

Australian Government rebate on Private Health Insurance for Natural Therapies

Submission to the
Department of Health and Ageing,
Private Health Insurance Branch

Highlighting complementary medicine research

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Executive Summary

The National Institute of Complementary Medicine (NICM) acknowledges the commitment by the Australian Government to improve health outcomes for all Australians through their access to and wise use of a wide range of medicines and healthcare interventions. This reflects the important aims of our National Medicines Policy. Accessibility, affordability, quality, safety and effectiveness remain paramount for complementary medicine.

NICM supports the government's review of the clinical effectiveness and safety of natural therapies as long as a rigorous methodology is utilised which enables an in-depth and comprehensive review of practice to take place without prejudice.

NICM supports the use of a methodology that reflects the use of multiple interventions (often diet and lifestyle recommendations, medicines and/or manual therapies) tailored to individual needs in a patient-centred approach. Evaluation of singular tools of trade (eg one herb for one condition) is unlikely to be true to complementary medicine or natural therapies practice and will risk missing key clinical benefits. Hence NICM believes a robust scientific review of natural therapy practice will require consideration of not only key tools of trade, but also whole (multi-component) systems of practice with multiple study endpoints including symptom relief, reducing disease severity, delaying disease progression, disease prevention, improving quality of life and patient satisfaction. Consideration should be given to those treatments and practices sought by patients who have not responded well to conventional medical treatment and derived benefits from complementary medicine approaches. Complementary medicine interventions are filling an important void in the Australian health care landscape.

Developing scientific evidence in support of practices and adoption of current evidence into practice is a work-in-progress for every healthcare profession. NICM recognises that no health care practices, including medical and allied health, claim to be entirely clinically effective or evidence based. NICM notes that services directly subsidised under Medicare and all healthcare professions regulated under the National Registration and Accreditation Scheme are in many cases not supported by sound scientific evidence of efficacy and their practices not strongly evidence based. Ultimately, the decision as to whether something is clinically effective will rest with the patient receiving treatment. As such, comprehensive public consultation is required to better understand the potential health benefits of complementary medicine to different patient populations.

NICM advises in favour of retention of the health fund rebate for most complementary medicine services on the basis of no major public safety risks, reasonable preliminary evidence of efficacy for certain diseases, and ensuring better access and affordability for individual patients irrespective of social and economic circumstances.

NICM Recommendations

Recommendation ONE: *Impact Analysis – An Essential Precursor to Policy Change*

NICM recommends against cutting support for CM services in the absence of a sound understanding of the social, economic and clinical context of use of complementary medicine. A comprehensive impact analysis is required to ensure any potential removal of the private health insurance rebate is economically sound (and does not increase the risk of cost shifting to the public purse through increased Medicare consultations), is socially desirable to consumers and medical practitioners, and improves health outcomes in alignment with all the central objectives of Australia's National Medicines Policy, including accessibility, affordability, quality, safety and effectiveness.

Recommendation TWO: *An Even Playing Field for Evaluating Complementary Medicine*

NICM recommends that any review of scientific evidence in support of unregulated practices in CM be 'pegged' to similar levels of evidence required of regulated practices, including physiotherapy, nursing, podiatry, clinical psychology and many medical and surgical practices. Regular updated reviews are required for all healthcare interventions where possible to accommodate emerging evidence.

Recommendation THREE: *Robust Scientific Review of Complementary Medicine Evidence*

NICM recommends that a robust scientific review of any CM practice should be comprehensive and cover *all* relevant scientific sources of information. To gather relevant up to date information there must be utilisation of CM specific and medical databases, including non-English language studies and reviews. Information from relevant scientific conferences disseminating peer-reviewed research should also be included to ensure the most up to date information is reviewed.

Recommendation FOUR: *A Pragmatic Approach to Evaluating and Acting on Complementary Medicine Evidence*

NICM recommends that the Review Committee adopts a pragmatic approach to the evaluation of evidence in recognition of the perceived benefits of CM treatment reported by individual consumers and practitioners. Three different ways forward are proposed as possible outcomes of the Review – continued government rebates where the body of available evidence provides some preliminary evidence of efficacy; continued government rebates for individual patients where an individual clinical need or benefit is expected (and supported through a medical practitioner referral); and cessation of government rebates where the treatment is demonstrably ineffective or unsafe for a particular condition. The Review Committee should not take an 'all or nothing' approach to the different disciplines and practices.

About the National Institute of Complementary Medicine

The National Institute of Complementary Medicine (NICM) was established with Commonwealth and State funding in June 2007 and is hosted by the University of Western Sydney. The Institute provides leadership and support for strategically directed research into complementary medicine and translation of evidence into clinical practice and relevant policy to benefit the health of all Australians. Its objectives include facilitating appropriate integration of complementary medicine within the Australian health system.

Under the recent 2012 Commonwealth research quality ranking system (*Excellence in Research for Australia* (ERA)) complementary medicine research at the University of Western Sydney (through the combined efforts of NICM and the UWS Centre for Complementary Medicine) was evaluated and received the highest ranking of '5', designating an outstanding research performance well above world standard. UWS was the only Australian research concentration in complementary medicine eligible for assessment by the Commonwealth under the ERA scheme in 2012.

INTRODUCTION

The National Institute of Complementary Medicine (NICM) acknowledges and welcomes the commitment by the Australian Government to improve health outcomes for all Australians through their access to and wise use of a wide range of medicines and healthcare interventions. This reflects the important aims of our National Medicines Policy. We appreciate the opportunity to contribute to this approach.

We acknowledge the Natural Therapy Review Advisory Committee (NTRAC) seeks to develop a better understanding of the evidence base that supports clinical efficacy, cost-effectiveness, safety and quality of specific natural therapies under review. It is anticipated this will contribute to determining eligibility to receive continued Australian Government Rebate on private health insurance for these natural therapies. The detailed evaluation of this evidence base has been largely commissioned to the Australian National Health and Medical Research Council (NHMRC).

Our NICM submission does not duplicate the task of the NHMRC but does provide important context and response to each of the elements of the NTRAC's Review - clinical efficacy, cost-effectiveness, safety and quality – including clarifications around the nature of natural therapies practice, its social and economic context, and comparable standards of scientific evidence in the Australian healthcare landscape of regulated healthcare practitioners.

The Australian National Medicines Policy has four central objectives based on active and respectful partnerships, which take into account elements of social and economic policy. The National Medicines Policy focuses on consumer needs in fulfilment of the central objectives of accessibility, affordability, quality, safety and effectiveness in use of medicines. The issue of scientific evidence for specific natural therapies (hereafter referred to as the broad field of complementary medicine) has been subject to considerable debate across the range of interventions and practitioners that make up the complementary medicine sector. Our NICM submission highlights key issues for consideration by the NTRAC Review process.

IMPACT ANALYSIS – AN ESSENTIAL PRECURSOR TO POLICY CHANGE

Recommendation ONE: NICM recommends against cutting support for CM services in the absence of a sound understanding of the social, economic and clinical context of use of complementary medicine. A comprehensive impact analysis is required to ensure any potential removal of the private health insurance rebate is economically sound (and does not increase the risk of cost shifting to the public purse through increased Medicare consultations), is socially desirable to consumers and medical practitioners, and improves health outcomes in alignment with all the central objectives of Australia's National Medicines Policy, including accessibility, affordability, quality, safety and effectiveness.

Public and medical acceptance of complementary medicine

Over the last three decades, there has been increasing public endorsement of complementary medicine (CM), most notably through its increased uptake. Over 70% of Australian adults use over-the-counter CM products and approximately one-third use CM therapies such as massage therapy, naturopathy and chiropractic. One of the main reasons people choose CM is to manage chronic disease, improve wellbeing and as a preventative healthcare approach.^[1-3] CM users exhibit healthier lifestyles, with more exercise, less smoking and better diets (73% eat at least minimum daily serves of fruit and vegetables, compared to 54% of the general population).^[4] 42% of users take CM to address national priority health conditions.^[4]

This growth has not been driven by large advertising campaigns or government supported infrastructures (such as publically supported clinical services, substantive investment in research or education), but rather through demand for CM services generated by word of mouth referrals representing a 'grass roots' consumer growth. 75% of naturopathic and western herbal consultations are referrals through word of mouth.^[5]

Appropriately qualified CM practitioners are sought after by patients. A national survey of over 1100 pharmacy customers found over 50% thought pharmacies should employ naturopaths.^[1] Those respondents signalling a desire for naturopaths in pharmacies included both consumers and non-consumers of complementary medicines, signifying a broad acceptance and interest in the role of naturopaths in this setting by Australian consumers. The same study found 72% of people using CM products rated their product as adequately effective. A separate national survey of 479 naturopaths and Western herbalists found 24% had been employed specifically in a community pharmacy.^[6]

The Australian Medical Association position statement on CM recognises 'that evidence-based aspects of CM are part of the repertoire of patient care and may have a role in mainstream medical practice'. The statement is also endorsed by the Royal Australian College of General Practitioners.

Over 70% of physicians, surgeons, anaesthetists and pharmacists (n=127) at a Victorian public teaching hospital rated acupuncture, yoga, meditation and massage as clinically effective CM practices.^[7] Similarly, a broader survey of Australian general medical practitioners thought acupuncture, meditation, yoga, hypnosis and massage were highly effective.^[8] Whilst only representing 'expert opinion' this should not be readily discounted as it also represents an important perceived clinical role for CM practitioners and an increased interest in active and appropriate integration of these interventions.

Complementary medicine practice fills a gap

Naturopaths, Western herbalists, nutritionists and Ayurvedic practitioners are health and wellness advocates, promoting good nutrition, lifestyle modifications and the importance of taking personal responsibility for health as a fundamental principle for improving quality of life and maintaining good health. Besides diet and lifestyle counselling, their tools of trade include nutritional supplements and herbal medicines which are unscheduled therapeutic agents available over the counter. These low risk interventions are usually prescribed according to individual patient clinical presentations. An initial consultation typically lasts one hour and a follow up consultation takes approximately half an hour. The 'long' consultation approach and individualised, low risk treatments fill a gap for patients used to short consultations with their general practitioner and receiving higher risk, albeit often standardised (one size fits all) treatments.

Many consumers with chronic disease look outside conventional medical care for other approaches to ease their symptoms and delay the course of disease. They use CM approaches to improve their wellbeing, address disease symptoms and prevent future disease or disease exacerbation. Consumers may choose CM interventions as a first line of treatment, or as a gentler first option, over potentially long-term pharmaceutical management or surgery, or may not be satisfied with the lack of treatment options proffered by their medical practitioner. For this care, consumers have elected to consult mostly unregistered healthcare providers with specifically relevant education.

Medical practitioners are predominantly focussed on detecting and treating episodes of illness and may lose interest (or priority concern) when consumers become sufficiently well again (in the GPs view). Many consumers interested in preventing exacerbation of disease, or not feeling quite as well as they'd hoped, see CM practitioners in an effort to have their issues addressed and live a healthier life.

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.^[9, 10] 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.^[11] 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.^[12]

Individuals with chronic diseases more frequently use CM than those without.^[13, 14] It appears that these individuals are more likely to use CM in conjunction with orthodox medicine rather than replace it. For example, an analysis of medical expenditure survey with 16,000 respondents in the US found that high users of conventional medicine were twice as likely to use CM as lower users.^[15] Similar results have been found by others.^[16-18] The Australian Women's Longitudinal Health survey also found that users compared to non-users of CM tend to report poorer health and more symptoms and illness. Again, participants did not necessarily use CM to replace conventional medicine but in a complementary fashion.^[19]

Surveys indicate that CM is used for a very broad range of conditions, with a focus on chronic diseases rather than acute care.^[11, 17, 20-28] 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.^[28] 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.^[29, 30] Similarly, an Australian study of TCM users reported that 58% of people used TCM for rheumatologic or neurological complaints.^[11]

Many CM therapies are perceived to have fewer side effects. Furthermore, CM therapy is believed to accommodate holistic values where the mind and body are seen as one,^[31, 32] and increasing individualism means that more people are not prepared to accept the traditional authority of doctors.^[32-34] Surveys indicate that many participants believe they will receive greater attention from CM therapists. In general, CM therapies are in keeping with self-management and notions of empowerment and control over one's own health.^[31, 32] It allows the selection of health therapies in keeping with one's own belief systems.^[35]

Who practices complementary medicine?

Complementary medicine is practised by both practitioners trained in their specific CM discipline and registered medical and allied healthcare practitioners. In 2003 there were at least 3,000 practitioners of naturopathy and western herbal medicine alone, representing an estimated 1.9 million consultations and \$85 million turnover in consultations per annum.^[36] Most practitioners had at least three years training in the CM discipline itself, and 11% had prior health practice qualifications. One-third of GPs reported engaging in integrative medical care, using a holistic approach that integrates conventional medical care with complementary therapies.^[37, 38] In 2008, 9.2% of GPs reported practising at least one of the following complementary therapies: acupuncture (8.0%), naturopathy/western herbalism (1.9%), homoeopathy (0.9%), chiropractic (0.9%), environmental and nutritional medicine (0.8%), osteopathy (0.7%) and Traditional Chinese Medicine (0.5%),^[38] however the extent of their training in the CM disciplines is uncertain. The number of massage and exercise therapists is substantially higher. Overall, the data suggest that the CM workforce (excluding currently regulated professions) consists of at least 8,000 active clinicians.

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.^[39] The Royal Australian College of General Practitioners has a special interest group in CM as does the Public Health Association of Australia. 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.^[35, 40, 41] Fifty-nine percent of general practitioners report an increasing patient demand for CM therapies.^[40] Ninety-three percent of Victorian GPs reported referring clients to CM practitioners at least once.^[40, 42]

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.^[43] 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.^[44] Eighty five percent of pharmacists also believed that further training and information on CM is required for pharmacists.^[45]

What is the extent of current Government subsidy to CM interventions?

NICM does not have at hand data related to the cost to Government of provision of the 30% rebate to CM interventions practised by unregulated practitioners and claimed through private health insurance. It should be noted that the rebates provided by the health funds for CM intervention tend to be small with about a quarter of treatment costs reimbursed until the annual limit is reached and the costs for herbal or nutritional medicines themselves are generally not eligible for rebate (even if effective). The Government subsidy for private health coverage of CM intervention would represent a small portion of subsidy to all ancillary services.

In its assessment and recommendation to Government the NTRAC should consider the risk of cost shifting from the consumer to Medicare should the 30% private health rebate for CM be removed. Consumers in search for non-conventional treatment options may well consult regulated health professionals including medical practitioners, who are permitted to bill the consultation to Medicare at a substantially higher cost than represented by the CM fraction of 30% of the current rebate for all ancillary services.

The majority of consumers who seek CM advice will continue to do so either directly through unreimbursed private payment to unregulated practitioners (for those who can afford it), or by shifting their care to medical practitioners with some training or capacity to advise in this area. The net effect will be to shift a proportion of costs to the public purse through increased Medicare claims, to encourage the practice and provision of CM advice by medical and allied health practitioners not necessarily as comprehensively trained in the CM discipline (this difference was noted in the review of the practice of Chinese medicine^[11]), and to disadvantage the healthcare workforce specifically trained in CM by reducing their capacity to earn a living. The removal of the current rebate is unlikely to make economic or political sense for Government and indeed, could be viewed as an initiative that protects professional territory in favour of registered medical and allied health practitioners. Any cursory analysis generates a weak economic argument for change. The bulk of costs for the CM interventions under review are currently already largely borne privately by consumers.

Health insurers have embraced CM in the last 30 years as a method of enticing consumers to join their funds. 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. Currently, the majority (if not all) health funds recognise key CM practices.

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.^[46] By 2000, 70% of employee sponsored health programs in the US covered chiropractic, 17% covered acupuncture and 12% covered massage.^[47] 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.

In summary the CM interventions under review by NTRAC have a high level of use in the Australian community, play an important role in healthcare as perceived by both patients and their doctors, who prefer them to remain accessible, affordable and well integrated with conventional services.

Support for CM services should not be reduced in the absence of a sound understanding of the social, economic and clinical context of use of complementary medicine. With the removal of the private health insurance rebates for CM there is a significant risk of directly increasing costs to Medicare. Removal of support for CM services may also have a negative effect on health outcomes and fulfilment of National Medicines Policy objectives.

AN EVEN PLAYING FIELD FOR EVALUATING COMPLEMENTARY MEDICINE

Recommendation TWO: NICM recommends that any review of scientific evidence in support of unregulated practices in CM be ‘pegged’ to similar levels of evidence required of regulated practices, including physiotherapy, nursing, podiatry, clinical psychology and many medical and surgical practices. Regular updated reviews are required for all healthcare interventions where possible to accommodate emerging evidence.

The scientific evidence base for complementary medicine

Evidence based medicine (EBM) is a phenomenon that has found resonance in all fields of healthcare. It advocates the case that scientific knowledge should drive practice, rather than the force of tradition. In many ways it could be described as an ‘idea whose time has come’. Specifically, if an intervention does not work it should be discarded no matter how long it has been used. The first evidence based review was undertaken by Chalmers, Enkin and Keirse in 1989 and its findings led to extensive changes in the clinical practices used in pregnancy and child birth.^[48] 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”.^[49] 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 Ayurvedic 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 predominantly 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.^[50] 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.^[51] 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. **The value of both scientific and traditional evidence is worthy of consideration in the NTRAC review.**

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. 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.^[52] 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.^[53] 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.

Determining the clinical effectiveness and evidence base of a profession

Professionals distinguish themselves from other occupations by the special character of the knowledge required to perform their tasks.^[54] Therefore, determining whether a professional service is ‘clinically effective’ and by implication, underpinned by evidence, requires a consideration of the key components which build the knowledge base of its practitioners and inform their clinical practice.

Any determination of whether a profession is ‘evidence based’ must be multi-faceted and include a comprehensive review of the educational content of undergraduate training, resources used to inform practice and the findings of whole systems and pragmatic research. It should also include a comprehensive review of the clinical effectiveness of the consultative process and key tools of trade in providing symptom relief, reducing the severity of disease, delaying disease progression, preventing future disease and improving quality of life (physical or psychological).

Importantly, EBM should acknowledge multiple dimensions of evidence including practical evidence based on individuals' interpretation of experience, theoretic evidence, expert evidence, judicial evidence and ethics-based evidence.^[55] As such, a patient's own experience of complementary therapies and their level of satisfaction with care received, perception of its usefulness and expert opinion should also be collected and reviewed as a means of determining clinical effectiveness.

Ultimately the practice of medicine, whether it is conventional or complementary, is a complex craft and a large part of its richness and success depends on its ability to draw on a wide array of practices and forms of knowledge.^[56] External scientific evidence is important but only one facet of practice. Clinical practice will always be shaped by clinical acumen and experience, respect for patient autonomy, patient centred care, and accessibility of treatments, safety and costs.

The decision to review unregulated healthcare professions to determine whether they are clinically effective might assume that regulated professions are generally proven clinically effective. This is not a conclusion which can be supported by scientific evidence as several recent peer-reviewed articles published in the *Medical Journal of Australia* have demonstrated.^[57, 58] The recent review by Elshaug et al in the MJA (2012) listed 150 potentially low value health care practices which are performed by practitioners of the 'regulated' professions.^[57] These medical practices and procedures were classified as ineffective or inappropriate in certain circumstances. Many of these also carry significant risks to patients and collectively cost the public purse millions of dollars.

Examples included:

- *In surgery*: arthroscopic surgery for knee osteoarthritis, radiofrequency facet joint denervation, radical prostatectomy, removal of adenoids, upper airway surgery for obstructive sleep apnoea syndrome and caesarean section without medical indication and routine dilation and curettage for missed abortion.
- *In medicine*: procedures and treatments considered ineffective or inappropriate in certain circumstances include: ordering routine blood tests in children with fever
- *In physiotherapy*: chest physiotherapy as an adjunctive treatment for adults with pneumonia
- *In clinical psychology*: CBT for schizophrenia, bipolar disorder and major depression

As such, the notion that the Government Rebate on private health fund insurance only covers evidence based professions and treatments must be qualified. Clearly, services directly subsidised under Medicare and delivered by health professions regulated under the National Registration and Accreditation Scheme are not all clinically effective nor based on substantial (even modest in some cases) scientific evidence. **Any review of scientific evidence in support of unregulated practices in CM ought to be 'pegged' to similar levels of evidence required of highly supported regulated practices, including physiotherapy, nursing, podiatry, clinical psychology and others.** Indeed, these regulated practices have also been determined as presenting considerable risks to public safety if practised by unqualified or unregulated practitioners – this is the basis of occupational regulation under the Australian Health Ministers Advisory Committee (AHMAC) criteria. As naturopathy and western herbal medicine practice has been deemed to date not to present any major risks to public safety (and hence remain largely unregulated by government) the burden of evidence may be lower than that for high risk practices.

The evidence base is incomplete and changing in all healthcare fields

In all healthcare professions, regardless of whether they are regulated by the government or not, complementary or conventional, there will be utilisation of interventions that are supported by scientific evidence, those with limited evidence, some with none yet available and other treatments with negative evidence casting doubt on efficacy. In other words, no professional practice can claim all its treatments are evidence based, regardless of whether it is regulated or not.

Due to the ever changing evidence base and reality that some treatments and populations will never be well investigated in large scientific studies, the evidence base will never be complete. A 'snapshot' of the best available evidence today will be different tomorrow.

This is especially true for treatments for which intellectual property is difficult to protect, including herbal medicines that are in the public domain and are unable to attract substantial research funding from industry, populations that have rare diseases or conditions, or for those treatments which improve the quality of life of people without defined disease and who are considered the 'worried well' or 'difficult' by medical practitioners. CM may offer additional assistance for chronic disease management, alternative approaches where conventional medicine has no satisfactory answers, accommodates patient preferences toward low risk treatments and promotes greater patient participation in care.

In summary, evidentiary requirements in support of unregulated healthcare practices should be no different to similar levels of evidence required of regulated practices. These include physiotherapy, nursing, podiatry, clinical psychology, some surgical and medical practices and others. It is well noted that in many of these fields clear scientific evidence in support of current Medicare funded practice is not available.

ROBUST SCIENTIFIC REVIEW OF COMPLEMENTARY MEDICINE EVIDENCE

Recommendation THREE: NICM recommends that a robust scientific review of any CM practice should be comprehensive and cover *all* relevant scientific sources of information. To gather relevant up to date information there must be utilisation of CM specific and medical databases, including non-English language studies and reviews. Information from relevant scientific conferences disseminating peer-reviewed research should also be included to ensure the most up to date information is reviewed.

Evaluating tools of trade

As with all treatments, a consideration of potential benefit compared with the potential risk of harm is necessary, together with consideration for the place in practice of the treatment in relation to other available options and their risks and benefits and importantly, patient preference.

A comprehensive review by Boehm et al published in *Health Information and Libraries Journal* identified **forty-five databases for CM**^[59] Databases covered herbal therapies (n = 11), traditional Chinese medicine (n = 9) and some dealt with a vast number of CM modalities (n = 9), amongst others. The amount of time the databases had been in existence ranged from 4 to 53 years. Countries of origin included the USA (n = 14), UK (n = 7) and Germany (n = 6), amongst others. The main language in 42 of 45 databases was English whereas two were available in German.

More specifically, from the data reported, the majority of the databases were dealing with herbal therapies (n = 11 databases, 206 456 entries), followed by Traditional Chinese Medicine (TCM) (n = 9 databases, 606 664 entries), all CM (n = 8 databases, 780 270 entries) and homeopathy (n = 4 databases, 28 040 entries). Furthermore, three acupuncture databases were identified (48 000 entries), and two dietary supplement databases (764 894 entries). Most of the databases included in the review were based in the USA (n = 14), followed by the UK (n = 7), Germany (n = 6), Australia (n = 3), China (4) and India (n = 3). Other databases originated in Brazil (n = 2), Singapore (n = 2), Korea (n = 1), Taiwan (n = 1) or were internationally based (n = 2).

Several complementary treatments have origins in several different cultures and continue to be investigated in key geographical locations besides the English-speaking countries. For instance, when

reviewing the evidence for herbal therapies, the use of Western, European, Chinese and Indian databases is necessary to accurately capture the relevant evidence and ensure that all significant studies are included. Furthermore, consideration should be given to understanding the chemical complexity of herbal extracts, issues of phytoequivalence, bioequivalence and clinical equivalence when reviewing the evidence.

Accessing non-CM journals such as those that cover ethnobotany, pharmacognosy, pharmacology, botany, anthropology and sociology research is also necessary to collate information about clinically demonstrated mechanisms of action, biological plausibility, traditional evidence and usage, clinical use and safety, and professional and practice-based research.

Appendix 1 provides a concise bibliometric review of key public databases and their application to the areas of western herbal medicine, naturopathy, massage therapy, nutrition, tai chi, shiatsu and yoga. Any reliable evidentiary review of any of these CM practices would need to be inclusive of an analysis of these studies. Additional important resources are also available through the TGA list of approved monographs^[60] and resources listed in **Appendix 2**.

In summary, robust scientific reviews of CM practice must by definition be comprehensive and cover *all* relevant scientific sources of information, including CM specific and medical databases, English and non-English sources.

Complementary medicine – an emerging field of scientific enquiry

In CM, as with all of medicine, knowledge was originally held by practitioners and eventually made more widely available in journals, textbooks and reports which formed the basis of education and practice until relatively recently with the advent of scientific research methodologies, electronic databases and other repositories of information. These ‘traditional’ sources of information guided the practice of medicine, in the absence of better quality information, for centuries. Over the last 4-5 decades, scientific investigation began in earnest to validate medical and surgical practices and improve them by producing better and safer outcomes. Governments and industry have spent billions of dollars in this endeavour which has helped to uncover many important insights about disease, novel treatments and safety issues.

In comparison to conventional medicine, CM is still an emerging area of scientific investigation, not having received the same level of significant government or industry funding that pharmaceutical medicine has enjoyed. The total Australian spend on health R & D in 2004-5 was almost \$3B, of which only \$10M was spent directly on CM R&D. The lack of patentability and other incentives have significantly hindered industry investment into the scientific investigation of herbal medicines and nutritional supplements. There is also lack of support for CM practitioners to pursue higher degree education and research, thereby underutilising a workforce with a genuine interest in this field.

With these facts in mind, it is simply not possible to expect that many unpatentable CM treatments will have achieved the same level of investigation as pharmaceutical drug therapies whereas a more realistic expectation is that many treatments remain under-investigated, if investigated at all under controlled conditions. Importantly, lack of scientific evidence does not indicate negative evidence but does indicate that further research is required.

Despite these significant hurdles, numerous CM specific databases have been established in the last decade to capture relevant information and disseminate findings. There has also been an exponential growth in the number of Medline indexed articles being published which relate to treatments and recommendations used by CM practitioners. Scientific research conferences such as those convened by the International Society for Complementary Medicine Research and the Consortium of Academic Integrative Medicine Centres in North America stimulate the conduct of

research and scientific enquiry, provide opportunities for international collaborations and disseminations of findings to a broad academic audience.

Whole system practice evaluation

Complementary medicine practice consists of whole systems or disciplines of health care (such as naturopathy, Western herbal medicine, Ayurvedic medicine and Chinese medicine) which utilise a range of modalities (interventions) including diet and lifestyle recommendations, nutritional supplements, herbal medicines, massage and relaxation techniques.

Most of the scientific evidence to date has focused on singular interventions rather than on the system in which they are utilised. Whilst this is useful, it does not necessarily indicate whether a whole system of practice is effective because all key components of the practitioners management work together to create an outcome. Relaxation techniques, dietary and lifestyle modifications will usually accompany herbal medicine prescriptions. The combination of recommendations is more likely to have greater clinical effect than the single components.

Assessing the efficacy of whole systems is more complex than assessing the efficacy of single modalities or treatments with randomised controlled trials (RCTs). Realistically, RCTs may have powerful internal validity, but poor external validity, depending on the specific randomisation and sampling procedures used. Pragmatic trials and observational studies can have good external validity as individualised treatments can be applied in real world settings as a reflection of real world practice. Qualitative research methods provide the opportunity to explore the meaning that patients ascribe to an intervention or system and allow better understanding of whether it is clinically effective for them.^[61]

Clearly studying whole systems of health care is complex and the problems raised are not unique to complementary medicine. It also applied to complex interventions in conventional medical healthcare such as multidisciplinary chronic care, patient centred primary care and palliative care.

Despite these significant issues, some whole system research has been conducted and a comprehensive government review should seek out and include such studies. Importantly, new scientific opportunities exist by extending our understanding of multi-target herbal therapy, advantageous in the management of chronic, complex, multi-factorial disease.

A PRAGMATIC APPROACH TO EVALUATING AND ACTING ON COMPLEMENTARY MEDICINE EVIDENCE

Recommendation FOUR: NICM recommends that the Review Committee adopts a pragmatic approach to the evaluation of evidence in recognition of the perceived benefits of CM treatment reported by individual consumers and practitioners. Three different ways forward are proposed as possible outcomes of the Review – continued government rebates where the body of available evidence provides some preliminary evidence of efficacy; continued government rebates for individual patients where an individual clinical need or benefit is expected (and supported through a medical practitioner referral); and cessation of government rebates where the treatment is demonstrably ineffective or unsafe for a particular condition. The Review Committee should not take an ‘all or nothing’ approach to the different disciplines and practices.

Quality of care - adoption of evidence based principles in education and practice

Evidence based medicine (EBM) has not only revolutionised the practice of orthodox medicine, but it is currently influencing the practice of complementary therapies such as massage therapy,

naturopathy, nutrition and Western herbal medicine. This is demonstrated in the changes to their education and practice over recent years which incorporates scientific thinking and principles and where available, scientific evidence to influence practice.

Naturopaths and Western herbalists

Naturopaths and Western herbalists provide an example of this modernisation of knowledge and practice. Practitioners employ the discourse of science to explain the medicinal action of plants, the putative mechanisms of action of nutritional supplements and potential health benefits of diet and lifestyle modifications. Scientific evidence has been particularly helpful in exploring the safety of these interventions and brought to light the possibility of drug interactions with commonly used CM treatments and adverse reactions which may have remained unidentified or poorly described by traditional (history of use) evidence.

The undergraduate education of naturopaths and Western herbalists consists of a science based education (e.g. anatomy, physiology, biochemistry, pathology, pharmacology, botany, research skills etc) and utilises diet, lifestyle, nutritional supplements and herbal medicines as informed by evidence and the patient's clinical presentation and preferences. One of the benefits of such a broad education is the ability to promote quality use of medicines (QUM) in regards to CM by these practitioners. It is noted that many consumers do not disclose their CM use to their medical practitioner. Additionally, Australian surveys demonstrate that medical practitioners and pharmacists don't ask patients about possible CM use and therefore patients miss out on the opportunity to receive individual specific information about their safe and appropriate use.^[7] Australian surveys also indicate that medical practitioners and pharmacists generally receive little training about evidence based CM and have limited knowledge about common complementary medicines and lack confidence to counsel patients.^[62, 63]

This was exemplified by national surveys of pharmacists, naturopaths and Western herbalists in which all groups undertook a knowledge quiz about the evidence to support commonly used CM products and drug-CM interactions. The national surveys of 736 pharmacists and 479 naturopaths and Western herbalists found naturopaths and Western herbalists scored significantly higher on the knowledge test than pharmacists, in particular the drug interaction section.^[64]

Increased professionalization and the changes in undergraduate education have had a significant impact on practice. The same national survey of 479 Australian naturopaths and Western herbalists found that 94% rated evidence from randomised controlled trials as essential/important and that they have embraced scientific evidence whilst maintaining the importance and use of traditional evidence, personal experience and patient feedback and reports.^[64] Another Australian study has identified naturopaths' substantial use of evidence based resources to aid in the clinical decision making process.^[65]

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.^[66] Another study in Peru compared the results of patients from clinics and hospitals in Peru's National Programs in Complementary Medicine and Pan American Health organizations. Treatments were compared for selected pathologies with the same degree of severity including: moderate osteoarthritis, back pain, anxiety neuroses, asthma, migraine headache and obesity.^[67] 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.^[67]

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.^[47] Similar cost saving results have been found for mind body self management techniques for arthritis and chronic pain.^[47, 68] Segal and colleagues (2004) 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.^[68]

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.^[69] Health insurance payments decreased by up 12% in the meditation group with a cost saving of \$US300 million per year compared to the non-meditation group.

In 2009 NICM commissioned *Access Economics* to undertake a cost-effectiveness review of five key CM interventions. The economic analysis found St John's wort was cost-effective compared to standard anti-depressants for patients with mild to moderate depression.^[70] Fish oils rich in omega-3 fatty acids were determined to be highly cost effective when used as an adjunctive treatment in people with a history of coronary heart disease, achieving reduced death and morbidity.^[70] Additionally, Phytodolor, a proprietary herbal medicine, was found to be cost saving in managing osteoarthritis compared with the principal non-steroidal anti-inflammatory drug Diclofenac.^[70] A more recent comprehensive review of cost-effectiveness studies identified evidence of cost-effectiveness and possible cost savings in specific clinical populations.^[71]

Other reviews are also noted including:

- There is unequivocal evidence that calcium supplementation, alone or in combination with vitamin D, is effective in the prevention of osteoporotic fractures and bone loss in older people. The 'number needed to treat' is comparable with other approved preventive therapies such as statins (drugs to prevent cardiovascular events).
- Cranberry tablets and juice as prophylaxis against UTI's.^[72]
- Various CMs to prevent complications associated with surgery.^[73]

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.^[35] This also involves the assessment of the risk of failing to perform the activity or use the agent in question. This leads to a concept of a risk-benefit ratio, in which the individual may be seen as seeking to minimize risks where possible, while gaining the maximum benefit. To our knowledge there have been no studies which have looked at the risk-benefit of CM therapy by itself or in conjunction with conventional therapy.

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.^[74] However, it is considered that the adverse reactions to CM therapies are poorly collected and are likely to be underestimated by these ADRAC figures.^[75] 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.^[36]

An Australian general practitioner survey suggests there is one adverse event arising from CM for every 125 consultations or about one per week.^[76] 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.^[77]

The Australian National Prescribing Service 2007 survey of 612 participants found 49% say complementary medicines are not as risky as prescription medicines, 52% say the ingredients in complementary medicines make them safe to use, majority say advantages of CM are related to reduced side effects - a natural, safer alternative, 52% say the ingredients in complementary medicines make them safe to use.^[78]

The Australian Health Ministers' Advisory Council Criteria are an appropriate way to evaluate risks presented by professional healthcare practices and there is a current submission regarding naturopathy and western herbal medicine.^[79] If the practice of naturopathy and western herbal medicine does not represent a significant public safety risk then they will not be regulated practices. If they are not regulated healthcare practices then there is no significant public safety risk in supporting continued private health fund rebates.

A way forward

The need to support and fund clinically effective and safe treatments to enable Australians to receive better healthcare is essential. Just as the reviews of primary health care have found, the current NTRAC process will identify some CM practices largely supported by a body of evidence, to a standard not dissimilar to current Government regulated and funded healthcare practices and some CM practices for which there is a paucity of scientific evidence.

For many CM treatments, the evidence base is complex and often incomplete. This is no different to the evidence base for many medical treatments. However in CM, there is the added difficulty of evaluating chemically complex herbal medicines, understanding a traditional evidence base, evaluating multi-component management plans and the relative paucity of large scale studies due to significant barriers impeding the conduct of well funded controlled studies (including limited intellectual property protection) and the need for novel methodologies where double blind studies are not feasible (such as interventions that are highly interactive between practitioner and patient, eg massage and physiotherapy).

A sensible method for evaluating the overall evidence of safety and efficacy is required and a pragmatic strategy should be developed and applied in response to the provision of private health fund rebates.

NICM proposes that an **all or nothing funding approach is too simplistic**. Any removal of Government rebates for private health insurance coverage of CM is likely to prevent the Australian public from receiving clinical benefits from those practitioners providing safe and effective treatments, prevent access to treatment where high level evidence is not yet available and prevent individual patients who are positive responders from receiving CM treatment. It cannot be presumed that patients can absorb the increased cost of treatment without the rebate and that in its removal health outcomes would remain uncompromised.

NICM suggests three different pathways are feasible in the continued provision or removal of Government rebates:

- a. The body of available evidence provides some preliminary evidence of safety and efficacy. Private health fund rebates should continue for these professions. NICM anticipates this would include various forms of massage and exercise, nutritional support and naturopathic practice, including herbal medicine.
- b. The body of available evidence for the nominated CM intervention is very weak and there is no preliminary evidence of efficacy for any clinical condition. In these cases private health fund rebates would not be applicable unless there is a requested need and/or clinical benefit for the *individual* patient. Evidence of the individual need or benefit would be confirmed in the form of an endorsement (referral) from the patient's general practitioner.
- c. The body of available evidence indicates a CM treatment is demonstrably ineffective or a formal risk-benefit assessment recommends against its use for a particular condition. Private health fund rebates should cease for this intervention for the nominated condition.

In summary, the Review Committee may like to consider different options to support CM services that reflect current evidence and perceived benefits of CM treatment. These may include continued government rebates where the body of available evidence provides some preliminary evidence of efficacy; continued government rebates for individual patients where an individual clinical need or benefit is expected (and supported through a medical practitioner referral); and cessation of government rebates where the treatment is demonstrably ineffective or unsafe for a particular condition.

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Appendix One – Bibliometric review of key public database evidence sources

Databases	Medline	Cochrane systematic reviews	EMBASE	CINAHL
Massage therapy (including remedial massage, myotherapy, Swedish massage, sports therapy massage)	37 meta-analyses 193 Systematic reviews 529 RCTs	108 meta-analyses 137 systematic reviews 577 RCTs	130 meta-analyses 284 Systematic reviews 800 RCTs	7 meta-analyses 44 Systematic reviews 21 RCTs
Western herbalism (including western herbal medicines) *excludes Chinese medicine	213/64* meta-analyses 960/458* Systematic reviews 2876/518* RCTs	640/134* meta-analyses 91/198* Systematic reviews 3059/436* RCTs	479/231* meta-analyses 813/386* Systematic reviews 2640/972* RCTs	138/59* meta-analyses 368/186* Systematic reviews 201/117* RCTs
Naturopathy (including diet, lifestyle nutritional interventions, western herbal medicines)	13 meta-analyses 99 Systematic reviews 106 RCTs	74 meta-analyses 100 Systematic reviews 106 RCTs	32 meta-analyses 70 Systematic reviews 154 RCTs	11 meta-analyses 23 Systematic reviews 53 RCTs
Nutrition (including diet and nutritional interventions)	535 meta-analyses 3442 Systematic reviews 7705 RCTs	271 meta-analyses 349 Systematic reviews 4836 RCTs	2416 meta-analyses 2273 Systematic reviews 14436 RCTs	30 meta-analyses 306 Systematic reviews 455 RCTs
Tai Chi	19 meta-analyses 99 Systematic reviews 136 RCTs	35 meta-analyses 35 Systematic reviews 117 RCTs	47 meta-analyses 90 Systematic reviews 193 RCTs	9 meta-analyses 75 Systematic reviews 53 RCTs
Shiatsu	12 meta-analyses 31 Systematic reviews 162 RCTs	13 meta-analyses 12 Systematic reviews 145 RCTs	37 meta-analyses 63 Systematic reviews 224 RCTs 42 Case series	1 meta-analyses 25 Systematic reviews 35 RCTs 5 Case series
Yoga	31 meta-analyses 112 Systematic reviews 211 RCTs	50 meta-analyses 53 Systematic reviews 183 RCTs	78 meta-analyses 123 Systematic reviews 297 RCTs	8 meta-analyses 86 Systematic reviews 66 RCTs

Search Terms (January 2013)

Massage (mesh) or massage and remedial or swedish or "sports therap*" or therap* or myotherap*

Ayurved* OR Herbal* OR "herbal medicine" OR "traditional chinese medicine" OR "traditional herbalism" or "ayurvedic medicine" or "traditional Chinese medicine" or "chinese herbal medicine" or "Botanical medicine" Herbal Medicine(mesh) or Medicine, Ayurvedic (Mesh) or Medicine, Chinese Traditional)mesh

*Exclude Chinese from results

(naturopath* or naturopathic medicine or aromatherapy or iridology) or iridology (mesh-embase)

Naturopathy(mesh) aromatherapy (mesh)-medline

(MM "Naturopathy") OR "naturopathy" or ""naturopathic medicine" or (MM "Iridology") OR "iridology" or

(MM "Aromatherapy") OR "aromatherapy"

Nutrition//Diet therapy

exp Nutrition Therapy/ or nutrition.mp or diet therapy.mp. or exp Diet Therapy/

or nutritional intervention.mp. – medline

diet therapy.mp. or exp Diet Therapy/ or Nutrition Therapy.mp or nutritional intervention.mp

-embase (MH "Diet Therapy+") OR "diet therapy"

(MH "Diet Therapy+") OR "diet therapy" or "nutrition therapy" – Cinahl

MM "Tai Chi") OR "Tai chi" or tai ji [mesh]

shiatsu.mp. or Shiatsu/ or acupressure/ MESH

MM "Yoga") OR "Yoga" OR (MM "Yoga Pose")

yoga.mp. or Yoga/

Appendix Two – Additional databases and scientific resources for CM evidence

Natural Medicines Comprehensive Database

<http://naturaldatabase.therapeuticresearch.com/home.aspx?cs=&s=ND>

Natural Standard

<http://www.naturalstandard.com/databases/>

Braun and Cohen

Braun, L., Cohen, M. (2010). Herbs and Natural Supplements: An Evidence-Based Guide (3rd Ed). Churchill Livingstone: Australia.

European Scientific Cooperative on Phytotherapy (ESCOP)

<http://www.escop.com>

European Medicines Agency

<http://www.ema.europa.eu/ema/>

Health Canada - Compendium of Monographs

<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/index-eng.php>

Mayo Clinic – Complementary and Integrative Medicine Program

<http://mayoresearch.mayo.edu/mayo/research/cimp/>