



## **Review of the Australian Government rebate on private health insurance for Natural Therapies**

Submitted by the National Herbalists Association of Australia

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## **Executive Summary**

### **Background and scope**

The main purpose of this report is to evaluate the current evidence associated with the practice of naturopathy and Western herbal medicine (WHM) in Australia. The substantial prevalence of use of naturopathy and WHM and the role of practitioners from these two professional groups in primary care and chronic care is also presented. To accurately verify the existence of evidence-based practice (EBP) principles with the complexities of naturopathy and WHM clinical decision-making and treatments, this submission encompasses a broad focus. This focus not only explores the current research associated with naturopathy and WHM practice according to NHMRC hierarchy of evidence guidelines, but also the professional infrastructure and research capacity in health service delivery within these two distinct but similar professional groups.

### **Infrastructure and research capacity**

The infrastructure supporting the continued application and growth of evidence-based practice (EBP) in naturopathy and WHM is highlighted and includes minimum education standards, the availability of baccalaureate and postgraduate coursework qualifications and continuing professional education opportunities such as seminars, conferences and publications. There is also support for research capacity building through the proliferation of peer-reviewed journals targeting research relevant to the practice of naturopathy and WHM alongside the existence of research organisations focused on the examination of a range of CAM including naturopathy and WHM.



## **Research evidence**

The current evidence for naturopathy and WHM is established in some areas and emerging in others. Whole systems research in naturopathy, arguably the most appropriate design for this philosophy-based practice, is emerging and the current findings reflect positive outcomes for a variety of health conditions. The research examining therapeutic tools such as nutritional medicine and herbal medicine is much more established and includes 21 articles providing NHMRC-defined level I evidence for cardiovascular disease in the last 2 years alone. The trend of this evidence indicates some benefit for the majority of conditions examined.

## **Recommendations**

Based upon this submission, it is recommended that the Minister of the Department of Health and Ageing continue to support private health insurance eligibility for naturopaths and Western herbalists. In addition, it is recommended that allocated funding be made available to support the continued examination of current and future practice of naturopathy and WHM.

## About the NHAA

The NHAA is a peak professional association representing appropriately qualified Western herbalists and naturopaths using herbal medicines as their primary treatment modality. It is the oldest professional association of complementary therapists, founded in 1920 with a current full membership of approximately 850 (our total membership is around 1200 including student and companion members). This represents approximately one third of practising Herbalists and Naturopaths in Australia. The NHAA is the only national professional association specifically concerned with the practice and education of Western herbal medicine (WHM) in Australia. Members are required to adhere to the Association's Constitution and the Code of Ethics (including standards of practice). Details of the Constitution and the Code of Ethics and Standards of Practice of the Association are detailed in Appendices 1 & 2.

The primary aims of the NHAA are to:

- Promote, protect and encourage the study, practice and knowledge of medical herbalism.
- Disseminate such knowledge by talks, seminars and publications.
- Encourage the highest ideals of professional and ethical standards.
- Promote herbal medicine within the community as a safe and effective treatment option.

The vision held by the NHAA for the professional practice of herbal medicine is summarised in the following statements.

- Practitioners and the practice of herbal and naturopathic medicine are fully integrated into the primary healthcare system in Australia.
- The NHAA is recognised as the peak body for herbal and naturopathic medicine.
- Herbal and naturopathic medicine is accessible to all.
- The integrity of the profession of Western herbal medicine and naturopathy is maintained.
- The standards and quality of education of the profession continue to be promoted.
- Career opportunities and research pathways for herbalists and naturopaths are created.
- The integration of traditional medicine and evolving science is continued.

The NHAA is governed by a voluntary Board of Directors. Full members of the Association elect the Board of Directors, with each board member serving a two-year term after which they may stand for re-election.



Full members of the NHAA have completed training in Western Herbal and Nutritional medicine sufficient to meet the educational standards as determined by the Examiners of the Board. These standards are set in consultation with tertiary educational institutions (standards in line with but exceeding the requirements of the NSW Health Training Package), and all members must adhere to a comprehensive Code of Ethics and Continuing Professional Education (CPE) program (see Appendices 2, 3 & 4). Membership consists of practitioners of Western herbal medicine who choose to use herbal medicine as their major modality of practice including Naturopaths, GPs, Pharmacists and Registered Nurses.

The NHAA publishes the quarterly *Australian Journal of Herbal Medicine*, a subscription journal covering all aspects of Western herbal medicine, and holds annual seminars on herbal medicine throughout Australia. An *International Conference on Herbal Medicine* has been held every 2-3 years since 1992.

Since its inception, the NHAA and its members have been at the forefront of herbal medicine and have been influential in areas ranging from education and practice standards, to government regulation and industry standards. The NHAA has a strong commitment to achieving high educational standards in herbal medicine practice and supports the regulation of the profession.

## The issue

It has been determined by the Australian government that the continued provision of private health insurance eligibility for naturopaths and Western herbal medicine practitioners should be dependent upon the evidence for efficacy, cost-effectiveness and safety of their practice.

## Background

### Defining Naturopathy and Western Herbal Medicine practice

Naturopathy is a system of medicine that is defined by a set of underpinning philosophies and principles. These include *primum non nocere* (first do no harm), *vis naturae medicatrix* (the healing power of nature), *tolle causam* (find the cause), *docere* (doctor as teacher), *tolle totem* (treat the whole person), *prevaneire* (prevention), and wellness (1.). It has also been defined by Australian regulatory training authorities by the therapeutic tools used by naturopathic practitioners with a primary focus on herbal medicine and nutritional medicine (2).

Herbal medicine has been practiced for over 2000 years throughout the world and dates back to the 4th century BC to the Greco-Roman era. (3) Modern herbal medicine practice derived from the traditional practices of herbalism in Europe, United Kingdom and North America, and as such this discipline is referred to as Western herbal medicine (WHM) (4). The philosophical principles that still underpin WHM practice today include a belief in a holistic treatment framework that believes in treating individuals within a wider social, emotional, economical, spiritual and cultural framework and, similar to naturopathy, adherence to the principle of 'first do no harm' (3). A workforce survey (5) of Australian naturopaths and herbalists sought to quantify the utilisation of therapies, products and treatments within practice. Their data suggests herbalists spend slightly more time applying herbal medicine in their practice (53.1%) compared with naturopaths (43.7%) but otherwise there is a similar amount of time spent using nutritional medicine (Herbalists: 41.7%; Naturopaths: 42.5%).

Herbal medicines can be found in a variety of forms including liquid herbal extracts, tablets and capsules. Most commonly liquid herbal extracts, or tinctures, are prepared using an ethanol or alcohol solvent although it is also possible for glycerol to be used in its place (6). Water extracts of medicinal herbs are also common and are more generically referred to as “tea”. The regulation of herbal medicines differs depending upon the form. The Therapeutic Goods Administration (TGA) regulates medicinal herbal products in the form of tablets, capsules and tinctures, leaving herbal teas unregulated beyond the guidelines applied to all food substances (7). For this reason, amongst others, naturopaths and herbalists more commonly recommend tinctures, tablets and capsules within their practice (8). All of these product forms generally involve a combination of a number of herbs either through proprietary formulations (e.g. pre-manufactured tablets and capsules) or extemporaneous dispensing (e.g. individualised herbal combinations of tinctures dispensed onsite) (6, 8). Consumers also have direct access to herbal medicines through retail outlets including pharmacy, health food stores and supermarkets (9). Today Western herbal medicine is increasingly being validated by scientific investigation, which seeks to understand the active chemistry of the plant along with other clinically relevant information such as efficacy, safety and toxicology, and dose. Herbal medicine also constitutes a substantial component of naturopathic practice and is the primary therapeutic tool for herbalists (5).

Naturopaths and herbalists may also use a therapeutic tool described as nutritional medicine or orthomolecular nutrition whereby they recommend and prescribe nutritional/dietary supplements such as vitamins and minerals to individuals to address identified deficiencies and assist with the management of diagnosed health conditions and general health complaints. This terminology and the associated approach to health has been attributed to Linus Pauling, the scientist renowned for his work with vitamin C (10). The use of orthomolecular medicine may include the use of individual nutrients, condition-specific proprietary formulations, or general multivitamins. The form of these supplements may vary from powders, tablets, capsules and intravenous/intramuscular injection. In general, the application of orthomolecular nutrition in naturopathic and herbal medicine draws on proprietary formulations regulated by the TGA, and similar to herbal medicines, consumers can access orthomolecular nutritional supplements direct from retail outlets such as pharmacies, health food stores and supermarkets (9).

## Prevalence of naturopathy and WHM use in Australia

Australian research indicates that more than two thirds (68.9%) of Australians have used at least one complementary and alternative medicine (CAM), and a similar number (64.0%) had visited CAM practitioners, in the previous 12 months including naturopathy and Western herbal medicine (16.3%) (11). Extrapolation of the data gathered through this research suggests 69.2 million visits to CAM practitioners are undertaken per year (11). Most of this CAM use is an out-of-pocket expense for users, with an estimated per capita annual expenditure of AUD\$182 on CAM products, and AUD\$264 on CAM practitioners, thereby contributing to an estimated total annual expenditure of AUD\$4.13 billion of which AUD\$1.73 billion is spent on CAM practitioners.

For more specific subsets of the Australian population, the prevalence of consultations with a naturopath or herbalist varies. A number of women will consult with a naturopath or herbalist for pregnancy-related health conditions (7.2%). (12) Individuals staying in hospital surgical wards report a substantially higher use of naturopathy (18.4%) and even greater levels of herbal medicine use (56.2%) (this figure does not differentiate from self-prescribed use of botanicals and engagement with a WHM practitioner) (13). This differs again for the population subgroups defined by demographics rather than health status such as middle aged women (45-50 years) who consult with a naturopath or herbalist (11%) (14).

## Role of naturopaths and Western herbalists in Australian health service delivery

### Naturopaths and Western herbalists as primary care practitioners

It has been reported that 1 in 3 Australians who use CAM practitioners consider them their primary care providers (15). In addition, naturopaths have been found to have a significant self-perceived primary care role (16). The use of CAM such as naturopathy and herbal medicine in primary care may be related to consumers' reduced confidence in the ability of conventional medicine to manage or treat the users' health condition effectively (particularly for those with chronic conditions), as well as concerns over possible adverse effects of pharmaceuticals and other interventions, and insufficient attention being paid to the social and emotional needs of individuals patients (17). This trend is particularly significant given the rates of chronic disease in Australia.

### Naturopathy and Western herbal medicine in chronic health care

Chronic diseases are classified by the Australian Institute of Health and Welfare (AIHW) as characterised by complex causality, multiple risk factors, long latency periods, a prolonged course of illness and functional impairment or disability (18). Current data suggests that >7 million Australians have at least one chronic condition (18), and these individuals were less likely to be in full time employment and were more likely to be unemployed and therefore not participate in the labour force compared with those without chronic disease (19). For those who do participate in the work force, there are significant economic costs associated with absenteeism (approximately 57,000 person years) and early death (113,000 person years). There were additional economic losses associated with chronic disease for individuals participating part time in the labour force. These figures do not represent reduced productivity while at work or the losses associated with those who participate in the unpaid labour force (carers, parents, and volunteers) and as such are likely an underestimate (19).

With this in mind, it is interesting to note the role that naturopaths and WHM practitioners have in the provision of care for individuals with chronic and significant health conditions. For example, results from a nationally-representative longitudinal study (20) has found that 22% of Australian women who identified with having depression consulted with a naturopath or herbalist, compared with 11% of women who did not have depression. This rate was higher (24%) for women who had experienced depression for a number of years. Similar results have been reported for women with cancer (15.7%), although it was clear from this analysis that naturopathy/herbalism was clearly used as an adjunctive treatment to conventional cancer treatment, a result not replicated in the examination of women with depression. International data supports this trend for conditions such as diabetes (21).

### **The application of evidence-based practice (EBP) in naturopathy and Western herbal medicine**

Historically, the practice of naturopathy and WHM has been informed by traditional knowledge (22). Since it was first described in the early 1990s, EBP has been asserted as the principal paradigm of health practice for modern times (23), and the professions of naturopathy and WHM have been moving towards the integration of EBP principles into clinical practice.

The validity of information sources and the process of critiquing their value is an important element in EBP, as is the evaluative process involved in appraising the relevance of the information available, and applying this information within different circumstances (24). Furthermore, in the application of EBP, health professionals are encouraged to place less value on their clinical experience and intuitive insights when making clinical decisions (23).

Although EBP places hierarchical priority upon information sources and levels of evidence (23), the experience and perceptions of professionals in clinical practice does not always reflect these priorities. Some commentators in conventional health professions have argued that there is philosophical incongruence between EBP and clinical reality (25-27). The growth in support for EBP has been inconsistent across many health professions including general practice (28) and nursing (29), with barriers to integration of EBP into health care delivery reported to be linked to time constraints, convenience of access, high quality and reliable research, and applicability of available information (28). Similar challenges are described by naturopaths and herbalists (30), although they do describe support for new research and discriminate against non peer-reviewed sources according to its validity and reliability (31). This support for EBP is also reflected in a survey of modern naturopathic and herbal medicine practice which suggests a substantial number of practitioners access peer-reviewed information sources to inform their clinical decision-making (32). In addition, a recent descriptive survey of a randomly selected nationwide sample of Australian CAM practitioners (n = 126) including naturopaths and Western medical herbalists, used the evidence-based practice attitude and utilisation survey (EBASE) to investigate attitudes to and knowledge of EBP (33). The researchers found that most practitioners believed EBP was useful (92%) and necessary (73%) in CAM practice.

## **The NHAHA submission: a broad focus for an accurate view of a complex professional practice**

It has been suggested by the World Health Organisation that it is important for health ministries to clearly target the population at large, and that recognising only those professions closest to the centralised health system may overlook some important players (34). Given the numbers of Australians consulting with a naturopath or herbalist it is clear that these professions are considered, at least by the general public, as important players.

Evaluation of the evidence for naturopathy and Western herbal medicine, in accordance with EBP principles needs to be considered in line with the NHMRC guidelines for levels of evidence (35). In addition, an accurate view of the application of evidence in practice requires a broader understanding of the factors that support and influence the application of EBP in naturopathy/WHM practice. With this in mind, and to counter the risks of tunnel vision when reviewing health policy described by the World Health Organisation (34), this submission highlights not only the current evidence but also applies a health services research (HSR)<sup>1</sup> approach to explore the infrastructure within naturopathy and Western herbal medicine professions which supports current and future application of EBP principles in clinical practice.

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<sup>1</sup>The definition of HSR is ever evolving with the latest Academy of Health (the professional organisation of the HSR field in the United States of America) definition stating “Health services research is the multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and cost of health care, and ultimately our health and well-being. Its research domains are individuals, families, organizations, institutions, communities, and populations.” 36. Lohr KN, Steinwachs DM. Health services research: an evolving definition of the field. *Health Serv Res* 2002;37(1):7-9.

## Responses and comments

### Professional infrastructure and research capacity in naturopathy and Western herbal medicine health service delivery

There is a growing body of evidence in research fields related to the practice of naturopathy and Western herbal medicine. Whilst this evidence-base may not be complete, it does reflect increased attention on the need for, and benefit of, empirical scientific data to supplement and extend knowledge derived from traditional information sources, a view also held by practitioners (30).

#### Evaluating health service delivery outcomes

A broader understanding of issues related to the evaluation of health outcomes from health service delivery has been highlighted in a recent study (37) that evaluated the application of appropriate care (defined as care in line with evidence-based or consensus-based guidelines) in health care in Australia. The study reported half of the care delivered in Australia was not in line with the agreed upon guidelines (38). This is of particular interest given the definition of “evidence-based” within this study included “level 4 evidence where necessary” (38), which according to NHMRC guidelines would be categorised as a “poor” evidence base (35).

However, as has been found with general practice (28), this does not undermine the positive effects within the population when primary care services are provided within the health system. Commentators have argued that a focus on diseases and treatments, rather than people, may do more harm than good (39). As such, evaluating primary care practice based upon the application of disease-specific evidence-based guidelines has been identified through numerous studies to deliver poorer quality care when compared with the practice of medical specialties (39). In contrast, the evaluation of functional health outcomes in the care of patients with chronic health conditions has identified similar outcomes at lower cost (39). Additional ecological research has expanded on this to find that primary care practice, despite having a lower rate of application of “evidence-based guidelines” is associated with lower cost, better health, and greater equity within the population (39).

A possible reason for this is the role of a primary care practitioner in ensuring appropriateness of care (39). This is particularly pertinent in the context of naturopathy and Western herbal medicine given the risks associated with incorrect self-prescription and drug-nutrient/drug-herb interactions (40-42). Consultation with a naturopath or Western herbalist trained in identifying potential interactions between herbal/nutritional medicines and pharmacological drugs reduces the risk associated with unqualified use or prescription of these medicines.



It has further been argued that “narrowly defined performance measures are likely to miss performance gaps for complex populations when poor access is the culprit rather than poor technical quality” (39). At present, there are significant equity issues related to naturopathic and Western herbal medicine care in Australia due to its exclusion from the universal health funding system (Medicare). The result of this privatised health-funding model is a link to care being more commonly accessed by individuals from higher socioeconomic backgrounds who have private health insurance (43). Given the emerging evidence of benefit associated with receiving naturopathic or herbalist treatments as presented in the following section, it is important that the potential value to the Australian population offered through access to naturopathic and Western herbal medicine care is not further hindered by removal of private health insurance rebates privileges.

Infrastructure supporting the continued application and growth of evidence-based practice in naturopathy and Western herbal medicine practice

These issues do not detract from the need to consider and apply current research in practice, within the context of clinical expertise and patient values (27), for naturopathy and Western herbal medicine. They also highlight the need for continued support within both professions for the capacity to integrate and apply findings from current and future research into clinical decision-making practices and the continued examination of traditional practices through further empirical research. The infrastructure and framework needed to achieve this is evident within the profession through a variety of areas including education, research, and capacity building.

*“Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research. Evidence-based medicine requires new skills of the physician, including efficient literature searching and the application of formal rules of evidence evaluating the clinical literature.” (23)*

The education standards of current and future graduates of naturopathy and Western herbal medicine, as required by the National Herbalists Association of Australia, requires the inclusion of discrete science and clinical science subjects alongside clear discussion of current research evidence. This requirement is evident in current baccalaureate curriculum through not only the integration of research evidence within reading lists and other learning material but also the inclusion of peer-reviewed and evidence-based textbook and online resources.



Alongside the overall attention to research evidence in current curriculum is the availability of baccalaureate (in naturopathy) and postgraduate coursework (in WHM) qualifications. As is inherent in the development and accreditation of such courses in Australia, graduates of these courses are expected to have been exposed to detailed discussion of research evidence and to develop the capacity for critical thinking. The combination of both of these factors encourages graduates who are not only abreast of current research but have the skills to critically evaluate new information (whether from research evidence or other non-empirical sources) in the future. This is an important attribute for the application of EBP.

Evidence-based practice also requires that practitioners are life-long learners. This attribute is not only encouraged through the courses described above but is supported after graduation through continuing professional education (CPE) opportunities. These opportunities are varied and include seminars, conferences and publications. The NHAA offers one major annual seminar, conducted in seven states/territories that equates to 10 hours of CPE. Additionally, the NHAA runs a biannual research conference, which typically includes the presentation of research through oral and poster presentation and workshops. The primary focus of both of these types of events is to assist practitioners to apply new evidence to practice.

### The support and development of research and research capacity building

Beyond the support provided by the NHAA to ensure the ongoing capacity for naturopathic and Western herbal medicine practitioners to integrate and apply EBP principles in their clinical practice, there are also a number of other resources focussing on research evidence for practitioners within these professions. These include not only a significant number of research journals dedicated to naturopathy, herbal medicine and related fields, but also easily accessed online research review sites. One such publication is the Australian Journal of Herbal Medicine (AJHM), which is published by the NHAA and has disseminated nearly 100 editions over the last 24 years drawn from international research (44). The AJHM is currently indexed to many health and medical research databases such as EBSCO, Elsevier, Thompson Gale, RMIT Informit and CABI. The publication also includes a summary of other new research evidence published elsewhere to maximise practitioners' exposure to emerging evidence relevant to naturopathy and Western herbal medicine practice.

Outside of the professional organisations such as the NHAA there are also other groups in Australia that are actively facilitating and supporting the development of an evidence-base for complementary medicines including those relevant to naturopathy and Western herbal medicine. One such organisation, based at the University of Western Sydney, is the National Institute of Complementary Medicine (NICM) (45), which prioritises clinically relevant research of CAM treatments and the translation of findings into practice and policy. Another newer research centre, based at University of Technology Sydney, is the Australian Research Centre for Complementary and Integrative Medicine (ARCCIM) (46), which was formed in 2012 to address the growing need for public health and health services research in complementary and integrative medicine. Research undertaken by ARCCIM focuses on complementary and integrative medicine practitioners, patterns of use and implications for practice and policy. Alongside these formal bodies, a well-established research group the Network of Researchers in the Public Health of Complementary and Alternative Medicine (NORPHCAM) (47), which is based in Australia but functions as a global body, also lists research capacity building amongst practitioners as one of their key objectives.

The culmination of the focus on evidence within the education of naturopaths and Western herbalists, the ongoing support from within the profession for the application of research into practice, and the activity of research groups and organisations which explicitly support research capacity building and translational research into practice is that of a multi-dimensional infrastructure supporting EBP for naturopaths and Western herbalists.

## **Research evidence of naturopathy and Western herbal medicine**

The exponential growth in the popularity of CAM has led to an increase in research into both whole systems of practice, such as naturopathy, and randomised controlled trials (RCTs) of individual treatments such as herbal medicines and nutritional supplements. This research has informed clinical practice and enabled consumers to make informed decisions about their healthcare.

### Naturopathy

Whole practice research (whole systems research), the study of complex CAM therapies at the systems level, as opposed to single-agent medicines or uni-dimensional effects (48), is an emerging field that aims to move beyond RCTs to more adequately evaluate the whole practice of a particular modality, and is therefore relevant to the practice of naturopathy. A PubMed database search located 12 whole practice research studies on the efficacy of individualised naturopathic treatment (Table 1) (49). This methodology has only relatively recently been incorporated into naturopathic research and as such is still evolving, however two whole practice research studies were found for cardiovascular disease (50, 51) and four concerning type-2 diabetes (49).

Table 1. Whole practice research examining health outcomes associated with naturopathic care

Year	Authors	Condition	Design, n	Principle findings
2012	Sealy et al (51)	Cardiovascular disease	RCT, n=246	3.6 percentage point reduction in 10-year cardiovascular risk and a 27.4% reduced prevalence of metabolic syndrome in the treatment arm, after one year of individualised care.
2012	Bradley et al (52)	Type-2 diabetes	Prospective study, n=40	At 6-months, significant improvement in glucose testing, diet, physical activity, mood, self-efficacy and motivation to change lifestyle. Mean HbA1c decreased by -0.90 % in the treatment cohort, a -0.51 % mean difference compared to usual care.
2011	Olberg et al (53)	Type-2 diabetes	Prospective observational pilot study, n=12	Improvements seen in HbA1c for all participants (mean - 0.4%).
2011	Murthy et al (50)	Hypertension	Clinical trial, n=104	A mean reduction of systolic blood pressure from 139.6 to 129.6 and 91.2 to 86.1 for diastolic blood pressure.
2009	Bradley et al (54)	Type-2 diabetes	Retrospective observational study, n=37	A -0.65% reduction in haemoglobin A1c (HbA1c), 0.51mmol/l reduction in triglycerides, -7mmHg reduction in systolic blood pressure and a -5mmHg reduction in diastolic blood pressure.
2009	Szczerko et al (55)	Tendonitis	RCT, n=77	Total Shoulder Pain and Disability Index scores decreased by 54.5% in the group receiving naturopathic care as opposed to 18% in the group doing standard physical exercises
2009	Cooley et al (56)	Anxiety	RCT, n=77	Final Beck Anxiety Inventory scores decreased by 56.5% in the group receiving naturopathic care as opposed to 30.5% in the group receiving standard psychotherapy.

<b>Year</b>	<b>Authors</b>	<b>Condition</b>	<b>Design, n</b>	<b>Principle findings</b>
<b>2008</b>	Shinto et al (57)	Multiple sclerosis	RCT, n= 45	Trend only towards improvements for participants in the naturopathic group in the General Health subscale of the SF-36, timed walk, and neurologic impairment.
<b>2007</b>	Szczurko et al (57)	Lower back pain	RCT, n=69	Significantly lower back pain was reported in the naturopathy group as measured by the Oswestry questionnaire. Quality of life was also significantly improved in this group in all areas except for vitality.
<b>2006</b>	Bradley and Oberg (58)	Type-2 diabetes	Retrospective analysis, n=55	All patients received dietary counselling, 69% were taught stress reduction techniques, and 94% were prescribed exercise in addition to herbal medicines and nutritional supplements as required.
<b>2004</b>	Secor et al (59)	Generalised pain	Prospective study, n=94	Significant reduction in pain.
<b>2003</b>	Cramer et al (60)	Menopause symptoms	retrospective cohort study, n=239	Women in the naturopathy group had improvements for anxiety, hot flushes, menstrual changes, and vaginal dryness about as frequently as patients who were treated conventionally in a multivariate analyses, and were seven times more likely to report improvements in insomnia.

### *Prevention of cardiovascular disease and treatment for hypertension*

A recent study investigated the effect of individualised naturopathic care in the prevention of cardiovascular disease in a multi-site RCT of 246 participants (51). The two groups were comparable at baseline, however after a 1 year a drop of 3.6 percentage points was noted in 10 year cardiovascular risk (95% CI:-5.1, -2.3), together with a 27.4% reduced prevalence of metabolic syndrome (95% CI; -41.7, -13.1) as compared to control participants. Another recent study investigated the effects of naturopathy and yoga for the reduction of blood pressure in 104 mild to moderate hypertensive patients who were not taking any conventional medication (50). Systolic blood pressure reduced from a mean of 139.6 to 129.6 mmHg and diastolic blood pressure reduced from a mean of 91.2 to 86.1 mmHg. Although more research needs to be conducted to fully understand and elucidate the naturopathic treatment of cardiovascular disease, this early work is promising in this area of chronic disease management.

### *Treatment of Type-2 diabetes mellitus*

A retrospective analysis investigated naturopathic treatments for patients with type-2 diabetes and associated symptoms (58). All patients received dietary counselling, 69% were taught stress reduction techniques, and 94% were prescribed exercise in addition to herbal medicines and nutritional supplements as required. Most patients (81%) were using naturopathic medicine as an adjunct to conventional treatment. Another retrospective, observational study (n = 34) found that clinical risk factors for patients with type-2 diabetes were significantly reduced after naturopathic treatment for an average of 27 months (54). Significant mean changes included a -0.65% reduction in haemoglobin A1c (HbA1c) (p=0.046), 0.51mmol/l reduction in triglycerides, -7mmHg reduction in systolic blood pressure (p = 0.02) and a -5mmHg reduction in diastolic blood pressure (p = 0.003). A more recent study offered type-2 diabetes patients (n = 40) from an integrated medical system, eight adjunct naturopathic visits (49). Participants were required to have HbA1c values between 7.5-9.5 % and at least one further cardiovascular risk factor such as hypertension, hyperlipidaemia or obesity. Participants had on average 3.9 naturopathic consultations and at 6 months, significant improvements were found in self-efficacy (p = 0.0001), glucose monitoring (p = 0.001), diet (p = 0.001), mood (p = 0.001), motivation to change lifestyle (p = 0.003) and physical activity (p = 0.02). Mean HbA1c decreased by -0.90 % (p = 0.02) as compared to the usual care cohort. Similarly, naturopathic dietary interventions have shown some promising results in a pilot study of type-2 diabetic patients, with a mean -0.4% reduction in HbA1c (49).

These studies represent an emerging evidence base that examines the whole system practice of naturopathy. Beyond this, there is currently limited data relating to the efficacy, safety and cost effectiveness of naturopathy and Western herbal medicine within a holistic model of practice, therefore the only way to effectively evaluate these disciplines successfully and impartially is to focus on their major therapeutic tools.

The two major therapeutic tools embedded in the education and training of Australian naturopaths, at either at a private college or a university, are herbal medicine and nutritional medicine (61). Recent years have seen exponential growth in both the amount of level 1 and level 2 evidence on herbal and nutritional medicine published in the medical literature as found on PubMed (see Tables 2 and 3). In the years previous to 1995 no systematic reviews are available on the PubMed database, while in the last 5 years alone there have been 438 systematic reviews published (60% of the total number of systematic reviews published on herbal medicine) (Table 2). Likewise, pre 1995, 45 RCTs existed in the PubMed database on the efficacy of herbal medicines and in the last 5 years 627 RCTs (50% of the total number published) have been published in this database.

Similarly, a search on the PubMed database identifies an absence in published systematic reviews of nutritional/dietary supplements in the years previous to 1995, which contrasts with the last 5 years where there have been 1067 systematic reviews published (64% of the total systematic reviews on nutritional/dietary supplements (Table 3). Likewise, pre 1995, 88 RCTs existed in the PubMed database on the efficacy of nutritional/dietary supplements and in the last five years 3038 RCTs (54% of the total) have been published in this database.

Table 2: The increasing publication of herbal medicine research

Dates for article publication	Any article n, (% of total)	Primary research n, (% of total)	RCT n, (% of total)	Systematic review n, (% of total)	Safety/ toxicology n, (% of total)	Cost effectiveness n, (% of total)
<b>No date restriction</b>	19766	2462	1262	728	1462	112
<b>2007-2012</b>	9856 (50%)	1118 (45%)	627 (50%)	438 (60%)	783 (54%)	67 (61%)
<b>2001-2006</b>	5975 (30%)	814 (33%)	427 (34%)	247 (34%)	418 (29%)	32 (28%)
<b>1995-2000</b>	2261 (12%)	357 (15%)	163 (13%)	43 (6%)	165 (11%)	8 (7%)
<b>Pre 1995</b>	1674 (8%)	173 (7%)	45 (3%)	0 (0%)	96 (6%)	5 (4%)

To the end of December 2012, 1462 articles had been published on the PubMed database on the safety/toxicology of herbal medicine and over half of these were published in the last 5 years (Table 2). Similarly, an increasing amount of articles have recently been published concerning the safety and toxicological status of nutritional/dietary supplements (Table 3). Beyond the direct effects of herbal medicine and nutritional medicine products, safety issues may also be associated with communication of this use with conventional care providers. In some instances this is linked to non-disclosure on the part of the consumer (62), while in others it may be connected to the location of CAM practitioners outside of mainstream health provision and therefore insufficient communication practices between conventional and CAM providers (63). In addition, the safety of herbal and nutritional medicines is linked to correct prescribing by a qualified individual to reduce the incidence of incorrect diagnosis, incorrect treatment, side-effects and drug interactions. It is a real concern that disallowing private health insurance eligibility for naturopathy and WHM will increase the out-of-pocket costs of consultations with these practitioners and consequently lead to increased self-diagnosis and self-prescribing of herbal medicines and nutritional supplements. Such an outcome will create a significant health risk for the general population and particularly for those with complex chronic health conditions.

Cost effectiveness studies have also increased in the last 5 years (Table 2 and 3). A recent Australia Access Economics report commissioned by the National Institute of Complementary Medicine in 2009, conducted a series of cost effectiveness studies on selected complementary medicine interventions where a reasonable body of evidence for safety and efficacy was available. The review included *Hypericum perforatum* (St John's wort) for mild to moderate depression, omega-3 fish oils for secondary prevention of heart disease and to reduce non-steroidal anti-inflammatory drug use in rheumatoid arthritis, and Phytodolor® (Steigerwald, Arzneimittelwerk Germany) a herbal medicine formulation for inflammation and pain in osteoarthritis containing aspen leaves and bark (*Populus tremula*), common ash bark (*Fraxinus excelsior*), and golden rod herb (*Solidago virgaurea*). St John's wort was found to be cost effective for the treatment of mild to moderate depression; omega-3 fish oils were found to be cost effective for the prevention of heart disease but not to reduce non-steroidal anti-inflammatory drug use in osteoarthritis, and Phytodolor® was found to be cost effective for the treatment of pain and inflammation in osteoarthritis (64).

Table 3. The increasing publication of nutritional/dietary supplement research

Dates for article publications	Any article n, (% of total)	Primary research n, (% of total)	RCT n, (% of total)	Systematic review n, (% of total)	Safety/toxicology n, (% of total)	Cost effectiveness n, (% of total)
No date restriction	27633	8915	5632	1674	413	189
2007-2012	13886 (50%)	4467 (50%)	3038 (54%)	1067 (64%)	207 (50%)	85 (45%)
2001-2006	9485 (34%)	3138 (35%)	1949 (35%)	491 (30%)	164 (40%)	79 (42%)
1995-2000	3082 (11%)	996 (11%)	557 (10%)	116 (7%)	32 (8%)	18 (9%)
Pre 1995	1180 (5%)	314 (4%)	88 (1%)	0 (0%)	10 (2%)	7 (4%)

### Western herbal medicine

To date the focus of WHM research has been on clinical trials rather than whole systems research, however whole systems research would be extremely valuable in order to understand and evaluate the whole practice of WHM. A recent paper reviewed proceedings of a pre-conference workshop before the International Congress of Complementary Research (CMR), sponsored by the Centre for Complementary Medicine Research at the Technical University in Germany and The International Society for Complementary Medicine Research (ISCMR), in München, Germany, May 11-13, 2007 (65). The workshop was designed to examine the methodological challenges and issues that are unique to whole systems research in herbal medicine. The key challenges were found to be defining herbalists and herbalism in relation to scope of practice, the role of the natural products industry in herbal research, designing placebos that have the same taste, colour and aroma as the actual treatment, researching the herb as a living entity, and designing trials to investigate and develop complex or multicomponent herbal treatments. Despite this, an increasing amount of RCTs and systematic reviews are being published on the efficacy and safety of WHM (Table 2), and best available evidence to evaluate WHM practice.

## **The management of cardiovascular disease: an example of EBP in naturopathic and Western herbal medicine practice**

In recognition that the ministerial review group is conducting a literature search to determine the levels of evidence that exist for naturopathy and WHM, we offer a brief example of evidence based practice for cardiovascular disease from the last two years. Given the similar rates of use of both nutritional and Western herbal medicine, the review of these therapeutics are suggested to be relevant to both professional groups.

A search of PubMed has located seven meta-analysis (66-72) and five systematic reviews (73-77) that have investigated the various therapeutic effects of omega-3 fatty acids or fish oil for cardiovascular disease in the last 2 years (Table 4). Omega-3 fatty acid has been shown to both assist in the prevention and to reduce the progression of atherosclerosis by reducing plasma concentrations of soluble intercellular adhesion molecule-1 (sICAM-1) in a meta-analysis of 18 RCTs (66). Other meta-analyses and systematic reviews have found positive effects of omega-3 fatty acid on cardiac function (67), inflammatory bio-markers (68, 75), vascular endothelial function (69, 70) and arterial stiffness (76). Conversely two papers, one meta-analysis of 14 RCTs (72) and one systematic review of 20 RCTs (73), have shown that supplementation with omega-3 fatty acid does not reduce the incidence of major cardiovascular events such as myocardial infarction, congestive heart disease, sudden cardiac death or stroke. While omega-3 fatty acids are incorporated into naturopathic clinical practice to reduce atherosclerosis and inflammatory biomarkers and improve vascular endothelial function (3) more research is needed to investigate why this supplement does not appear to prevent major cardiovascular events.

Table 4: NHMRC\* level 1 evidence of naturopathic medicines for the treatment of cardiovascular disease, in the last two years

Date	Author(s)	Condition	Intervention, design	Findings
<b>Omega-3 fatty acids or fish oil</b>				
2012	Yang et al (66)	Atherosclerosis	Omega-3 fatty acids Meta-analysis of 18 RCTs	Omega-3 supplementation can reduce plasma concentrations of soluble intercellular adhesion molecule-1 (sICAM-1).
2012	Xin et al (67)	Cardiac function in patients with congestive heart failure	Fish oil, Meta-analysis of 7 RCTs	Left ventricular ejection fraction significantly and left ventricular end-systolic volume was significantly decreased compared to placebo group (more significant in patients with nonischaemic heart failure). Also improved the New York Heart Association functional classification and peak oxygen consumption in patients with non-ischaemic heart failure.
2012	Xin et al (68)	Inflammatory biomarkers in congestive heart failure	Fish oil, Meta-analysis of 7 RCTs	Tumour necrosis factor alpha, interleukin 1 and interleukin 6 were significantly decreased compared to placebo. High sensitivity C reactive protein, soluble intracellular adhesion molecular 1 and vascular cell adhesion molecular 1 were not significantly affected, which may be due to dose or duration of supplementation.

<b>Date</b>	<b>Author(s)</b>	<b>Condition</b>	<b>Intervention, design</b>	<b>Findings</b>
<b>2012</b>	Xin et al (69)	Vascular endothelial function in congestive heart failure	Fish oil, Meta-analysis of 16 RCTs	Fish oil supplementation significantly improved flow-mediated dilation.
<b>2012</b>	Wang et al (70)	Vascular endothelial function in congestive heart failure	Omega-3 fatty acids Meta-analysis of 16 RCTs	Omega-3 FAs supplementation significantly increased flow-mediated dilation at a dose ranging from 0.45 to 4.5 g/d over a median of 56 days as compared to the placebo group.
<b>2012</b>	Smith (73)	Major cardiovascular events	Omega-3 fatty acids Systematic review & Meta-analysis of 20 RCTs	Omega-3 PUFA supplements did not reduce major cardiovascular events such as sudden cardiac death, myocardial infarction or stroke when compared to control.
<b>2012</b>	Rangel-Huerta et al (75)	Inflammatory biomarkers in congestive heart failure	Omega-3 fatty acids Systematic review of 26 RCTs	Omega-3 fatty acids decreased plasma biomarker levels, reflecting reduced inflammation and endothelial activation in cardiovascular disease.
<b>2012</b>	Kwak et al (72)	Major cardiovascular events	Omega-3 fatty acids Meta-analysis of 14 RCTs	Omega-3 PUFA supplements did not reduce major cardiovascular events such as sudden cardiac death, congestive heart failure, myocardial infarction, transient ischemic attack or stroke when compared to control.

Date	Author(s)	Condition	Intervention, design	Findings
2012	Delgado-Lista et al (77)	Major cardiovascular events	Omega-3 fatty acids, systematic review of 21 RCTs	10% overall decrease in the risk of a cardiovascular event of any kind, 9 % decrease of risk of cardiac death, 18% decrease in the risk of fatal or non-fatal coronary events. These results were more significant in people with high cardiovascular risk.
2012	Rizos et al (74)	Major cardiovascular events	Omega-3 fatty acids Systematic review & Meta-analysis of 20 RCTs	Omega-3 PUFA supplements did not reduce major cardiovascular events such as sudden cardiac death, myocardial infarction, transient ischemic attack or stroke when compared to control.
2011	Liu et al (71)	Prevention of atrial fibrillation	Omega-3 fatty acids, Meta-analysis of 10 RCTs	No significant effects. Larger trials required to rule out any benefit.
2011	Pase (76)	Arterial stiffness	Dietary intervention, a systematic review of 38 RCTs	Omega-3 fish oils and soy isoflavones effective for the treatment of arterial stiffness.
<b>Soy products</b>				
2012	Beavers et al (78)	Endothelial function	Isoflavone containing soy products, meta-analysis of 17 RCTs	Soy isoflavones have a modest but significant effect on endothelial function.
2011	Dong et al	Blood pressure	Soya protein, meta-analysis of 17 RCTs	Average decrease of 2.21 mmHg for systolic BP (SBP) and 1.44 mmHg for diastolic BP. The results were markedly greater in hypertensive participants.

Date	Author(s)	Condition	Intervention, design	Findings
<b>Folate and other B group vitamins</b>				
2012	Jardine et al (79)	Homocysteine and cardiovascular events in subjects with kidney disease	Folate, systematic review and meta-analysis of 11 RCTs	Folic acid treatment to reduce homocysteine does not reduce cardiovascular events in people with kidney disease.
2012	Huang et al (80)	Plasma homocysteine, cardiovascular and all-cause mortality	B vitamins, Meta-analysis of 19 RCTs.	A significant protective effect was shown for stroke. No effect shown for sudden cardiac death, myocardial infarction, congestive heart disease, or all-cause mortality.
2011	Zhou et al (81)	Major cardiovascular events	Folic acid Systematic review & Meta-analysis of 16 RCTs	No effect shown for sudden cardiac death, myocardial infarction, stroke, or all-cause mortality.
<b>Magnesium</b>				
2012	Kass et al (82)	Blood pressure	Magnesium, Meta-analysis of 22 RCTs	Systolic blood pressure reduction of 3-4 mm Hg, diastolic blood pressure reduction of 2-3 mm Hg. Effect size increased in line with larger doses.

Date	Author(s)	Condition	Intervention, design	Findings
<b>Vitamin C</b>				
2012	Jurasckek et al (83)	Blood pressure	Vitamin C, Meta-analysis of 29 RCTs	Systolic blood pressure reduction of 3.84 mm Hg, diastolic blood pressure reduction of 1.48 mm Hg for normotensive participants and -4.85 (SBP) and -1.67 (DBP) for hypertensive participants.
<b>Ginseng</b>				
2012	Jia et al (84)	Angina	Ginseng, Meta-analysis of 18 RCTs	Moderate evidence that ginseng is more effective than nitrates for treating angina pectoris. Larger trials with longer follow-up periods are needed to confirm.
<b>L-arginine</b>				
2011	Dong et al (85)	Blood pressure	L-arginine, Meta-analysis of 11 RCTs	Systolic blood pressure reduction of mean 5.39 mm Hg, diastolic blood pressure reduction of mean 2.66 mm Hg.

*\*Level I evidence of an intervention: defined by the National Health and Medical Research Council as a systematic review of randomised controlled trials (35)*

Other research in the last 24 months has reported the benefits of both magnesium and vitamin C for lowering blood pressure in a meta-analysis of 22 RCTs (82) and 29 RCTs (83) respectively. L-arginine (85) and soy protein (86) have also proved beneficial for hypertension, with soy shown to reduce arterial stiffness (76) and improve endothelial function (78). A meta-analysis of 18 RCTs found that ginseng is more effective than nitrates for treating angina pectoris in a meta-analysis of 18 RCTs (84). Two systematic reviews on folate (79, 81) and one meta-analysis on B group vitamins (80) generally, found they were not effective for the prevention of major cardiovascular events.



A recent review of 27 studies found that CAM was used by up to 61% of cardiac patients (87). Patients used a range of supplements such as nutritional supplements (< 68%) and herbal medicines (<46%). A large proportion of patients did not inform their medical practitioner about their CAM use, which could lead to potentially hazardous interactions with conventional cardiac medication (3). It is important that these supplements and herbal medicines are prescribed and dispensed by a qualified naturopathic or WHM practitioner and that there is open discourse between the practitioner, patient and doctor about all prescribed and non-prescribed conventional and complementary medicines.

## **Recommendations**

Recent years have seen an exponential increase in the number and quality of naturopathic and herbal medicine research published in the medical and health literature. While evidence for the whole practice of these disciplines is still emerging, to date there are a substantial number of primary research, systematic reviews and meta-analyses examining the major therapeutic tools of both herbal and nutritional medicine. Health services research in relation to naturopathy and WHM is also an expanding field of inquiry. In line with the increased evidence from these research disciplines, there is significant evidence of naturopathy and Western herbal medicine providing the infrastructure and encouraging research capacity building within the profession. With this in mind, the Minister of the Department of Health and Ageing is advised of the following recommendations:

1. Continued support for private health insurance eligibility for naturopaths and Western herbal medicine practitioners; and
2. Allocated funding towards naturopathy and WHM related research projects being made available to support the continued examination of current and future practice. Such funding should prioritise whole systems practice research design.

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## Appendices

### Appendix 1 - NHAA constitution

[http://www.nhaa.org.au/index.php?option=com\\_content&view=article&id=457&Itemid=415](http://www.nhaa.org.au/index.php?option=com_content&view=article&id=457&Itemid=415) and attached as a separate file.

### Appendix 2 - NHAA Code of Ethics and Standards of Practice

[http://www.nhaa.org.au/index.php?option=com\\_content&view=article&id=81&Itemid=76](http://www.nhaa.org.au/index.php?option=com_content&view=article&id=81&Itemid=76) and attached as a separate file.

### Appendix 3 - NHAA Continuing Professional Education Guide

<http://www.nhaa.org.au/images/stories/CPE%20Guide%202012.pdf> and attached as a separate file.

### Appendix 4 - NHAA Continuing Professional Education Diary

<http://www.nhaa.org.au/images/stories/CPE%20Diary%20Print%202012.pdf> and attached as a separate file.