Complementary Medicine Research
a snapshot

Summary of findings
based on work commissioned by
The NSW Ministry for Science & Medical Research

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Introduction

Nationally, an estimated $2.3 billion was spent in 2000 by Australians on complementary medicine (CM) products and therapists. Half to three quarters of Australians use a CM product each year and between 15-30% visit a practitioner. The growing utilisation of products and therapists has led to an increased focus by Government, conventional medical and complementary medicine practitioners and the public on the evidence base for the efficacy and safety of products and therapies. There is also significant interest in the evidence for CM products and therapies to address the burden of disease.

In 2005, the NSW Office for Science and Medical Research commissioned a short review of complementary medicine research in NSW, which was undertaken by Professor Alan Bensoussan from the Centre for Complementary Medicine Research at the University of Western Sydney and Professor Stephen Myers from Southern Cross University.

The review was undertaken to gain an understanding of current research activities relating to complementary medicine and opportunities to further research and development where its role and efficacy is proven.

To place research into complementary medicine in context, Professors Bensoussan and Myers provided an overview of the size and value of the complementary medicine industry; workforce profile, training and regulation; use and evidence for efficacy.

This paper provides a summary of the review findings. It is provided to participants in the November 2006 *Complementary Medicine: Future Directions Forum* to aid discussion in developing strategies to build industry and research capacity in NSW and more broadly; across Australia.

The paper contains an overview of the scope and definition of complementary medicine and a snapshot of:

- The size and value of the industry
- Incidence of use
- Funding sources & profile
- Research capacity & activity
- Workforce profile
- Regulation
- Integration of complementary & mainstream medicine
- Challenges in developing the scientific evidence base
- Evidence of efficacy, safety & cost-effectiveness

Scope & 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. As with other health professionals, individual jurisdictions have responsibility for regulating practitioners. Currently, only chiropractic and osteopathic medicine practice are regulated Australia wide and Chinese medicine practice is regulated in Victoria.

The term *complementary medicine* is a broad term pertaining to the field in general. The term *complementary medicines* refers 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). In contrast to the clear definition of complementary medicine products, there is no precise definition of CM and it is usually defined in terms of what it is not, i.e. not orthodox or conventional medicine. Terms include 'natural medicine', 'non-conventional medicine' or therapies, 'holistic medicine', 'complementary therapies', 'alternative medicine', 'unorthodox therapies', 'integrative medicine' and 'traditional medicine'.

In the United States, the National Institutes for Health 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.*

The boundaries between the CM domain and the dominant medical domain are also not always fixed or sharp. What constitutes CM varies of over time, place and culture, as does the degree of integration with mainstream health. The soft definition of CM and its boundaries 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.

Table 1

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

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.

Size & value of the industry

Synopsis: The estimated value of the Complementary Medicine (CM) industry in Australia is $1.5 to $2.5 billion per annum, comprised of $1-2 billion in CM products with CM services accounting for an additional $600 million (excluding insurance, research and investment in infrastructure). The industry continues to grow steadily at approximately 10% per annum. 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 CM medicine products and services is expected to increase.

Data sources

Precise information on the size of the complementary medicines (CM) market is not currently available for a number of reasons, including:

- Lack of a separate CM sector in Australia Bureau of Statistics (ABS) market data, with information dispersed among food, grocery, pharmaceuticals and cosmetics
- Availability of complementary medicines through a range of sources, including a variety of therapists and 'over the counter' products.
- Because of the diversity in CM modalities, there is no one representative body that collects industry data.

Estimates of the value of the CM industry have therefore been calculated using sales of products obtained from manufacturers and distributors, and extrapolations from consumer surveys.

The Australian market and producers

Extrapolating from a South Australian survey, it was estimated that by the year 2000, Australians were spending $1,671 million on CM products and $616 million for CM therapists. 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. Overall expenditure was $2.3 billion 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.

Pharmacy and grocery store sales also provide an indication of market size and sales trends. Pharmacy sales of dietary supplements including herbal, vitamins and minerals and other products have steadily increased since 2000. Pharmacy sales of dietary supplements were estimated to have increased by 10.4% in the 12 months to December 2002. 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%.

In 2004, $350 million was spent on vitamins, minerals, dietary supplements and herbals in grocery stores. Mayne 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 organisations with only three turning over more than $50 million per year. Most are not listed on the stock exchange. There are nine sizable companies which primarily market CM products listed on the stock exchange (excluding major distributors of pharmaceuticals in Australia who also distribute CM products). Six of these companies are recent additions and several are in the top 100 performing listed companies. Only three of these companies produce solely CM products. An estimated 20% of Australian CM production is exported.

Australian therapist services

A 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.

The standardised expenditure for therapists increased by 62% from $309 million to $616 million between 1993 and 2000, primarily due to an increase in the frequency of use rather than cost of therapy.

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. 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.

The use of acupuncture by medical practitioners has significantly increased in Australia since the introduction of the Medicare rebate for its use in 1984. Reimbursements to doctors rose from $7.7 million the financial year 1984-85 to $17.7 million in 1996-97. However, this does not reflect the full extent of use as it is estimated that non-medical traditional Chinese medicine practitioners conduct twice as many consultations and Medicare claims cannot be made by non-medical acupuncture practitioners.

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

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 them. 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. Revised estimates in 2000 placed the size of the global market for CM at $US31.7 billion and growing by 11% annually. 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. However, in 2002 the Hong Kong Trade Development Council 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. 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. The production of raw materials for making herbal products has been recently estimated to be $US24 billion per year.

In 1997 the UK expenditure for CM based on extrapolations from consumer surveys was estimated to be £1.6 billion. 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 stabilise 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 reports regarding safety and efficacy of the products.

International therapist services

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 (from 427 million to 629 million). This exceeded the total number of visits to US primary care physicians. Expenditure on 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 expenditure for all US hospitalisations. The increases were due to an increase in the total number of people seeking CM rather than to an increase in the number of visits per person.

Incidence of use

Synopsis: Each year between 50-75% of the Australian adult population use at least one complementary medicine (CM) product and one in four Australians use CM services. There are in excess of fifteen million consultations nationwide each year in herbal medicine, naturopathy, acupuncture, chiropractic and osteopathy alone. Surveys indicate that CM is used for a 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. .

Australia

Surveys indicate the use of complementary practitioners and medicines in the Australian community is widespread and has risen significantly over the past three decades. In 2000 it was estimated that almost one in four Australians visited a CM practitioner every year.

The 2001 National Health Survey revealed 3.5% of the population (661,400) had consulted a CM practitioner in the two weeks prior to the survey (4.1% female and 2.9% male). The majority of consultations (423,800) were for persons aged 25-54 years. About 2% (387,900) of Australians consulted a chiropractor, 1% (129,800) a naturopath and 1.5% (177,300) an acupuncturist, herbalist, hypnotherapist or osteopath.

In 1996 it was estimated that there were 2.8 million consultations per year in traditional Chinese medicine and in 2003 1.9 million consultations per year in naturopathy and western herbal medicine. From these figures, it is estimated that there were 5 million consultations in 2005 in these three CM disciplines alone. An additional 10 million consultations are estimated to occur each year in chiropractic and osteopathy. In comparison, there are approximately 220 million Medicare claims per year for conventional medicine.

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. 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, people in Sydney being the most frequent users. By 2000 it was estimated Australians were spending $1.7 billion per annum, nearly four times the public contribution to all pharmaceuticals. This expenditure proportional to contributions to pharmaceuticals had almost doubled since 1993.

New South Wales

In 1998, 44% of a small convenience sample on the NSW north coast reported visiting a CM practitioner.

Queensland

A 2003 survey of 171 adults in Queensland found 36% regularly used CM practitioners, the most common being a naturopath.

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. These surveys made a clear distinction between self-prescribed complementary medicines and attending CM practitioners. 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 being most commonly reported. The use of CM practitioners increased from 20% to 23%, chiropractors being the most frequently used therapist in both surveys.

Overseas

In 2002, The World Health Organization (WHO) 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. WHO estimates of CM use include 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%.

United States

In the US there are now more CM than conventional medical consultations in primary care, while demand for, and expenditure on, CM doubled over the decade of the 90s. The most rapidly growing therapies were herbal medicine (380% increase) and high dose vitamins (130%).

A large population based survey was conducted as part of the National Health Interview 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. If prayer and the use of megavitamins are excluded, then 36% are using some form of CM each year.

Kessler et al (2001) investigated the long-term trends in conventional medicine use for three age cohorts in the US. The results found 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.

Canada

The Canadian national population health survey (1994-95) with a sample of 17,626 individuals estimated 15% of Canadians aged 15 and over (3.3 million people) used some form of alternative health care, chiropractic being the most common therapy used. It has also been estimated that 70% of Canadians have used CM at some stage.

United Kingdom

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

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.

Demographic characteristics associated with CM use

Women of child-bearing age and middle-aged individuals are currently more frequent users of CM. 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.

CM use is positively associated with increased education and wealth. 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. 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.

Use by groups with chronic diseases

Individuals with chronic diseases use CM more frequently than those without. It appears that these individuals are more likely to use CM in conjunction with orthodox medicine rather than replace it. Surveys indicate that CM is used for a broad range of conditions, with a focus on chronic diseases rather than acute care. 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. 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. Similarly, an Australian study of Traditional Chinese Medicine (TCM) users reported that 58% of people used TCM for rheumatologic or neurological complaints.

The use of CM by specific disease groups also 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. Results of a national survey of 925 Australian HIV/AIDS patients supported this trend.

In the US, 63% of cancer centre patients have been found to use at least one form of CM other than spiritual healing and physical therapies. Another survey of a random selection of 2,000 tumour registry patients found 75% had used at least one CM modality in the last 12 months.

CM use is reported to be high in cancer sufferers in Australia. A survey conducted in 1994 in South Australia indicated 46% of children with cancer had used at least one form of CM therapy. In 2001, 87% of children admitted to a major hospital in South Australia had been exposed to one alternative therapy with 17% having used six or more different CM therapies.

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. 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. 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.

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. Furthermore, CM therapy is believed to accommodate holistic values where the mind and body are seen as one, and increasing individualism means that more people are not prepared to accept the traditional authority of doctors. Surveys indicate that many participants believe they will receive greater attention from CM therapists. In general, CM therapies are perceived to be in keeping with self-management and notions of empowerment and control over one's own health. It allows the selection of health therapies in keeping with one's own belief systems.

Funding sources & profile

Synopsis: Government agencies and industry were surveyed and asked to identify funding programs potentially relevant to complementary medicine (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. In addition, researchers were surveyed about funded projects over the last five years. The data should be regarded as indicative given the limited timeframe for responses.

Government responses

National Health & Medical Research Council (NHMRC)

The NHMRC funds health and medical research through competitive grants and has several types of funding frameworks to which CM researchers can apply including Development (Industry) grants, Enabling grants, Project grants, People support and Program grants.

The NHMRC provided data on total funding for general medical research and a list of CM research applications. Since 1999, the NHMRC has received 9,710 research applications of which 62 (0.6%) were identified as pertaining to CM research (Table 1). Eight CM projects had been funded during this period, representing a success rate of 13%, significantly lower than the 25% success rate for NHMRC applications in general. In 2000-04 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. No funding was allocated to CM research by the NHMRC in either 2004 or 2005.

Table 1: NHMRC research applications and funding x year, 2000-2005

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 ($millions)	82.0	82.1	204.8	271.6	300.7	N/a	1,677.4
Total CM funding ($millions)	0.5	0.2	0.7	0.9	0.0	0	2.35 (2000-05)
% of NHMRC funding allocated to CM research	0.6	0.2	0.3	0.3	0	N/a	0.1 (2000-04)

CM grant applications were examined to determine which topic areas were of most interest to NHMRC applicants (Table 2). The three most frequently researched CM areas and the most successful for receiving funding were nutritional supplements, acupuncture and western herbal medicine.

Table 2: Research area of CM related NHMRC applications, 2000-2005

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

Targeted funding ($450.000) has recently been allocated for CM research. In response to the Expert Committee on Complementary Medicines in the Health System review, the NHMRC, in collaboration with the Commonwealth Department of Health and Ageing, called for applications for a 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.

Australian Research Council (ARC)

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. Programs include Federation Fellowships, the Discovery Program, the Linkage Program, Centres & Networks Funding and Special Research Initiatives.

The ARC provided a list of projects with relevant RFCD codes that had been funded since 2000 (application year 1999). Only one CM research project received ARC funding during the period 2000-04, 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 (Table 3).

Table 3: ARC research applications & funding 2000-2004

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)	N/a	N/a	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%	-

AusIndustry

AusIndustry provides a range of programs that are designed to assist Australian businesses to conduct research and development, including the Biotechnology Innovation Fund (BIF), Commercial Ready, Commercializing Emerging Technologies (COMET), Pharmaceuticals Partnerships Program, R&D Tax Concession and the Innovation Investment Fund.

Eleven CM projects were identified as being funded through the BIF program, with an average level of funding for each project of $250,000 (Table 4). 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.

Table 4: BIF funding for CM research, 2001-2004

	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

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.

Department of Education Science and Training

The Department of Education, Science and Training (DEST) provides research funding through a number of frameworks including block and competitive grants. None of the 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), Cooperative Research Centres (CRC) and International Science Linkages (ISL).

DEST were unable to provide detailed information about the level of funding provided to support CM research and 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, being 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.

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

CSIRO

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, including Health Sciences and Nutrition, Preventative Health and Molecular Science. One CM related projects identified was a collaboration being undertaken by the Molecular Science department on medicinal herbs related to cardiovascular disease.

NSW Department of State and Regional Development

The NSW Department of State and Regional Development (DSRD) has several development programs, including BioBusiness, Proof of Concept, Professional Leadership and Development, the New Export Opportunities program and the Australian Technology Showcase (ATS).

Two CM projects under *Proof of Concept* were awarded a total of $200,000 in the five years since 2000. The Department 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 also been marketed through the Australian Technology Showcase including Novogen Ltd, Ultraceuticals, Sunscreen technologies, and VRI Biomedical Ltd, which have developed new natural based products.

NSW Department of Health and Area Health Services

The NSW Area Health Services (AHS) were undergoing restructuring at the time of the review and the majority were unable to respond to the request for information within the timeframe required. Of those responding, it appears no systematic information was available on CM research. Other sources of information on AHS research funding in NSW were sought from the literature available on health research funding in NSW.

NSW Health provide research infrastructure funding of approximately $20 million per annum. However, none of this has gone to any CM organisation. NSW Health also administers a Research and Training program through the AHS including 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.

Industry responses

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 organisations 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 organisations 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."*

Researcher responses

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%) (Table 5).

Table 5: Funding x state as reported by CM researchers

Category	NSW	QLD	SA	VIC	WA	Total	% NSW
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
Total funding (%)	51%	7%	3%	33%	6%		

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 (Table 6). 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 (Figure 1). 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%) 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.

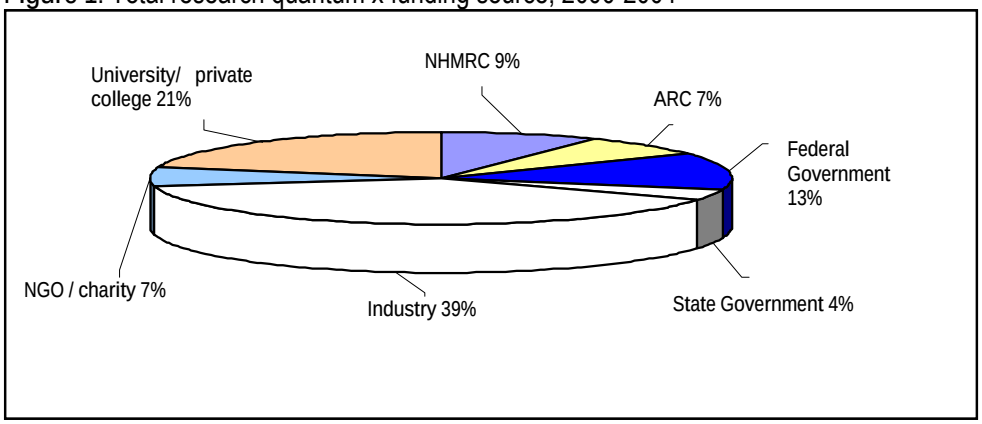
Table 6: Funding reported by CM researchers, government agencies and industry, all sources, 2000-2004

Source	Number of projects	Research quantum ($M)	% 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

Note: CM researchers reported only $1.8M of the $2.35M CM research funds identified by the NHMRC. Conversely, CM researchers reported $1.9M compared to $0.2M CM research funds identified by the ARC. The higher figure has been used for calculation in each case.

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."*

Figure 1: Total research quantum x 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.

Research capacity & activity

Synopsis: A survey was conducted of 104 organisations that were most likely to be undertaking complementary research CM research, including relevant university research centres, individual researchers, private CM education facilities, relevant professional associations and prominent Australian CM companies. Twenty-seven centres or individuals (of 104 approached) reported involvement in CM research. 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. Where possible the number of research staff, students, projects and level of research funding was calculated for the each State. Research themes, comments about infrastructure, funding programs, research capacity and priorities, collaboration and industry participation in research were obtained from the responses to the open ended questions. Additional information was obtained from centre websites.

Infrastructure for CM research

In response to the survey, twenty-seven centres and individuals ('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 organisation 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 (Table 1), suggesting a 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 (Table 1). 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.

Table 1: Research infrastructure x state as reported by CM researchers

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

According to CM researchers, NSW has the greatest number of funded projects with 104 (50%) in total, followed by Victoria with 55 projects (26%).

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 2). However, one NSW participant reported that research was not being carried out because of absence of funding for required equipment and facilities.

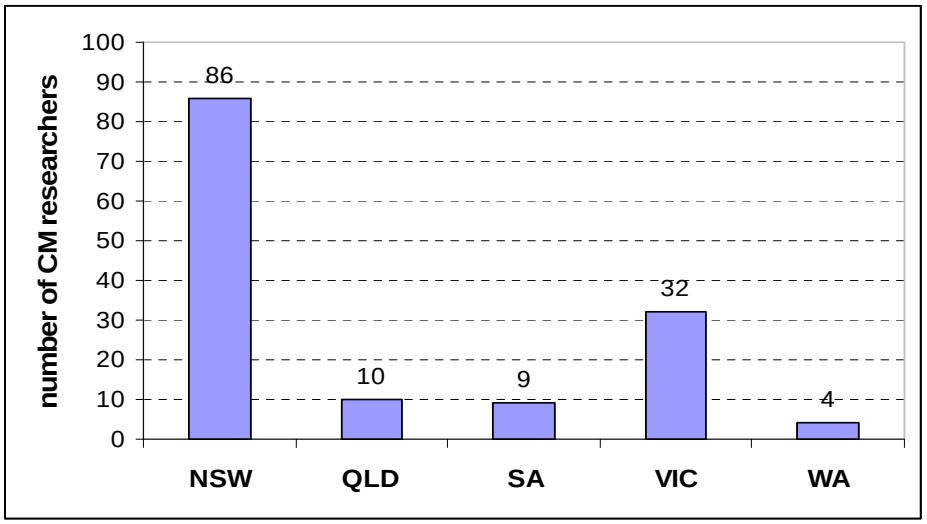
Table 2: CM research facilities x state

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.
VIC	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

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 (Table 1, Figure 1).

Figure 1: CM researchers x state

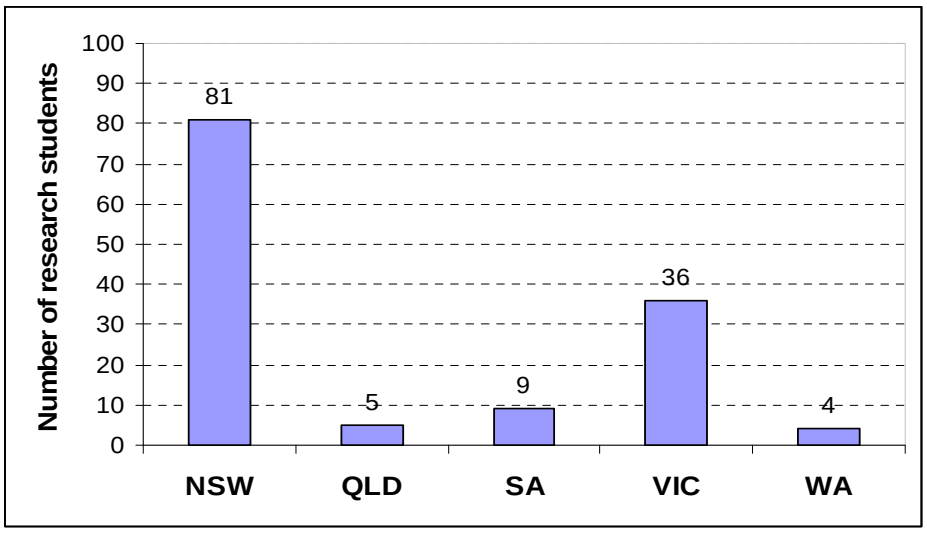


The number of research staff in CM research units ranged between 1 and 11 with most having two to three researchers. Centres with larger numbers of research staff, reported having researchers who worked on a part time basis or only contributed a small proportion of their time to CM research (5-50%). 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 (Table 1, Figure 2). 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 2: CM postgraduate research students x 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.

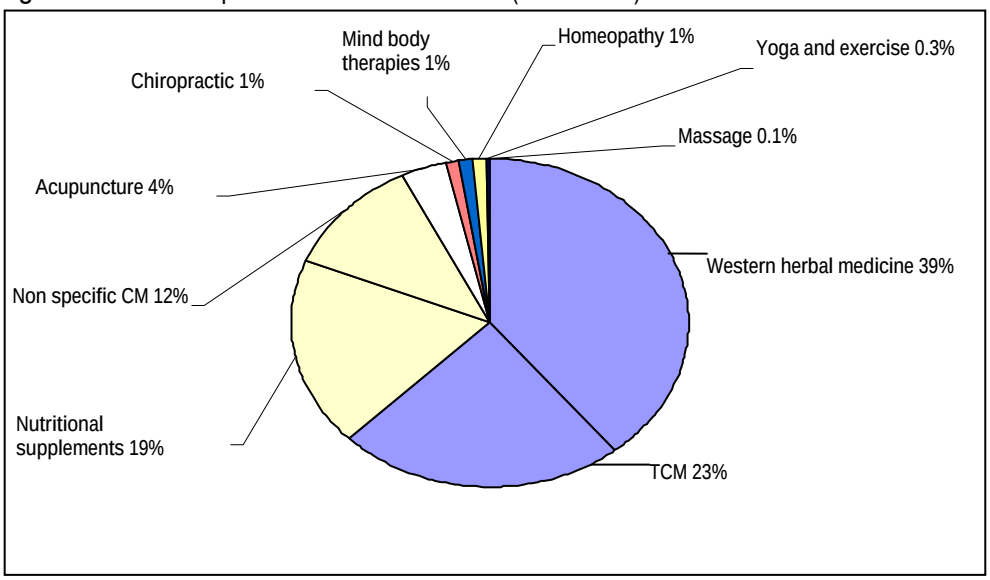
Research priorities

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 (Table 3, Figure 3).

Table 3: Research quantum and number of projects x field of research (2000-2004)

Specific CM therapy under research	% 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

Figure 3: Research quantum x field of research (2000-2004)



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 holistic 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.

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.

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.

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 Table 4.

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 (i.e. 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."*

Table 4: Collaborative research projects x state x type of collaboration as reported by CM researchers

		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	

With the 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.

Workforce profile

Synopsis: Over the last ten years complementary medicine (CM) has become increasingly established as a core university activity both in terms of teaching and research.

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. 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. Over one third of practitioners belong to more than one professional association making it more difficult to accurately estimate the CM workforce. 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. At the time it was estimated there were approximately 2,500 TCM practitioners in Australia. A similar survey of naturopathic and western herbal medicine associations estimated 3,117 practitioners. 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. 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%.

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. Since registration for TCM practitioners commenced in 2002 in Victoria there have been 984 applications, with 685 practitioners registered in 2002. 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.

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.

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.

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.

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. By 2000, 70% of employee sponsored health programs in the US covered chiropractic, 17% covered acupuncture and 12% covered massage. 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. There is some evidence that insurance coverage impacts on CM use.

Regulation

Synopsis: There is a trend overseas towards increased statutory regulation of CM practitioners and products although within Australia, with the exception of chiropractors and osteopaths, and TCM practitioners in Victoria, CM practitioners are currently largely self-regulated. However, there is increasing Government interest in practitioner regulatory options and improving regulation of products.

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 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; and
- 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. 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 – monopolising, tolerant and mixed.

Monopolising 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. Despite this, CM practitioners have fought and won battles against conventional care professional organizations due to the support of consumers. 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.

Australian regulation of complementary medicine products

CM products are primarily regulated by the Commonwealth government under the *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.[2] 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.

Integration of complementary & mainstream medicine

Synopsis: There is evidence of some integration between mainstream and CM practice. However, in addition to political issues, there are a number of ethical and legal issues affecting the rate of change.

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.

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. 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. 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. 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. Eighty five percent of pharmacists also believed that further training and information on CM is required for pharmacists.

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. Fifty-nine percent of general practitioners report an increasing patient demand for CM therapies. Fifty percent of general practitioners in one study had completed some form of CM training. Ninety-three percent of Victorian GPs reported referring clients to CM practitioners at least once.

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. 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.

International trends

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

In the US over 10% of hospitals and 65% of clinics offer both CM and orthodox modalities. Respected organizations such as the Arthritis Foundation and American Cancer Society provide information about CM to patients and health care clinicians. 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. Similar increases are described in the UK with a growing trend for National Health to pay for services of CM. 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.

The World Health Organization provides evidence of integration in other countries, as follows.

- 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.

Challenges in developing the scientific evidence base

Synopsis: Complementary medicine presents specific challenges in terms of research design that may require adjustment to standard mythological processes.

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. 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". 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.

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. 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. 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. 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". 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.

A further challenge is that to date, the benefits of many health practices under review 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 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 interaction between patient and practitioner (such as occurs with acupuncture and chiropractic) and combination of interventions presents challenges for clinical trials, e.g. in creating suitable placebos, and the effects of studying each component separately or in combination.

Evidence of efficacy, safety & cost-effectiveness

Synopsis: The major factor affecting complementary medicine (CM) utilisation by the community and its uptake into mainstream healthcare is the developing scientific evidence base for CM, in a context where evidence has now become a major driver of healthcare. Scientific literature exists demonstrating that some complementary medicine interventions have high level evidence for their effectiveness and 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, there remains a substantial gap between the current level of usage and the scientific evidence that supports it.

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. 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.

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.

Summary of efficacy

Given the time constraints involved, the review of available scientific literature was confined to meta-analyses and systematic reviews of randomised controlled trials in major modalities, including nutritional supplements, naturopathy, western herbal medicine, acupuncture, Chinese herbal medicine, chiropractic, homeopathy, and Ayurvedic medicine. It is therefore important to note that the data presented must be seen as a segment of the evidence supporting CM and not the totality of evidence available. Further, these CM interventions are generally prescribed as part of an individualised whole person approach to therapy while the review evaluates mainly the individual tools of the practice and therefore does not represent an evaluation of the effectiveness of these practices in totality.

Further details of individual modality effects are set below. In summary, the review found that: there is a substantive body of scientific literature on the efficacy of various CM interventions, in particular:

- 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 also clear from the review 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. A 2005 update of this data suggests that by 2050 the number of dementia patients will be 25% higher than projected in the 2003. It is currently estimated that 1,000 new dementia patients will be diagnosed each year in Australia. Severe dementia carries the highest disability weight for all illnesses, equal with severe rheumatoid arthritis and higher than that of final stage terminal cancer.

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."

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.

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. 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 the reviewers knowledge there have been no studies which have looked at the risk-benefit of CM therapy by itself or in conjunction with conventional therapy.

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. However, it is considered that the adverse reactions to CM therapies are poorly collected and are likely to be underestimated by these ADRAC figures. 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. 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. Another survey of 1,500 western herbal and traditional Chinese medical therapists conducted in 2002 found 243 adverse reactions since 1979. 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. 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.

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. 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 organisations. Treatments were compared for selected pathologies with the same degree of severity including: moderate osteoarthritis, back pain, anxiety neuroses, asthma, migraine headache and obesity.

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.

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. Similar cost saving results have been found for mind body self management techniques for arthritis and chronic pain. Acupuncture has also been shown to reduce pain, medication and even need for surgery in osteoarthritic patients waiting for knee replacement. Segal and colleagues 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.

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. 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.

Efficacy of individual modalities

Review findings of individual modalities are set out below.

1. 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 randomised control trials (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.

2. 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

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.

3. Acupuncture

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).

4. Chinese herbal medicine

Nine relevant systematic reviews were identified. 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).

5. 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.

6. 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.”

7. 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.

Notes -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.

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.