings to the community and reduced morbidity.

Over the last five years more than $26 million has been invested in CM research. Industry contributed the greatest proportion of funding to CM research at $10.4 million or approximately 40% of funds (a significant proportion of which was from overseas), with a further 29% from commonwealth sources and 21% from universities. From 2000-2005 a total of $2.35 million was received for CM research from the NHMRC (success rate of 13% contrasts 25% success rate for NHMRC applications in general). NHMRC CM research funding represents 0.1% of the $1.68 billion research funds available during this period. No funding has been allocated to CM research by the NHMRC in 2004 or 2005. The ARC contributed $1.9 million for CM health research over the same period. The NHMRC and ARC currently contribute 16% of total CM research in Australia.

Health research has been demonstrated to be of significant value to national growth and development in both human and financial terms by optimising Australia's capacity to address the burden of disease. A strong health and medical research sector supports and enhances the health care sector and industry associated with it.[124] CM research is clearly under-funded in relation to the high level at which CM is utilised, the size of the industry and the urgent need for evidence based practice guidelines.

4.2 NSW capacity to undertake CM research

By all measures (number of grants received, degree of funding, number of CM research active staff, key CM research centres, postgraduate research students), approximately 50% of Australian CM research activity occurs in NSW. Two of the larger university designated CM research centres (albeit still moderate in size when compared to orthodox medical research centres) are located in NSW (CompleMED at University of Western Sydney and HMREC at Sydney University). An additional larger CM research centre (ACCMER) is located both in NSW and Queensland as a joint venture between the University of Queensland and Southern Cross University. There are four smaller NSW research concentrations in CM (Natural Therapies Unit at the Royal Women's' Hospital, University New England Division of Human Biology; University Technology Sydney (UTS) College of Traditional Chinese Medicine; Charles Sturt University Faculty of Health Studies) and an estimated 7-10 NSW units which conduct a lesser amount of CM research. Furthermore, many of the CM and pharmaceutical companies are situated within NSW making it easier to develop the necessary links between industry, practice and research in order to foster exchange, good manufacturing practice and investment and marketing of new products.

The quality of research performed by these centres and researchers is well respected internationally, with high level publications and international media interest. The extent of active collaboration between centres and other individual CM researchers is relatively small although this may largely reflect the lack of research funding support for CM. Some degree of collaboration already occurs between some the NSW centres and capacity could easily be expanded given the appropriate infrastructure and resources.

Currently, NSW leads other states in terms of CM research infrastructure, staff and post-graduate students involved in CM research. There exists a clear foundation for further capacity development - the opportunity exists for NSW to capitalise on the current situation and foster CM research as a NSW medical and health research strength.

There is also a need to maintain and improve our position within a global market. A recent international profiling exercise showed that there were seven CM centres of research excellence - three in the US, two in the UK and one each in Germany and Switzerland. It is important to note that all these centres are located in countries where there has been a specific government commitment to fund CM research.[1] As the 'clever country', Australia and, in particular NSW, should not be left behind in the development of the CM industry.

4.3 Strengths and opportunities

CM enjoys a developing scientific evidence base and is represented by a rapidly expanding industry founded on a large and expanding community usage. There is potential to significantly impact on health and health costs.

Australia has enormous potential to be an international leader in evidence based CM products and services. We enjoy a strong international reputation in medical research and have an internationally well respected regulatory approach to CM products. Australian medical research expertise is high and clinical trial costs are relatively low, contributing to the appeal of Australia as an important research environment. Asia represents a significant opportunity for Australia in the development of well researched CM products. We are ideally situated to assist many of our regional neighbours in developing the best of their indigenous medicines into scientifically validated medicines. Many Asian neighbours regard Australia as a cost-effective stepping stone into the western marketplace for herbal medicines and would see significant merit in the added value of high quality CM research undertaken in Australia. Adding to the appeal, the Australian TGA regulations are not as 'soft' as the

dietary supplement approach of the US (Dietary Supplement and Health Education Act), nor so harsh as to mandate evidence that would be required for new chemical entities that hold no history of clinical use. Intellectual property law is also well developed in Australia, offering companies increased security. The strategic approach to CM research needs to be developed and maintained over the next 5-10 years to allow Australia to play a role in the development of Asian CM. Failure to do so would represent a substantial lost opportunity for NSW and Australia. There is an opportunity cost if NSW fails to participate sufficiently in CM research in lost intellectual property and commercialisation opportunities, particularly in the context of the Asian market.

Clear strengths in NSW are the availability of qualified and experienced CM researchers, relevant education programs and some access to funds. NSW is well placed to take further advantage as a possible hub leader in this rapidly developing research field.

4.4 Barriers to CM Research

The high use of CM not only raises issues related to evidence, but raises other public policy concerns such as the structures and regulation to protect the public, the access to information sources and treatment, education and training of CM and other health professionals to an appropriate level, and integration with conventional care in ways which make the best use of resources. There is an obvious challenge in the diversity of coverage of CM, and the consequential need for research to catch up to the level of community use.

There are several factors that have contributed to low levels of CM research in Australia.

- *Inadequate government funding*. Commonwealth agencies (such as the NHMRC and ARC) have historically provided a proportionally lower level of funding for CM research compared to other health research. There are no special schemes in place to accommodate the growing need and demand for evidence in CM. The funding review panels of these funding agencies are perceived by CM researchers to be inadequately skilled in reviewing CM research applications and to be biased against the value of such work. Funding from other state and national agencies such as the DRSD have contributed financially to industry investment in CM research (through, for example, the NSW State and Regional Development *Proof of Concept* funding) but also do not provide direct research funds for CM and have provided relatively little funding overall to CM research in the last five years. In contrast, the Victorian state government has recently provided an initial grant of $500,000 to develop an (Australian) Research Centre for Complementary and Alternative Medicines. The Expert Committee on Complementary Medicines in the Health System (2003) signalled the urgent need to increase funding for CM research.[40] However, the Commonwealth government indicated that no funding would be allocated prior to consideration of the needs and priorities of this field. The TGA is due to establish a working group with the NHMRC to consider these issues. However, in this current environment of inadequate support, researchers are struggling to grow. With inadequate funds to do so, researchers remain relatively isolated, and by all accounts a brain drain has commenced in this field with some key CM researchers moving to greener pastures overseas.
- *Limited capacity for the CM industry in Australia to support CM research.* In 2000 the Australian government signalled its willingness to provide $1 million over three years to CM research on the condition that industry matches this funding. The CM industry declined to contribute on the basis of recent increases in TGA fees and concern over the predicted downturn with the introduction of the GST on CM products.[125] However, the results of the survey conducted for this report suggest that industry already provides a significant amount of funding for CM research (40%). It is likely that industry demand for CM research will increase due to regulatory pressures, but their ability to voluntarily increase their contribution to research funding is

doubtful given the level of funding that is already being provided and the lack of intellectual property protection.

- *Lack of capacity and infrastructure.* The MSMR has recognized that the NSW research potential to address the burden of disease is compromised by disaggregation, unproductive competition for research funds, inadequate links between basic clinical and public health and health services research.[121] Opportunities to attract peer reviewed grant monies are compromised by lack of cohesion and opportunities to create economies of scale, share equipment and infrastructure and attract overseas investment. All these factors are relevant to CM to an even greater degree than medicine in general.
- *Lack of research training and expertise*. There is no tradition for research within the CM profession and therefore a lack of relevant skills and expertise. Research infrastructure for CM is in a nascent and fragile stage of development with few centres of excellence and relatively low staffing levels in these centres. This lack of research expertise will also have contributed to the lack of success for competitive funding.
- *Many CM medicines are in the public domain*. Juxtaposed to the pharmaceutical industry, which is the world's most financially successful business, CM is a poor cousin. The majority of medicines available to the public and utilised by CM practitioners are in the public domain and, in many instances, have been for hundreds of years. For this reason, companies are reluctant to invest money in CM research as there is no clear mechanism to protect the resultant intellectual property.
- *Non-scientific explanatory theories.* CM is not a single entity and consists of many philosophical and explanatory systems some of which are not clearly understood or accepted within biomedical science. In addition, there may be a lack of interest in this field by conventional scientists.
- *Methodological issues.* There are specific methodological difficulties in performing CM research. For instance, CM practices (such as acupuncture and chiropractic) often involve significant interaction between patient and practitioner. Clinical trials in these areas (as with physiotherapy) face the difficulty of creating a suitable placebo. CM treatments are also often individualized (tailored to the patient) and based on a different diagnostic process from western medicine. CM practices are often complex interventions involving many components such as the combination of acupuncture, herbs, dietary and lifestyle advice. The effect of studying each component separately or in combination as part of a whole system needs to be considered. Forming strong collaborative teams between research scientists and CM practitioners should be an important part of any Australian funding strategy to ensure such methodological concerns are effectively addressed.
- *Lack of practitioner regulation.* Lack of regulations and standards for practice and education contribute to an environment where research is less likely to be valued, understood or used. It also contributes to the level of scepticism of western medical scientists towards CM therapies and their motivation in collaborating in CM research projects.

In summary, under the current minimal funding arrangements and dispersed CM research efforts it is extremely difficult for CM researchers to undertake even a small fraction of the medical research required to strengthen the evidence for CM products and services. Nor is the CM research community able to develop sufficient momentum or sufficiently strong core branches of expertise. Neither corporate nor competitive funding agencies have yet developed the vision or mechanism to adequately fund CM research which is critically needed to promote health, minimise risk and realise economic advantage. An appropriate solution to fund and build capacity in CM research is required. Any proposed scheme of CM research funding would need to address each of the above factors to be successful.

4.5 Overseas responses

Funding models for CM research are well established in some overseas jurisdictions. The United Kingdom and the United States are exemplary.

4.5.1 Pump-Priming: UK Government strategies for supporting CM research

The House of Lords Select Committee on Science and Technology Report - on Complementary and Alternative Medicine (2000) recommended that government should 'pump-prime' (provide seed funding for) research into CM.[62] Dedicated research funding (an estimated £5 million over three years) is being provided to create centres of excellence and developing the infrastructure for high-quality research. The focus of this program is on research capacity building. Host institutions have been identified to provide methodological advice, appropriate skills development and research support, and to 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. Prior to this, less than one-tenth of one percent of the British National Health Service research budget went towards CM research. Research funding from UK medical charities has also increased from £70,000 (0.05% of research budget) in 1999 to more than £400,000 (0.31%) in 2002.[126]

The UK capacity building initiative consists of four elements:

- *Identification of host academic institutions* with a demonstrable track record of appropriate research activity with CM organisations to provide the methodological advice, skills development and research support. These institutions should hold track records in multi professional research or demonstrate experience or commitment to CM research, be able to provide support and training in qualitative and quantitative methodologies, and be experienced in proposal design and competitive bids.
- *Individual award schemes* at post doctoral and training fellowship levels to be provided through joint applications with the host academic institutions.
- *Establishment of a commissioning mechanism* responsible to the NHS Research and Development Council to manage the award selection process. This advisory committee would consist of academics, experts in research methodology, practitioners, representatives of professional bodies, representatives from the field and consumer representation.
- *Development of a research network* with the aim to provide peer support and opportunities to share ideas on research methodologies and disseminate findings, and be responsible for the development of annual conferences.

This model is appealing because it invests in enthusiasm; there is no specific ring-fencing of money. A broad competitive base is maintained for research grants, yet it creates a supportive environment that allows for mentoring and appropriate review.

4.5.2 Ring-fencing: government support for CM research in the United States

The US Senate determined an appropriate response to the dramatic growth in usage was to ring-fence money for CM 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 National Institutes for Health (NIH), with a research budget which has increased from $50 million in 1992 to $123 million in 2005.[127] This funding is available for research into CM topics on a nationally competitive basis. In 2003, the US White House Commission on CAM Policy (http://www.whccamp.hhs.gov/finalreport.html) recommended that federal agencies should receive increased funding for CM research and, in addition, that US Congress create appropriate incentives for the private and non-profit sector to support CM research, with a focus on improving self-care, promoting wellness and tackling areas of scientific debate raised by CM. The NCCAM currently fund 11 key focus centres, in part to draw those CM practitioners and experts into the fold of a larger research enterprise. It has also awarded over 100 doctoral, post doctoral and career awards.[128]

This model is appealing because it is openly competitive to all researchers and organisations. There are no elite host academic institutions, yet still achieves an increased focus on CM research. The risk exists that some research proposals may get funded without adequate merit.

Neither the UK nor the US approaches ideally lend themselves for adoption in a NSW CM research environment.

4.6 A NSW strategy for funding CM research

A number of changes are recommended to enable the potential benefits of CM research to be realised. The MSMR has proposed a strategic approach be taken by the NSW government in relation to medical research in order to reduce the challenges associated with research and increase the NSW contribution to the national and international research effort.[121] Many of these elements are appropriate to CM research in NSW and we propose the development of a complementary medicine research plan as part of the broader NSW Science and Medical Research Plan. Specifically, the proposed complementary medicine research plan will:

- Create a needed concentration and direction of complementary medicine research effort,
- Strengthen NSW's role as a national and regional leader in complementary medicine research,
- Create increased efficiencies through greater collaboration, economies of scale, and shared resources,
- Provide greater appeal for active participation by industry, and
- Assist to address key public health issues.

Proposed strategies to strengthen the NSW base of CM research and to assist in the development of an appropriate evidence-based CM industry include:

1. Providing infrastructure support to stabilise capacity in CM research centres (such as post-doctoral research fellows, some physical infrastructure and/or arrangements for shared access),
2. Strengthening the links and collaboration between current NSW based CM researchers and centres,
3. Facilitating through seed funding the development of collaborative CM research proposals to be submitted for national competitive funding,
4. Providing infrastructure support to develop minimum datasets and databases, and link with national and state health services to collect information on CM research,
5. Providing an advocacy role for improving CM research funding within national and state funding bodies,
6. Strengthening standards of practice and education through appropriate regulatory mechanisms,
7. Bringing stakeholders together to identify state and national CM research priorities,
8. Conducting forums to develop guidelines for CM research methodology,
9. Facilitating implementation of CM research into practice guidelines,
10. Facilitating the networking between industry and research for the commercialisation of CM research.

The CM research centres operating within NSW have established some collaborative networks between CM and conventional medicine, and between CM researchers and industry. A NSW initiative with government support would have the capacity to drive and coordinate further collaborations, undertake effective consultations and would develop mechanisms to identify and

prioritise key research areas in CM. Key recommendations are provided below to develop CM research and the CM industry in NSW.

4.7 Recommendations

1. The NSW government should provide infrastructure support to a strategic hub for NSW complementary medicine research.
Coordination of CM research activities is the first step required to enable potential benefits in the field to be pursued and realised. Opportunities exist to improve the coordination of the research effort between CM researchers, to better identify CM research priorities, to strengthen the pathways for CM research funding, and improve success with national competitive grants.

The principal mechanism to facilitate the delivery of the above strategies is to establish a Committee for CM Research to oversee its development in NSW. The initial role of the NSW Committee would be to conduct a forum to establish key program areas, identify research priorities for CM research in NSW (aligned with state and national priorities) and begin to develop collaborative networks to address those priorities. The Committee would assist to establish research platforms, encourage excellence and foster good governance in CM research. This mechanism can be initiated without the requirement of substantial infrastructure in terms of facilities, but rather represents the development of a coordinated approach. A central coordination or 'hub' will help optimise use of current facilities and concentrate activities that exist. The NSW Committee for CM Research would liaise with interstate partners to develop larger national programs. The NSW Committee for CM Research would need to have a broad membership and include universities and/or research centres that are conducting CM research, professional organisations and relevant industry partners.

Once established, the Committee would seek funding from the NSW Government to implement specific programs that develop research platforms, including infrastructure, relevant to CM research, promote methodological and research excellence, facilitate collaborative research and seed fund priority research areas, and facilitate knowledge exchange between research, industry, policy and practice. The NSW Committee would promote collaborative research between centres, and specifically liaise with groups in specialist areas and between centres and leading medical institutes where there is promise. This would facilitate the identification of research priorities (gaps in evidence), the development of relevant high quality research and ultimately the incorporation of evidence into practice guidelines and education programs.

The NSW Committee for CM Research will need to support the establishment of new research teams, provide a range of scholarships and fellowships to foster research by clinical researchers and the exchange of talent between industry and the public sector. The CM Research Committee should develop grant programs (in particular seed programs) to assist research centres and teams with capacity development and nationally competitive funding applications.

CM infrastructure grants should be linked to research institutes which have the necessary facilities to undertake CM research, mentor and train CM researchers and generally increase capacity in the field. Grants which encourage collaboration between CM and biomedical and social science researchers may increase the quality of research applications for competitive funding.

2. The NSW government, through the newly established NSW Committee for Complementary Medicine Research, should establish collaborative teams and complementary medicine research platforms to build excellence and critical mass in NSW complementary medicine research.
Most CM practitioners lack sufficient expertise in scientific research, whilst on the other hand medical researchers may not have considered CM as a potentially fruitful area of investigation and have limited knowledge of CM practices. Effective applied clinical research will require strong collaborations to be developed and supported between CM clinicians and medical researchers. Research teams on grant applications will need to reflect this. In the long run this will also help the emergence of CM practitioner-researchers. CM research not only needs specific skills and teamwork but, in particular, prominent medical alliances. It requires a deliberate policy that supports a collegiate approach, whereby those involved in CM and in conventional medicine genuinely communicate with each other to develop the research agenda.

A collaborative approach to research between CM research institutions within NSW and Australia will make the most of the different kinds of expertise available and required to study CM. Whilst strong CM research concentrations exist in NSW, collaboration occurs in a haphazard fashion based on isolated research activities. The CM centres do not have the resources to develop the required networks nor have the infrastructure capacity to maintain a significant research focus or platform. Another reason for developing networks is for researchers, practitioners and industry stakeholders to come together and contribute to the identification of national research priorities to ensure they are relevant to practice, have commercialization potential and do not duplicate effort.

There is, in addition, a need to strengthen CM research training and career development. Some respondents to the survey indicated that training of CM practitioners in research methods and evidence-based practice was necessary to encourage practitioners' involvement in research, develop a solid foundation of researchers and increase use of research evidence in practice. Funding for postgraduate CM research scholarships and post-doctoral fellowships is required to develop a critical mass of future CM researchers. This will assist the support and mentoring of early career researchers and leadership in more experienced researchers. Survey respondents also recommended that workshops be held to develop methodologies appropriate for CM research and to increase skills in the design and development of research proposals for novice and early career CM researchers. Mentoring and network programs with research leaders in medicine were also believed to be a promising strategy to improve research skills in the field. Support for research training and career development should be targeted specifically to institutions where there is a critical mass of current research infrastructure and research mentors.

3. Relevant departments and agencies within the NSW government (such as the MSMR, Department of Health and NSW Department of State and Regional Development) should liaise further with relevant Commonwealth agencies (such as NHMRC, ARC and Department of Industry, Tourism & Resources) to provide an ongoing quantum of research funding for complementary medicine.
Government funding for CM research needs to be increased in order to build an effective CM research capacity in NSW and Australia, to capitalise on significant commercial opportunities and to assist in fulfilling national research priorities. Seed funding and funding for small and large grants, particularly in identified research priority areas, was viewed as necessary to address the relative lack of evidence related to CM practices. There was an identified need for access to funds for post-doctoral positions, similar to those provided in the United Kingdom. However, it should be noted that survey respondents recommended CM research funding be both 'pump-primed' and 'ring-fenced'. Respondents generally signalled a preference for the US NCCAM model of funding where an organisation specifically related to CM research coordinates and allocates funding according to identified research priorities - "*Establish a pool of qualified CM researchers and support them.*" This could

remain within the umbrella of the NHMRC. In fact, survey respondents recommended that NHMRC provide a special stream of funding specifically for CM research and that a specific CM research panel is established to review CM research applications. Fundamental mechanisms need to be facilitated and promoted within national competitive granting authorities (NHMRC, ARC) that address concerns with regards to the lack of opportunities to research high use CM healthcare interventions and the perceived bias of NHMRC review panels.

It is important to ensure if a funding pool for CM becomes available that the research undertaken supports the core disciplines and issues in CM and is not seen as another pool of research funding by opportunistic researchers in general bioscience and medicine who decide to add some CM to their research portfolio.

4. Relevant NSW government agencies (such as the NSW Department of State and Regional Development) should continue to strengthen vehicles for public private partnerships in NSW CM research by leveraging Commonwealth and industry funding and requiring funding input from hub partners.

Whilst the CM industry has provided significant research funds, additional funding from local industry should be promoted. Industry and government partnerships can be strengthened by enhancing existing programs such as the *BioFirst* and *BioBusiness* programs to support commercialisation of CM research discoveries. Further support schemes could be developed, for example, where industry jointly with government funds a research position (for example, post-doctoral research fellow) rather than a specific research project (currently required for '*Proof of Concept'* funding). Under such a scheme the industry would contribute to priority setting of the research activities, and there would be identified a general field of research from which intellectual property could emerge, reducing the potential for bias as a result of direct industry funded projects.

It is noted that industry is reluctant to invest more in CM research because of difficulty in protecting intellectual property and gaining market advantages. The Expert Committee on Complementary Medicines in the Health System (2003) recommended that the TGA set up a working group to explore options to facilitate a market advantage for companies that invest in research, such as a five year exclusive regulatory licence.[40] This recommendation was recently accepted by the Commonwealth government (March 2005) and the industry awaits its implementation.

5. The NSW government, through the newly established NSW Committee for Complementary Medicine Research, should work with relevant stakeholders (government, industry and researchers) to establish priorities for complementary medicine research in Australia.

There are many uncertainties surrounding CM and its practice. The public health questions regarding CM can only be addressed through a well defined research agenda. It is expected this would include supporting relevant public health and health services research in priority areas such as patient safety, health economics, management of chronic disease and ageing. 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 priorities may differ for different stakeholders. For example, government would wish to know whether CM can contribute cost effective healthcare, while patients seek to extend their healthcare choices, CM practitioners to establish the unique knowledge base of their discipline, and scientists to extend their own knowledge boundaries.

The NSW Committee for CM Research and annual state conference would assist in the establishment of CM research priorities relevant to NSW, and coordination of the research program groups to focus on the chosen priorities. The State conference will ensure the participation and co-ordination of all

relevant stakeholders including researchers, clinicians, consumer representatives and industry. Criteria need to be established to guide the development of CM research priorities, including:

- identifying disease burden in the community (highest morbidity, highest cost),
- biological plausibility of the intervention,
- promising preliminary research in CM,
- gaps in evidence,
- potential cost-effectiveness and risk-benefit,
- current conventional treatment options,
- evidence that there are safety concerns, and
- that the research design is feasible and is likely to yield unambiguous results.

A primary outcome to CM research needs to be the development of relevant, informed clinical practice guidelines. In addition, surveillance systems for CM use need to be established, along with better reporting of adverse events. Standardisation of practice and education through practitioner regulation needs to be encouraged.

The identified CM research priorities will only be fulfilled through the establishment of a clear government program to fill the gaps in current CM research capacity and infrastructure. This includes establishing the NSW Committee for CM Research, developing established CM research centres and facilitating the work of CM research program networks.

The United Kingdom CM funding scheme considered the important areas for research fell in six main categories:[62]

- Research into the effects of each individual therapy, its efficacy, safety and cost effectiveness,
- Research into the mechanisms of action for each individual's therapy, including patterns of response and research into the placebo effect,
- Research into the CM genre itself, including social research into the motivation of those patients seeking CM and the usage patterns of CM,
- Research into new research strategies that are sensitive to the CM paradigm,
- Research into the efficacy of diagnostic methods used,
- Research into the implementation and effects of CM in specific health care settings.

These views were generally reflected in the comments by our survey respondents.

There is evidence to suggest that CM groups which are more formally organised are most likely to recognise the importance of scientific research on their practice and therapies. For example, one survey found that chiropractors agreed that scientific research was essential to demonstrate safety and effectiveness, homeopathic practitioners were divided on this topic and Reiki practitioners had virtually no interest in undertaking such research.[62, 129] The priority area for each type of CM will vary depending on what evidence exists.

6. The NSW government, through the newly established NSW Committee for Complementary Medicine Research, should develop mechanisms to strengthen networking and dissemination of information on complementary medicine research.

Currently, the CM research field is largely fragmented and disjointed. There is a need to develop a register of researchers interested and active in the field and their areas of expertise. CM would be better facilitated by having an annual face-to-face meeting and perhaps an electronic newsletter to keep parties up to date with developments. There is a need to link with international, national and state centres for clinical trials and other forms of collaboration and exchange. Infrastructure and funding to develop and support such linkages are required. There is a need to fund high quality CM researchers to attend and present at overseas international conferences (for networking and marketing possibilities). It is recommended that a website and database for NSW CM research be developed and linked with databases available overseas.

A central coordinating body for CM research is required to provide advocacy for CM research, including with government funding bodies, international and national research organisations, industry, development of information for consumers, progression of CM journals to Medline and sections within medical journals related to CM. There is clearly a demand by both public and health professionals for accurate information about the safety, efficacy and cost effectiveness of health treatments and therapies. For instance, a Cochrane Collaboration group around CM could be developed in Australia and linked with the principal Cochrane CM group at the University of Maryland, Baltimore.

4.8 Start-up investment required to commence a NSW strategy for CM research

In establishing the NSW Committee for Complementary Medicine Research investment is needed to:

- Support the coordinator's role, basic administration and the annual conference,
- Provide seed funding to support priority area programs (such as preparing background evidence reviews) and research platforms (ensuring appropriate teams and infrastructure are in place), and
- Actively promote new public private partnerships (for example, by way of university based post-doctoral fellowships and research scholarships).

Furthermore, there is a need to maintain ongoing dialogue with relevant government agencies. In particular there is a need to facilitate and promote mechanisms within national competitive granting authorities (NHMRC, ARC) that address concerns with regards to the lack of opportunities to research high use CM interventions and the perceived bias of review panels. There is a need for increased and adequate funding by commonwealth agencies for the investigation of CM practice.

In any financial solution it would be sensible to utilise a mechanism that generates research funds from within the growing CM industry but manages them in an equitable and competitive fashion which acknowledges national health priorities and CM research priorities. We recommend that a quantum of funds be allocated over the next five years to initiate and support a NSW complementary medicine research strategy. This quantum should be proportional to the size of the industry and we recommend it be set at between $500,000 and $1.5 million per annum, approximately 2-5% of the Goods and Services Tax (GST) collected from the NSW component of the complementary medicine industry. Since July 2001 an estimated $160 million of GST has been collected each year from sales of CM products and services in Australia (10% of $1,671 million).[1] It is expected that a significant proportion of this is subsequently distributed to the States. If the equivalent of 2-5% of the GST raised from the NSW based CM industries was re-invested in CM research annually over the next five years, this would create a reasonable annual budget that would assist to develop research not only of CM products, but also of techniques such as acupuncture, osteopathy and chiropractic and whole practice research.

The proposed scheme would represent approximately less than 1% of expenditure on other national health research priorities, and would not draw from the existing pool of health research funding. For CM research funds to be hypothecated from taxes is not usually a preferred approach by government and is not specifically advocated here however, it provides a reasonable measure of the quantum of funds reflected by industry size, activity and potential for growth. Given the current size and activity of the CM research community this quantum is likely to be well utilised on strong, well-directed research activities, most especially if research collaborations continue to be strengthened. Importantly, it is very likely that this annual investment of funds in CM research will be repaid manifold through the direct growth of the sector and additional taxes raised (including GST).[1, 124]

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APPENDIX A THE POTENTIAL BENEFITS OF COMPLEMENTARY MEDICINE

A.1 Introduction

This section reports the current scientific literature on the benefits of a number of major CM modalities, including nutritional supplements, naturopathy, western herbal medicine, acupuncture, Chinese herbal medicine, chiropractic, osteopathy, homoeopathy and Ayurvedic medicine. Such an evaluation is important as it provides an understanding of the currently published clinical evidence that underpins the efficacy of CM.

One major difficulty in the determination of the benefits of these health practices is that they have not been the subject of any systematic investigation to determine health outcomes related to the actual way these disciplines are practised in a community setting. Whole practice (or whole systems) research is a newly emerging research field within CM (Ritenbaugh et al. 2003) and while a number of projects are currently being implemented and planned there is no data available about the efficacy (or safety) of these disciplines within their holistic model. The only way to objectively evaluate these disciplines in the interim is to focus on their major therapeutic tools. The limitation of this approach is that the effectiveness of a specific therapeutic tool, such as a nutrient or herbal medicine, is a poor reflection of the complex clinical interaction that occurs in a whole practice setting. In clinical practice a CM practitioner will utilise multiple therapeutic tools, which will be accompanied by dietary and lifestyle assessment and advice, patient education and counselling. The specific therapeutic tools reviewed here are not used exclusively by CM practitioners and the use of these substances falls under the purview of many health professions with the research generally being undertaken outside the holistic context of CM practice.

The scientific literature reviews were restricted to meta-analyses and systematic reviews of randomized controlled trials as the magnitude of individual research studies and reports in a number of the review areas precluded any other approach within the time frame for this review. The extensive body of peer reviewed literature covering *in vitro* and experimental research into these modalities, such as the broad ranging pharmacological research in CM and neurophysiological research in acupuncture, has not been incorporated into this review.

Articles on alternative medicine formed 0.4% of MEDLINE listed articles for the period 1966-96, however, the annual total is steadily increasing (WHO, 2002a). There has been a growth in new journals that focus on CM and also the development of CM sections in established medical journals. There are growing numbers of randomized controlled trials (RCTs) with information on 5,000 randomized controlled trials involving CM available through the Cochrane collaboration [118].

Significant economic and health benefits have been achieved through the research of complementary medicine. The World Health Organization calculates that overall, 25% of modern medicines are descended from plants first used traditionally (WHO, 2002b). Furthermore, sixty one percent of the new chemical entities introduced as drugs during 1981-2002 can be traced to or were inspired by natural products [130].

A.2 Search methodology

Preliminary literature searches determined that the total number of citations on most of these subjects was beyond the scope of the review and that a sub-set of these citations would be required. A simple search on Medline, the medical database of the National Institutes of Health, on the term "complementary medicine" gives over 97,000 citations in March 2005. A logical choice for the sub-sets was to utilise only meta-analyses and systematic reviews which are the highest levels of evidence, and this was the source data used for the reviews. It was decided that a systematic approach to the literature would provide an objective understanding of the type and range of literature demonstrating benefits for the modalities reviewed here. The systematic approach would also be more random in identifying papers, which appeared appropriate for an objective review of

the literature. The development of an objective methodology that could be replicated independently was chosen for these reasons.

In order to identify published systematic reviews and meta-analyses for each of the modalities under review computerized English language literature searches were performed using both the Medline and EMBASE Drugs and Pharmacology electronic databases using thesaurus terms and free text. In the case of naturopathy, western herbal medicine and nutritional supplements searches were limited to the period 2001 to 24 February 2004. For the remaining modalities both databases were searched from the dates of inception (1966 for Medline and 1990 for EMBASE) to December 2004. Bibliographies were hand-searched for further relevant publications. The Cochrane library was also searched for reviews.

To assist in the presentation of the data, the papers were clustered into the body system most appropriate to their research question and a brief summary of modalities with positive outcomes is included here. Key systematic reviews papers are summarised in Appendix B.

A.3 Nutritional supplements

There were 38 meta-analyses and systematic reviews on nutritional supplements. There is a substantive body of clinical trials that demonstrate the efficacy of nutritional supplements. These benefits run across a wide range of conditions and body systems. Key examples include:

Cardiovascular

A meta-analysis of the effects of N-3 polyunsaturated fatty acids on coronary disease demonstrated that they lowered the risk of fatal myocardial infarction (30%), sudden death (30%) and overall mortality (20%) (Bucher et al. 2002).

Gastrointestinal

A meta-analysis of RCTs on the role of probiotics in the prevention of antibiotic associated diarrhoea was undertaken using nine studies (D'Souza et al. 2002). It found a 60% reduction in relative risk. A meta-analysis of 18 RCTs on the use of probiotics in the management of acute diarrhoea in a paediatric population demonstrated that probiotics reduced the days of diarrhoea by 0.8 days (Huang et al. 2002). Another meta-analysis investigated studies specifically undertaken on *lactobacillus* for the same condition and population (Van Niel et al. 2002). It found that *lactobacillus* supplementation reduced the duration of the diarrhoea by 0.7 days and the frequency on day 2.

Neurological

Twenty-one RCTs were reviewed using a meta-analysis and showed that acetyl-L-carnitine produced a significant positive effect over placebo in mild cognitive impairment and mild Alzheimer's disease (Montgomery et al. 2003). A systematic review of the efficacy of melatonin for the treatment of insomnia in elderly subjects included six RCTs (Olde Rikkert and Rigaud. 2001). Sleep latency (time between subject's self-appointed sleep time and sleep onset) decreased significantly in four studies and sleep efficiency (the percentage of time that the subject was in bed following sleep onset that was spent asleep) increased in three of the studies.

Musculoskeletal

A meta-analysis of 15 RCTs was undertaken to determine the efficacy of glucosamine sulphate and/or chondroitin sulphate on knee osteoarthritis (Richy et al. 2003). A significant positive effect was found for glucosamine when compared with placebo for the radiological evolution of osteoarthritis. For the pain and physical function outcomes measure, the results for glucosamine and chondroitin were combined, as there was no significant difference between them. The agents were effective across a range of validated measures. A meta-analysis of 11 randomised controlled trials (Soeken et al. 2002) examined the safety and efficacy of S-adenomethionine (SAMe) for the treatment of osteoarthritis. The analysis found that SAMe produced an improvement in physical function when compared with placebo. When SAMe was compared with NSAIDs, they were found

to be equivalent for both pain and physical function. A review of safety found that subjects treated with SAMe were 58% less likely to experience side effects when compared with subjects taking NSAIDs.

A systematic review (Soeken et al. 2003) of herbal medicine in rheumatoid arthritis (RA) found 14 RCTs that met the inclusion criteria, most of which were herbs which had only one study. A meta-analysis on two studies of gamma-linolenic acid (GLA), showed significant improvements in pain, tender joint count, swollen joint count and stiffness compared with placebo. Only the swollen joint count failed to reach significance. The review concluded that GLA has moderate support in the treatment of RA.

The prevention of postmenopausal osteoporosis by calcium supplementation was examined in a meta-analysis of 15 RCTS (Shea et al., 2002). The change from baseline was significant after two years for total bone density (BD), for lumbar spine BD, hip BD and distal radius BD.

Female Reproductive
Eleven randomised, placebo controlled studies were reviewed in a meta-analysis to define the effect of calcium supplementation for the prevention of pre-eclampsia (Hofmeyr et al. 2003). Calcium significantly reduced the risk of high blood pressure by 19%. This effect was higher (55%) in women with a high risk of hypertension and with low baseline calcium levels. Calcium also significantly decreased the risk of pre-eclampsia by 32% and there was a higher effect in subjects with high risk of hypertension and low calcium levels. A smaller number of babies with a birth weight less than 2.5kg were born to subjects who were supplemented with calcium.

A review of RCTs and systematic reviews investigated the role of nutritional interventions during pregnancy in reducing maternal morbidity, mortality and preterm labour (Villar et al. 2003). They determined that vitamin A and β-carotene reduce maternal mortality, that calcium supplementation is beneficial for women with low calcium intake and a high risk of pre-eclampsia, that fish oil and magnesium may prevent preterm labour and that iron and folate are effective for preventing and treating severe anaemia, even postpartum.

A.4 Western herbal medicines
There were 34 meta-analyses and systematic reviews on herbal medicines. Key examples include:

Cardiovascular
A systematic review (Hermansen et al. 2003) of the evidence for the effect of soy and other natural products on lipid parameters showed that a meta-analysis of 38 RCTs on soy products demonstrated that they decreased levels of total cholesterol, LDL and triglycerides by 9%, 13% and 11% respectively. Studies from seven clinical trials on soy products with high levels of active constituents reported significant reductions in LDL cholesterol from 4-21%. Positive results were also found for psyllium (6-7% reduction LDL), oat bran with high levels of beta-glucan (2-17% reduction on LDL) and plant sterols (4-18% reduction in LDL). Small reductions in LDL were found from a meta-analysis of 67 clinical trials on dietary fibre. A systematic review on the effect of artichoke extract on total cholesterol levels found two studies that fulfilled inclusion criteria (Pittler et al. 2002). One study demonstrated an 18% reduction in total cholesterol.

A meta-analysis of eight randomized controlled trials using hawthorn (*Crataegus oxycanthia*) extract to assess its effect in congestive cardiac failure demonstrated it was more effective than placebo in maximal workload using bicycle ergometry (Pittler et al. 2003). The adverse events were mild and the authors concluded that it was a safe and effective adjunctive treatment for this condition.

A meta-analysis of 13 RCTs was undertaken on horse chestnut seed extract (HCSE) in the treatment of chronic venous insufficiency (Pittler & Ernst. 2002). The study demonstrated that HCSE reduced leg volume by 46.4 ml, increased the likelihood of improvement in leg pain by 400%, and increased

the probability for improvement for oedema 150% and 170% for itching in comparison to a placebo. Adverse events were mild.

Gastrointestinal
A meta-analysis of a proprietary herbal preparation (Iberogast) in functional dyspepsia included four RCTs (Gundermann et al. 2003). A clear and highly significant therapeutic effect was found with minimal side effects. A systematic review of herbal medicines in the treatment of non-ulcer dyspepsia was undertaken in 17 trials (13 on combination herbs and four on single herbs) (Thompson Coon & Ernst. 2002). There was an improvement in symptom scores ranging from 60% to 95% compared to baseline and/or placebo or the comparator drug, with few reports of adverse events.

Neurological
A two-stage meta-analysis of 22 RCTs on the effects of St. Johns Wort (*Hypericum perforatum*) in depression (Whiskey et al. 2001) showed St John's wort to be significantly more effective than placebo. A sub-analysis of studies that fulfilled the intention to treat analysis and adhered to predefined inclusion criteria (age, diagnosis, depression scores) was performed (n=6 placebo and n=4 active comparator trials). This sub-analysis in more rigorous studies demonstrated that St John's wort was more effective than placebo and similarly effective to standard antidepressants. Adverse events were mild and transient with fewer reports than for standard antidepressants.

A meta-analysis of the effects of *Ginkgo biloba* on cognitive impairment and dementia was undertaken on 33 RCTs (Birks et al. 2002). The analysis showed benefits associated with Gingko (dose less than 200mgs daily) compared with placebo at less than 12 weeks when measuring clinical global improvement (15.32, 95%CI 5.9-39.8, p=<.0001). Benefits were also noted when the dose was higher than 200mgs/day measured at 24 weeks. The authors concluded that Gingko appears to be clinically safe, with encouraging evidence regarding efficacy especially in improving cognition and function.

A meta-analysis of *Kava* extract for treating anxiety was undertaken on 11 RCTs (Pittler and Ernst. 2003). This analysis showed a significant reduction in anxiety in subjects receiving the study treatment compared to placebo.

Musculoskeletal
A systematic review of herbal medicines for the treatment of osteoarthritis found 12 RCTs and two systematic reviews that fulfilled the inclusion criteria (Long et al. 2001). The results showed promising evidence for the efficacy of Articulin-F, Capsaicin, Devil's claw, Reumalex and Willow bark in osteoarthritis, and a reduction in the consumption of NSAIDs in the use of ASU extract of avocado and soya bean. Adverse events were mild and transient including gastrointestinal symptoms, pruritus and headache. Capsaicin caused temporary burning pain on application in some patients. It was concluded that the herbal remedies reviewed could offer a viable alternative in the treatment of osteoarthritis.

Male Reproductive
A meta-analysis on the effects of saw palmetto (*Serenoa repens*) for benign prostatic hyperplasia identified 21 RCTs that met the inclusion criteria (Wilt et al. 2002a). Results showed that treatment with *Serenoa repens* improved urinary symptoms and flow measures compared with placebo. Adverse events were mild, transient and infrequent. A meta-analysis of the effects of *Pygeum Africanum* for benign prostatic hyperplasia identified 18 RCTs that met the inclusion criteria (Wilt et al. 2002b). Subjects taking the study medication were twice as likely to report an improvement in urological symptoms, with a 19% reduction in nocturia, 24% reduction in residual urine volume and a 23% increase in peak urine flow for individuals taking *Pygeum Africanum* compared to placebo.

Renal
A systematic review of the effect of cranberry products in the prevention of urinary tract infections (UTI) found seven RCTs that met the inclusion criteria (Jepson et al. 2001). They included studies on cranberry juice (5), cranberry tablets (1), and both juice and tablets (1). The reviewers concluded that cranberry products might reduce the number of symptomatic UTIs in adult women over a 12-month period.

A.5 Acupuncture
Our examination of systematic reviews and meta-analyses on the efficacy of acupuncture revealed 37 papers that met the inclusion criteria from a total of 171 papers that were located.

Acupuncture trials provide sufficient evidence to indicate its potential benefit in treating dental pain and nausea with few related adverse effects. However, the reviews of acupuncture generally state the quality of studies is poor. Key examples of evidence include:

Musculoskeletal
A review of 5 RCTs and 1 high quality quasi-randomised RCT of acupuncture for the alleviation of lateral epicondyle pain indicates that acupuncture was more effective than the control treatment (Trinh et al. 2004). Three RCTs were identified for a review of the efficacy of acupuncture for fibromyalgia (Berman et al. 1999). Only one of the three studies was of high methodological quality and it suggests that real acupuncture is more effective than sham in improving fibromyalgia symptoms.

A meta-analysis of pain trials in 1998 concluded acupuncture to be superior to various control interventions (Ernst & White. 1999). In an earlier meta-analysis of acupuncture for chronic pain pooled results of many subgroups attained statistical significance in favour of acupuncture (Patel at al. 1989). Various potential sources of bias, including problems with blindness precluded a conclusive finding although most results favoured acupuncture.

A review of 16 trials of the effectiveness of acupuncture in acute dental pain concluded that acupuncture is effective in alleviating pain either during dental operations, following surgery or during experimentally induced dental pain (Ernst & Pittler. 1998). In 1998 Rosted also reviewed the effectiveness of acupuncture in dentistry (Rosted. 1998). Eleven out of 15 papers were in favour of acupuncture and have shown acupuncture to be better than sham acupuncture or having a similar effect as conventional treatment. All of the papers with the highest methodological quality were in favour of acupuncture. The review concluded that acupuncture is effective in the treatment of facial pain and temporomandibular dysfunction. A separate review of acupuncture for temporomandibular joint dysfunction also supported acupuncture as a symptomatic treatment (Ernst & White. 1999).

In 2001 a systematic review was performed by Ezzo to evaluate the efficacy of acupuncture in osteoarthritis of the knee (Ezzo et al. 2001). A total of 7 trials with 393 participants meet the inclusion criteria for the review. Four of the 7 studies were deemed to be of high quality. There was strong evidence that real acupuncture is more effective for pain than sham acupuncture.

Cardiovascular
Six controlled trials with 425 participants were identified and reviewed for summary evidence of benefit of acupuncture in stroke rehabilitation (Ernst & White. 1996). The review concluded that the studies, whilst methodologically weak, suggest that acupuncture may be a useful adjunct for stroke rehabilitation.

Neurological
A Cochrane review of the efficacy of acupuncture in hastening recovery and reducing long-term morbidity from Bell's palsy found 3 studies. These suggested a beneficial effect of acupuncture but the poor quality of the trials precludes firm conclusions (He et al. 2004).

A 1999 review of acupuncture for recurrent headaches found the existing evidence suggested that acupuncture has a role in the treatment of recurrent headaches (Melchart et al. 1999). In 2001 a Cochrane review on the efficacy of acupuncture for idiopathic headache concluded that the existing evidence supported the value of acupuncture in idiopathic headaches, however the quality and amount of evidence were not fully convincing (Melchart et al. 2001).

Gastrointestinal
A systematic review in 1996 of acupuncture for nausea and vomiting associated with chemotherapy, pregnancy or surgery showed that 11 out of 12 high-quality trials with nearly 200 participants showed an effect in favour of acupuncture (Vickers, 1996).

A.6 Chinese herbal medicine
Nine relevant systematic reviews were identified. Examples of potential benefits of Chinese herbal medicine include:

There appears to be moderate evidence for beneficial effects associated with low side effect profiles from the use of Chinese herbal medicine for the treatment of hepatitis B and possibly atopic eczema. However, the lack of scientific rigour associated with clinical trials precludes a definitive answer at this time.

Hepatology
Four reviews reported on the use of Chinese herbal medicine in the treatment of hepatitis B. They conclude, albeit cautiously, that Chinese herbal medicine may be a safe and useful remedy for hepatitis B. A 2002 meta-analysis of RCTs on the use of Chinese herbal medicine in the treatment of chronic hepatitis B identified 27 RCTs that compared Chinese herbal medicine, alpha interferon or Chinese herbal medicine combined with interferon alpha in the treatment of hepatitis B. Chinese herbal medicine significantly increased seroreversion of HbsAg and was equivalent to interferon alpha in the seroreversion of HbeAg and hepatitis B virus. The review concluded that even though the RCTs were of poor methodology quality there was evidence of efficacy of Chinese herbal medicine in the treatment of hepatitis B and further more rigorous research is required (McCulloch et al 2002). An earlier systematic review of 22 RCTs (n=1947) showed a positive effect on the clearance of viral markers compared to placebo or no intervention. No significant difference was seen in the clearance of biological markers compared to interferon alone (Lui et al 2001).

Dermatology
A recent review of four randomised trials concluded that Chinese herbal medicine might have some benefit in treating atopic eczema (Zhang et al. 2004).

A.7 Chiropractic and osteopathy
Examination of systematic reviews on the efficacy of chiropractic and osteopathy revealed 13 papers that met the inclusion criteria from a total of 77 papers located.

One review in 2001 of 9 RCTs (n=683) showed moderate evidence that spinal manipulation has a short-term benefit in the treatment of chronic headache and migraine (Bronfort et al. 2001). It was concluded that the treatment is more efficacious than massage in relieving cervicogenic headache and is comparable to the effects of commonly prescribed prophylactic medication. Subsequently in 2004, Bronfort reviewed the effects of non-invasive physical treatments on 5 categories of headache (migraine, tension, and cervicogenic, a mixture of migraine and tension and posttraumatic headache) in a total of 22 studies (n=2628) (Bronfort et al. 2004). The review concluded that spinal manipulation has some efficacy as a prophylactic treatment in the short-term management of migraine compared with amitriptyline. Cervicogenic headache responded to spinal manipulation in both the short and the long term compared to no treatment, and spinal manipulation is a more effective prophylactic treatment for cervicogenic headache in the short term compared to massage and placebo.

Gross reviewed the literature to determine the effects of manipulation and mobilisation alone or in conjunction with other treatments to improve outcomes for individuals with mechanical neck disorders (MND) (Gross et al. 2004). This review of 33 trials (n=1,974) showed that a combination of exercise and mobilisation or manipulation improved pain, function and global perceived effect for individuals with MND when compared with individuals who received no treatment.

Shekelle and Hurwitz (1992) investigated spinal manipulation for low back pain in a review of 25 RCTs (n=1500) (Shekelle & Hurwitz. 1992). The reviewers concluded that spinal manipulation is of short-term benefit to individuals with acute and uncomplicated low back pain. The data was not sufficient to make a judgement of the efficacy of spinal manipulation in chronic back pain. Ferreira and co workers (2003) also reviewed the literature on the efficacy of spinal manipulation in low back pain (Ferreira et al. 2003). They concluded that spinal manipulative therapy was slightly more effective than placebo or no treatment, massage or short wave therapy for non-specific back pain of less than 3 months duration.

A.8 Homeopathy

In 1991 Kleijnan, Knipschild and ter Riet published an assessment of 107 controlled studies for the efficacy of homeopathic intervention (Kleijnan et al., 1991). These reviewers concluded that despite the shortcomings of the research methods of individual trials, the meta-analysis demonstrated some evidence for the efficacy of homeopathy.

A meta-analysis by Linde et al (1997) examined 89 of 186 identified trials, the selected trials covering a total of over 10,500 patients (Linde et al. 1997). The authors concluded that the results of the meta-analysis were "not compatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo." However, the study suggested that there are few, if any, implications for clinical practice as "there was insufficient evidence that homeopathy is clearly efficacious for any single clinical condition."

A.9 Ayurvedic medicine

A total of 21 references were located, however only one systematic review on the efficacy of Ayurvedic medicine fulfilled the inclusion criteria.

Endocrine

A review by the Southern California Evidence Based Practice Centre examined Ayurvedic interventions for diabetes mellitus (Anonymous 2001). Thirty-five studies were included in the single review that met the inclusion criteria. The review concluded that there is evidence to suggest that the single herbs *Coccinia indica*, holy basil, fenugreek and *Gymnema sylvestre* and the herbal formulas Ayush-82 and D-400 have a glucose lowering effect and deserve further study. However, significant methodological shortcomings were observed.

A.10 General conclusions

This review of the benefits of complementary medicine was limited to an evaluation of the tools of practice. The evaluation of systematic reviews and meta-analyses has demonstrated that a substantive body of scientific literature exists. Pragmatic issues of time and resources demanded constraint of the review to a time-limited window of systematic reviews of randomised controlled trials. These reviews demonstrated that a number of the therapeutic interventions have strong evidence for their effectiveness.

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APPENDIX B SUMMARY OF KEY PAPERS

Nutritional supplements

Year	First Author	Condition	Treatment Studied	Number of RCTs and subjects	Primary Outcome	Principal findings
2002	Althuis MD	Glucose intolerance and Type 2 Diabetes	Chromium	RCT = 15 (n=618)	Glucose, insulin and glycated haemoglobin concentrations after intervention	No effect on nondiabetic subjects. Inconclusive results on diabetics
2001	Arnold LE	Adults with attention-deficit hyperactivity disorder	24 Alternative therapies	Not reported	Behavioural and psychosocial measures	Some alternative treatments effective but mainly in certain patients. More research required
2001	Benton D	Intelligence in children	Micronutrients	RCT = 22 (n=4,428)	Verbal and non-verbal measures of intelligence	Only children with deficiencies profit from supplementation
2003	Branch JD	Body composition variables and performance tasks	Creatinine	RCT = 100 (n=1,847)	Body composition variables and performance tasks	Short term creatinine is more effective for lean body mass with isometric, isokinetic and isotonic and upper body exercise. Creatinine does not improve running or swimming performance
2002	Brown KH	Growth in children	Zinc	RCT = 37 (n=2,637)	Body weight and height	Zinc supplementation improves both height and weight measures
2002	Bucher HC	Coronary heart disease	n-3 polyunsaturated fatty acids	RCT = 11 (n=15,806)	Fatal non fatal myocardial infarction and overall mortality	Intake of n-3 polysaturated fatty acids reduces overall mortality due to myocardial infarction and sudden death in patients with coronary heart disease
2002	Cremonini F	Antibiotic-associated diarrhoea	Probiotics	RCT = 7 (n=811)	Presence/ absence of diarrhoea	Results suggest strong benefit of probiotic administration on antibiotic-associated diarrhoea. Further data required.
2002	Dempsey RL	Strength	Creatinine	RCT = 16 (n=414)	Strength	Oral creatine supplementation combined with resistance training increases maximal weight lifted in young men. No evidence for older or female groups.
2002	D'Souza AL	Antibiotic-associated diarrhoea	Probiotics	RCT = 9 (n=not reported)	Number of subjects in absence of diarrhoea	Probiotics can be used to prevent antibiotic-associated diarrhoea. Further data required for the treatment of antibiotic-associated diarrhoea
2002	Gelenijnse JM	Hypertension	Fish oil	RCT = 36 (n=2,114)	Blood pressure	High intake of fish oil may lower BP, especially in older and hypertensive subjects
2002	Gorsky M	Premalignant oral lesions	Topical retinoids	RCT = 4 (n=61)	Clinical response to medication	Although direct application of higher concentrations of retinoic acid results in suppression of oral leukoplakias only, its use in the treatment of recurrent and persistent lesions may be justified. Further data required.

Year	First Author	Condition	Treatment Studied	Number of RCTs and subjects	Primary Outcome	Principal findings
2001	Hauselmann HJ	Knee osteoarthritis	Nutripharmaceuticals	RCT = 20 (n=1,515)	Pain	Glucosamine sulphate and chondroitin sulphate provide a small to moderate improvement in pain - function compared with placebo - and are comparable to NSAIDs without the adverse effects. Soybean/avocado unsaponifiable residues have a modest effect on pain but require further data.
2003	Hermansen K	LDL:HDL ratio and other lipid parameters	Soy and other natural products	RCT = 145 (n=7,105)	Lipid levels	The new soy-based supplements may play a valuable role in reducing cardiovascular risk
2003	Higgins JPT	Dementia and cognitive impairment	Lecithin	RCT = 12 (n=376)	Dependency, global impression, functional performance, behavioural, quality of life, cognitive function, effect on carer and death	Evidence from randomised trials does not support the use of lecithin in the treatment of patients with dementia, although some moderate effects were found.
2003	Hofmeyr GJ	High Blood pressure and related maternal and fetal neonatal adverse outcomes during pregnancy	Calcium	RCT = 11 (n=6,8641)	High blood pressure, pre-eclampsia, preterm delivery, low birth weight	Calcium appears to be beneficial for women at high risk of gestational hypertension and in communities with low dietary calcium intake. Further data required.
2003	Holdcraft LC	Fibromyalgia and related syndromes	Physical, homeopathic, herbal, nutritional and alternative treatments	RCT = 22 (n=1,116)	Stiffness, pain and quality of life measures	Some herbal and nutritional supplements have the best evidence for effectiveness with FMS.
2002	Huang JS	Acute diarrhoea	Probiotics	RCT = 18 (n=1,917)	Duration of diarrhoea in days	Bacterial probiotic therapy shortens the duration of acute diarrhoeal illness in children by approximately one day.
2003	Latham LK	Preventing falls and improving physical function of older people	Vitamin D	RCT = 13 (n=2,496)	Measures of strength, physical function or measure of fall frequency	Although there is insufficient evidence for vitamin D alone for improvement of the physical performance of older people, some data suggests a benefit from vitamin D combined with calcium supplementation. Further data required.
2003	Montgomery SA	Mild cognitive impairment and mild Alzheimer's disease	Acetyl-L-carnitine	RCT = 21 (n=1,479)	Cognitive measures	There is a significant benefit seen at 3 months and increasing over time, in both clinical scales and psychometric tests. Treatment was well tolerated.

Year	First Author	Condition	Treatment Studied	Number of RCTs and subjects	Primary Outcome	Principal findings
2003	Nissen SL	Lean mass and strength gains	Creatinine, HMB, Chromium, and Androstenedione/ DHEA	RCT = 48 (n=1,044)	Lean mass and strength	Creatine and HMB have data supporting their use to augment lean mass and strength gains with resistance training.
2002	Nye C	Autism	Vitamin B6/magnesium	RCT = 2 (n=20)	Compulsive behaviour, obsessive-compulsive behaviour, hyperactivity, impulsivity	Due to small numbers of studies, quality of studies and small sample sizes, no recommendation was advanced.
2001	Olde Rikkert MGM	Insomnia	Melatonin	RCT = 6 (n=95)	Sleep latency, Sleep efficiency, and wake time during sleep	There is sufficient evidence that low doses of melatonin improve initial sleep quality in selected elderly insomniacs. Further data required.
2001	Oppenheimer SJ	Iron deficiency anaemia	Iron	RCT = 11 (n=4,536)	Type and number of infections	Oral iron given as a supplement in nonmalarious areas may reduce infectious morbidity in disadvantages populations. Oral iron supplementation in the tropics in children has been associated with increased risk of clinical malaria and other infections including
2002	Papadimitro-poulos E	Osteoporosis	Vitamin D	RCT = 25 (n=4,017)	Bone density and fractures	Vitamin D decreases vertebral fractures and may decrease nonvertebral fractures.
2001	Pittler MH	Weight reduction	Guar Gum	RCT = 11 (n=174)	Body weight	Guar gum is not efficacious for reducing body weight
2003	Pittler MH	Weight reduction	Chromium picolinate	RCT = 10 (n=473)	Body weight	The meta-analysis suggests a relatively small effect of chromium picolinate for reducing body weight.
2003	Richy F	Knee osteoarthritis	Glucosamine and Chondroitin	RCT = 15 (n=1,775)	Joint space narrowing, WOMAC, Lequesne Index, visual analogue scale pain, mobility and responding status	This study demonstrates the structural efficacy of glucosamine and indistinguishable symptomatic efficacies for glucosamine and chondroitin. Further data required.
2003	Schwedhelm E	Systemic Oxidative Stress	Antioxidants	Not reported	Antioxidant status, lipid peroxidation, DNA damage, Protein damage	Antioxidants mainly derived from dietary sources show the greatest benefits in epidemiological surveys. In clinical trials several drugs and micronutrients have their potential to prevent further harm in secondary prevention. Further research is required.
2002	Shea B	Postmenopausal Osteoporosis	Calcium	RCT = 15 (n=1,806)	Bone densities and fractures	Calcium supplementation alone has a small positive effect on bone density.

Year	First Author	Condition	Treatment Studied	Number of RCTs and subjects	Primary Outcome	Principal findings
2002	Soeken KL	Osteoarthritis	S-adenomethionine	RCT = 11 (n=1,442)	Pain, functional limitation and AEs	SAMe is as effective as NSAIDs in reducing pain and improving function limitation in patients with OA without the adverse effects associated with NSAIDs.

2001	Stevinson C	Premenstrual syndrome	Herbal, physical and nutritional supplements	RCT = 27 (n=1,872)	Subjective rating, MDQ, POMS, diaries and symptom scales	On the basis of current evidence, no complementary/alternative therapy can be recommended as a treatment for premenstrual syndrome
2002	Van Niel CW	Acute infectious diarrhoea	Lactobacillus	RCT = 8 (n=765)	Clinical course of diarrhoea	The results suggest that Lactobacillus is safe and effective as a treatment for children with acute infectious diarrhoea.
2003	Vivekanathan DP	Cardiovascular disease prevention	Antioxidant vitamins	RCT = 12 (n=219,901)	Mortality and cardiovascular death	The lack of a salutary effect was seen consistently for various doses of vitamins in diverse populations. The results, combined with a lack of mechanistic data for efficacy of vitamin E, do not support the routine use of vitamin E.
2003	Villar J	Prevention and treatment of maternal morbidity and preterm delivery	Calcium, magnesium, fish oil, vitamins E and C, iron and folate and vitamin A,	RCT = 123 (n=not reported)	Pre-eclampsia, pregnancy hypertension, anaemia and haemorrhage related outcomes, maternal infection and obstructed labour/caesarean section	Iron and folate reduce anaemia. Calcium given to women at high risk of hypertension during pregnancy or low calcium intake reduced the incidence of pre-eclampsia and hypertension. Vitamin E and C and fish oil are promising for preventing pre-eclampsia and preterm delivery. Vitamin A and beta-carotene reduced maternal mortality in a large study. Further data is required.

Herbal Medicines

Year	First author	Condition	Treatment	Number RCTs and subjects	Primary outcome	Principal findings
2002	Pittler MH	Hypercholesteremia	Artichoke leaf	RCT =2 (n=167)	Reduction in total serum cholesterol	Limited evidence on efficacy ansafety
2003	Pittler MH	Chronic heart failure	Hawthorn extract	RCT=8 (n=632)	Mean change in maximal workload	Hawthorn has a significant benefit as an adjunct treatment in chronic heart failure.
2003	Thompson Coon JS	Hypercholesteremia	Herbal medicine products	RCT = 25 (n=1,430)	Reduction in total cholesterol between 10 and 33%	Potential hypercholesterolemic activity for herbal medicines tested, high safety profile for all herbs tested.
2003	Yeh GY	Glycemic control (diabetes)	Herbal medicine products	RCT = 58 Other = 0 (n=4,565)	Fasting and postprandial plasma glucose, glucose tolerance test response, insulin and C peptide levels, protein glycosylation, clinical insulin requirements	Insufficient evidence to show efficacy, however the herbs had a high safety profile.
2003	Spanier JA	Irritable bowel syndrome	Herbal medicines	RCT=7 (n=259)	None recorded	No therapy was supported by the results.
2003	Gundermann KJ	Functional dyspepsia	Iberogast	RCT=4 (n=592)	Changes in GIS sum score	Highly significant overall therapeutic effect of Iberogast.
2002	Thompson Coon JS	Non-ulcer dyspepsia	Herbal medicine	RCT=17 (n=1,808)	Changes in GIT symptoms	Potential for some of the herbs trialled to act in the relief of non-ulcer dyspepsia.
2001	Evans JR	Macular degeneration	Ginkgo biloba	RCT = 33 (n=3,278)	Changes in CGI scale, changes in ADL, changes in mood and emotional function,	Some evidence of improvement in cognition with use of Ginkgo biloba.
2001	Whiskey E	Depression	Hypericum perforatum	RCT=22 (n=2,736)	Hamilton depression scale	St John's wort was significantly more effective than placebo but not significantly different in efficacy compared with active anti-depressants. However there were less side effects with St John's wort compared to active antidepressants.
2002	Birks EV	Cognitive impairment and dementia	Ginkgo biloba	RCT =33 (n=3,278)	Clinical global improvement scale measuring cognitive function, functional performance, behavioural disturbance, global impression, quality of life, dependency, acceptability of treatment and safety	Promising evidence of improvement in cognitive function associated with Ginkgo biloba

Year	First author	Condition	Treatment	Number RCTs and subjects	Primary outcome	Principal findings
2002	Kasper S	Depression	Hypericum extract	RCT=3 (n=544)	Hamilton rating scale	Hypericum was effective in reducing the core somatic symptoms of depression as well as the insomnia and anxiety associated with depression more effectively than placebo.
2003	Pittler MH	Anxiety	Kava extract	RCT=11 (n=645)	Hamilton anxiety scale	Kava was concluded to be a safe and effective short term treatment in the management of anxiety.
2003	Hofmann D	Bronchial asthma	Dry extract of ivy leaves	RCT=3 (n=75)	Body plethysmographic and spirometric tests	Ivy leaf extract improved respiratory function in children with chronic bronchial asthma. Database insufficient to provide conclusive evidence, long-term efficacy unproven.
2001	Little CV	Osteoarthritis	Herbal medicines	RCT =5 (n=471)	Changes in pain, mobility, grip strength and usage of NSAIDs, changes in serum lipids and fatty acid levels. QOL measures	Convincing evidence for the efficacy and safety of avocado-soybean unsaponifiables, other treatments not recommended.
2003	Soeken K	Rheumatoid arthritis	Herbal medicine	RCT=14 (n=645)	Global symptom score, VAS pain., joint stiffness, tenderness, and swelling	Moderate evidence to support the use of y-Linolenic acid.
2001	Long L	Osteoarthritis	Herbal medicine	RCT=12 Systematic reviews=2 (n=1,063)	Global symptom score, VAS pain., joint stiffness, tenderness, and swelling	Some of the herbal treatments showed potential for efficacy.
2002	Borrelli F	Menopause	Cimicifuga racemosa	RCT=4 (n=226)	Improvements in the Kupperman menopause scale and Hamilton anxiety scale. Changes in the biochemical markers of menopause	Clinical efficacy of C. racemosa not proven
2001	Stevinson C	Premenstrual syndrome	Herbal medicine	RCT=7 (n=592)	MDQ. PMTS scale, VAS	No convincing evidence found
2002	Kronenberg F	Menopause	Herbal medicine	RCT=10 (n=962)	Serum hormone levels, intensity of hot flushes and the Kupperman index	Only Black cohosh demonstrated efficacy in relieving hot flushes.
2001	Kelly AJ	Child birth	Castor oil	RCT=1 (n=100)	Vaginal delivery not achieved within 24 hours, uterine hyperstimulation and increases in fetal heart rate, caesarean section and maternal or fetal death	Poor quality study, no conclusive evidence provide of efficacy.
2003	Huntley AL	Menopause	Herbal medicine	RCT=18 (n=1,295)	Physical and psychological symptoms of menopause	No conclusive evidence regarding efficacy of herbal medicines trialled, however Black cohosh provided promising results.

Year	First author	Condition	Treatment	Number RCTs and subjects	Primary outcome	Principal findings
2002	Wilt T	Prostatic hyperplasia	Serenoa repens	RCT=21 (N=3,139)	Urological symptom scores, urodynamic measures, residual urine volume, changes in prostate size, nocturia, overall improvement in health.	Serenoa repens provides mild to moderate improvement in urinary symptoms and flow measures. Long term effects are unknown.
2002	Wilt T	Prostatic hyperplasia	Pygeum africanum	RCT=18 (n=1,562))	Change in urinary symptom scale scores	Study treatment may be of use in the treatment of prostatic hyperplasia.
2001	Jepson RG	Urinary tract infection	Cranberries	RCT=7 (n=604)	Number of UTI in each group, microbiological confirmation of UTI.	Study treatment may reduce the symptoms of UTI, however evidence is unclear.
2002	Siebert U	Chronic venous insufficiency (CVI)	Horse chestnut seed extract (HCSE)	RCT = 13 (n=1051) 3 obser studies (n=10,725)	CVI related symptoms, leg volume, ankle and calf circumference, oedema, pain, sensation of tension, swelling, leg fatigue and heaviness, calf cramps and itching.	HCSE appears to be a safe and effective treatment for CVI
2002	Pittler MH	Chronic venous insufficiency	Horse chestnut seed extract	RCT=14 (n=941)	CVI related symptoms, leg volume, ankle and calf circumference, oedema, pain, sensation of tension swelling, leg fatigue and heaviness, calf cramps ar itching.	HCSE appears to be a safe and effective treatment for CVI.
2002	Jacobs BP	Liver disease	Milk thistle	RCT=14 (1,209)	Liver biopsy histology, biochemical markers and mortality data	Data too limited to allow recommendation on efficacy.
2002	McCulloch MB	Chronic hepatitis B	Chinese herbs	RCT=27 (n=not given)	Seroreversion of HbsAg, HbeAg, HBV DNA	Quality of studies poor, no conclusive evidence of efficacy or safety.
2003	Ernst E	Cancer	Mistletoe	RCT=10 (n=2,470)	Clinical outcome measures, biochemical markers, survival rate, quality of life.	Studies did not demonstrate efficacy of mistletoe.
2003	Martin KW	Antiviral agents	Herbal medicine	RCT=33 Non-RCT=8 (n=3,306)	Changes in serum levels HbsAg, HbeAg, HBV DNA, pain scores and healing of lesions	Overall positive results from herbs trialled, reviewers state t hat negative trials may not have been published.
2003	Kienle GS	Cancer	Mistletoe	RCT=16 (n=2,495) Quasi RCT=2 (n=155) Non-RCT=5 (n=1,896)	Clinically relevant outcomes including survival rate, quality of life, remission rate, disease free survival	Poor methodological quality, however some statistically relevant outcomes in 12 studies
2001	Liu JP	Hepatitis B	Chinese medicinal herbs	RCT=3 (n=307)	Viral and serum markers	Jianpi Wenshen recipe showed significant effects compared to interferon in clearing viral markers.
2001	Liu JP	Hepatitis B	Genus Phyllanthus	RCT=22 (n=1,947)	Serum HBV markers, conversion of HbeAg to anti-Hbe, biochemical response, liver histopatho-logy and quality of life.	Phyllanthus species had a positive effect in the clearance of serum HbsAg, validity of evidence reduced due to poor trial quality.
2003	Liu JP	Hepatitis C	Medicinal herbs	RCT=13 (n=818)	Virological and biochemical response, improvement of histological activity index, and quality of life.	No firm evidence supporting the use of medicinal herbs in the treatment of Hepatitis C.

Acupuncture

Year	First author	Condition	Number RCTs and subjects	Primary outcome	Principal findings
1989	Patel M	Chronic Pain	RCT=14 (n=740)	Pain	While few individual trials had statistically significant results, pooled results of many subgroups attained statistical significance in favour of acupuncture
1996	Ernst E	Adjuvant therapy in stroke rehabilitation	RCT=5 CCT=1 (n=425)	Various	Evidence that acupuncture is a useful adjunct for stroke rehabilitation is encouraging but not compelling.
1996	Vickers AJ	Antiemesis	RCT=33 (n=3123)	Nausea and/or vomiting resulting from cancer chemotherapy, surgery or pregnancy	Except when under anaesthesia, P6 acupuncture point stimulation seems to be an effective antiemetic technique
1997	Beecroft N	Schizophrenia	CCT=4 (n=unknown)	Various	Papers suggest that acupuncture and low power laser treatment may be as effective as chloropromazine in schizophrenia, however no scientifically sound conclusions can be drawn.
1998	Ernst E	Back pain	RCT=12 (n=unknown)	Pain	Acupuncture was shown to be superior to various control interventions although there is insufficient evidence to state whether it is superior to placebo
1998	Ernst E	Acute dental pain	RCT=11 CCT=5 (n=464)	Pain	Acupuncture is effective in relieving pain either during dental operations, following surgery or during experimentally induced dental pain in humans
1998	Rosted P	Dentistry (Analgesic, facial pain and temporomandibular dysfunction)	RCT=15 (n=unknown)	Not specified	Eleven out of 15 papers were in favour of acupuncture and have shown acupuncture to be better than sham acupuncture or having a similar effect as conventional treatment.
1999	Ernst E	Temporomandibular joint dysfunction (TMJD)	RCT=3 (n=340)	Clinical dysfunction index	Results suggest that acupuncture may be an effective therapy for TMJD, however none of the studies was designed to control for a placebo effect
1999	Berman BM	Fibromyalgia	RCT=3 (n=149)	Pain	Limited high quality evidence suggests acupuncture is more effective than sham acupuncture for improving symptoms of patients with fibromyalgia syndrome
1999	Melchart D	Recurrent headaches	RCT=22 (n=1042)	Clinical outcomes related to headache (e.g. pain, global assessment)	The existing evidence suggests that acupuncture has a role in the treatment of recurrent headaches, however the quality and amount of evidence is not fully convincing.
2001	Melchart D	Idiopathic headache	RCT=26 (n=1151)	Clinical outcomes related to headache (e.g. pain, global assessment of headache)	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.

Year	First author	Condition	Number RCTs and subjects	Primary outcome	Principal findings
2001	Ezzo J	Osteoarthritis (OA) of the knee	RCT=7 (n=393)	Pain	The existing evidence suggests that acupuncture may play a role in the treatment of knee OA
2004	Trinh KV	Lateral epicondyle pain	RCT = 6 (n=282)	Alleviation of lateral epicondyle pain	Acupuncture was effective in the short-term relief of lateral epicondyle pain
2004	He L	Bell's palsy	RCT=3 (n=288)	Number of patients with incomplete recovery consisting of cosmetically disabling persistent squelae of facial paralysis 6 months after onset	Three small studies in this review suggested a beneficial effect but the poor quality of the trials precludes firm conclusions.

Chinese herbal medicine

Year	First author	Condition	Number RCTs and subjects	Primary outcome	Principal findings
2001	Liu JP	Hepatitis B	RCT=9 (n=936)	Viral response Hepatocellular cancer Mortality	Chinese herbal medicine may have some efficacy in treating hepatitis B
2002	McCulloch MB	Chronic hepatitis B	RCT=27 (n=not given)	Seroreversion of HbsAg, HbeAg, HBV DNA	Quality of studies poor, no conclusive evidence of efficacy or safety.
200	Liu JP	Hepatitis C	RCT=13 (n=818)	Virological and biochemical response, improvement of histological activity index, and quality of life.	No firm evidence supporting the use of medicinal herbs in the treatment of Hepatitis C.
2004	Zhang W	Atopic eczema	RCT=4 (n=159)	Self rated clinical response Doctor rated clinical response	Chinese herbal medicine may have some efficacy in treating atopic eczema

Osteopathy and chiropractic

Year	First Author	Condition	Treatment	Number RCTs and subjects	Primary outcome	Principal findings
1992	Shekelle	Low back pain	Spinal manipulation	RCT=25 (n=>1500)	pain relief, improvement of function and global recovery	Short-term benefit in acute and uncomplicated low back pain.
1999	Kjellman	Neck pain	Chiropractic and physiotherapy	RCT=27 N not given	Pain, range of motion and activities of daily living.	Positive effect for some physical treatments
2001	Bronfort G	Chronic headache	Spinal manipulation (SMT)	RCT=9 (n=683)	Pain levels, duration, severity, frequency, improvement, use of analgesics, quality of life	Higher efficacy than massage in the treatment of cervicogenic headache
2003	Ferreira	Pain, disability levels, global perceived effect and return to work.	Spinal manipulation	RCT=27 (n=4007)	pain, disability levels, global perceived effect and return to work	spinal manipulative therapy was slightly more effective than placebo or no treatment
2004	Gross AR	Mechanical neck disorders (MND)	Manipulation and mobilisation	RCT=33 (n=1,974)	Pain relief, global perceived function, disability/function, patient satisfaction	Short and long term benefits from treatments for MND
2004	Bronfort G	Chronic recurrent headache	Non invasive physical treatments	RCT=22 (n=2,628)	Headache pain intensity, headache index, frequency, duration, improvement, analgesic use, activities of daily living, quality of life, functional health status, or patient satisfaction	Positive results for some non invasive physical treatments

APPENDIX C RESEARCHER SURVEY INSTRUMENT

SURVEY FORM

Thank you for agreeing to participate in the review of CM research in Australia. The purpose of the review is to provide recommendations to the Ministry of Science and Medical Research about the potential to improve capacity in CM Research in Australia and in particular NSW. The information you provide will contribute to the review. We would like you to complete a brief three page survey. The information we are seeking includes:

* Your thoughts on CM research and ways to improve capacity in this area.

* The number and expertise of your staff and students who are working in CM research and an estimate of the percentage of time they allocate to CM research.

* The level of infrastructure for CM research in your institution.

*The CM research productivity for your institution, including the specific area of CM research and the level of research collaboration.

If you are unsure whether a project is classified as CM research, please include it in the first instance. Please copy the forms if you require more space for any of your answers or insert rows as required in the electronic version.

Please email this response to r.priest@uws.edu.au, or FAX response (including contact details in case of the need for clarification) to Ms Ros Priest, the Centre for Complementary Medicine Research University of Western Sydney.
FAX (02) 9772 6810

NAME OF INSTITUTION (Research centre, faculty and university or department)

Staff member completing this form NAME Position title

Email Phone number

COMPLEMENTARY MEDICINE (CM) SURVEY

These questions relate to your ideas about how the capacity for CM research could be strengthened in Australia.

1. What is the potential for supporting future collaborative CM research (ie between institutions, with overseas researchers or research groups and with western scientists and medical professionals or groups)?

2. What are the best strategies to capitalize and promote CM Research within existing research structures (ie infrastructure and funding vehicles)?

3. What are the best ways of attracting international research funds?

4. How can CM research be better facilitated?

Please use this space to make any other comments about CM research capacity

Please complete the following table providing information about the number, and expertise of personnel and the % time related to CM research within your research group or institution
NB. No names are required

Table 1: Staffing and expertise

STAFF		**Position title and/or Academic level**	**Area of expertise (research clinical areas and / or discipline)**	**Tick if also a student listed below**	
Researchers	1				
	2				
	3				
	4				
	5				
Visiting Academics	1				
	2				
Research officer	1				
	2				
	3				
	4				
	5				
Administrative assistants	1				
	2				
	3				
RESEARCH STUDENTS		Student category (PhD, Masters, UG Honours)	Area of study	Scholarship (yes/no)	Scholarship source (eg University, Industry, Govt.)
	1				
	2				
	3				
	4				
	5				

Please list any specialist equipment, laboratory facilities held and specific CM research expertise and services offered by the institution

Please estimate the number of competitive CM grant applications (successful and unsuccessful) your CM research group has submitted each year since 2000.

2000
2001
2002
2003
2004
2005

If you have had <u>successful</u> CM research grants in the last five years please complete the details for these projects in the next table on pg 4.

Table 2. Successful research projects since 2000

Please use the codes below to complete this table

Specific CM therapy under research

1. Acupuncture/acupressure
2 Aromatherapy
3 Exercise -eg Alexander technique
4 Biofeedback
5 Chinese herbal medicine
6 Chiropractic
7 Homeopathy
8 Massage
9 Mind body eg meditation, relaxation, imagery, hypnosis
10 Nutritional or diet supplements eg vitamins
11 Osteopathy
12 Reflexology
13 Self help groups
14 Western herbal medicine
15 Other please specify

Funding source

1 NHMRC
2 ARC
3 DEST
4 Industry
5 NGO or charity
6 University/school
7 State Govt bodies
8 other (specify)

Broad Research Area

1 Basic science (laboratory)
2 Clinical research and medicine
3 Public health
4 Preventative medicine
5 Health services research
6 Infrastructure development

Broad Health Area (NHMRC)

1 Bone, joint and muscle diseases
2 cancer, cancer prevention and related disorders
3 Cardiovascular health and disease
4 Endocrine diseases and diabetes
5 Human genetics and inherited disorders
6. Infection and immunity
7 Injury
8 Liver, kidney and gastrointestinal health
9 Mental health and neurosciences
10 Reproductive health
11 Respiratory diseases
12 Social and environmental issues
13 other health issues diseases or conditions (pls specify)

Year funding awarded	Project Name	Specific CM therapy under research	Funding source	Dollar value of funding	Broad Research Area	Broad Health Area (NHMRC)	Research collaboration Please tick if this research involved the following types of collaboration		
							Collaboration with more than one research group or research institution in Australia	Collaboration with overseas researchers	Collaboration between CM researchers and western clinical researchers or medical trained people