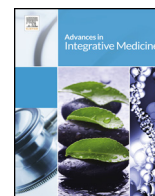


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Australasian Integrative Medicine Association (AIMA))

## BEST PRACTICE FOR INTEGRATIVE MEDICINE IN AUSTRALIAN MEDICAL PRACTICE

### January 2014

Australasian Integrative Medicine Association (AIMA)  
 NSW 2260, Australia  
 E-mail address: [admin@aima.net.au](mailto:admin@aima.net.au)  
 Web: [www.aima.net.au](http://www.aima.net.au)



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  - b. Dieticians Association of Australia (DAA)
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  - b. Australian Traditional Medicine Society (ATMS)
  - c. Chiropractic and Osteopathic College of Australasia (COCA)
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## ABSTRACT

The 'Best Practice for Integrative Medicine in Australian Medical Practice' is an Australasian Integrative Medicine Association (AIMA) endorsed document as principles to assist medical practitioners for the safe and appropriate integration of evidence-based complementary medicine into medical practice. In Australia, the use of Integrative Medicine (IM) by medical practitioners, particularly general practitioners (GPs) as a part of routine clinical practice is increasing. A National Prescribing Survey (NPS) survey indicated that approximately 30% of GPs in Australia describe themselves as practising IM. About two thirds of Australian consumers have used one or at least one CM in the previous 12 months, with 28% on a regular basis. The document is designed to assist the understanding of IM by the medical profession and for authorities to refer to when seeking guidelines in this field of medicine. The authors undertook an extensive consultation process to develop these principles.

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## Purpose of the guidelines

These principles aim to provide guidance for the safe and appropriate incorporation of integrative medicine (IM) into medical practice.

## Definitions of Integrative Medicine

Integrative Medicine (IM) refers to the blending of conventional and evidence based natural/complementary medicines and/or therapies along with lifestyle interventions and a holistic approach – taking into account the physical, psychological, social and spiritual wellbeing of the person – with the aim of using the most appropriate, safe and evidence-based modality(ies) available.

Integrative medicine embraces and encourages a holistic approach to clinical practice incorporating patient involvement in self healthcare, prevention and lifestyle interventions. The RACGP defines general practice as “the provision of primary continuing comprehensive whole patient medical care to individuals, families and their communities”.<sup>1</sup>

Integrative medicine encompasses more than complementary medicine, although the integration of complementary medicine is an important and obvious aspect of integrative medicine.

Integrative medicine does not reject or compete with conventional healthcare and overlaps significantly with what is currently widely accepted as quality general practice. The purpose of IM is to maximise health benefits to the community. Integrative medicine emphasises a number of issues including:

- a focus on wellness and illness prevention,
- being holistic in nature by focusing on physical, psychological, spiritual, social and lifestyle issues,
- incorporating evidence-based, safe and ethical complementary therapies,
- individualising the approach to any particular patient or clinical situation using the best of all available modalities in conjunction with informed patient choice,
- integrating all of the above into conventional medical care, and
- acknowledging that advances in health care will be dependent on scientific advances, improvements in health care delivery systems, cultural change as well as practitioner and patient education.

For the purposes of these principles, complementary medicine will refer to therapies and medicines that are not conventionally used by doctors, but may complement medical management and be successfully integrated into medical practice.

## Standards for Integrative Medicine in Australian General Practice

The standards for integrative medicine for Australian general practice are reflected in the *Integrative Medicine* statement in the *RACGP Curriculum for Australian General Practice*<sup>2</sup> (Appendix 1).

The Royal Australian College of General Practice (RACGP) is responsible for setting and maintaining standards of clinical care, education, training and research for general practice in Australia.

General practice training, as determined by the standards set and maintained by the RACGP, is intended to equip graduates with both core clinical skills and the ability to assess and address the learning needs arising from differing clinical contexts over a

professional lifetime; integrative medicine is recognised as part of this training.

While this level of expertise is expected of general practitioners, it provides a professional benchmark for expected level of care in the provision of IM related services.

## Rationale

The use of IM by medical practitioners, particularly general practitioners (GPs) as a part of routine clinical practice is increasing. A National Prescribing Survey (NPS) survey indicated that approximately 30% of GPs in Australia describe themselves as practising IM, by combining orthodox with CM.<sup>3</sup> In addition, about two thirds of consumers have used one or at least one CM in the previous 12 months, with 28% on a regular basis.<sup>4</sup> These surveys also demonstrated that only 53% of patients disclosed this use to their doctors, which in view of the potential for adverse reactions has been identified as a health risk.

Additionally, patients with a range of medical conditions from the simple to the chronic, complex and severe who are using integrative therapies will from time to time see other specialists or be patients in hospitals where the treatments they are undertaking may be relevant to the treatment they are to receive in a secondary or tertiary setting. Hospital-based practitioners will also need a comprehensive understanding of integrative medicine concepts and CM therapies to ensure optimal patient care.

As the use and evidence base for the use of complementary medicines and integrative therapies increases in Australia, medical practitioners – especially general practitioners – require clear guidance regarding information on the array of therapies available to patients. They also need to be able to access quality information and the scientific evidence and be aware of any risks associated with the use of CMs, which their patients may require in order to assist those patients to reach an informed decision about treatment.

## Readership

This document will be available to all medical practitioners education bodies and other specialist colleges, medical associations such as the Australian Medical Association and the Australasian Integrative Medicine Association, the Medical Board of Australia, the Professional Services Review Panel and Medicare Australia. Extensive consultation with some of these groups occurred prior to finalising the Best Practice Guidelines document.

## Purpose and aim

### The Best Practice for Integrative Medicine in Australian Medical Practice aims to:

- guide individual medical practitioners in the ethical and appropriate practice of IM in the context of general practice or other clinical medical settings, e.g. specialist medical practitioners,
- assist regulatory medical and professional bodies by providing suitable standards and guidelines in understanding this area of practice.

<sup>1</sup> The Royal Australian College of General Practitioners. What is general practice? Definition of general practice and general practitioners, 2005. Available at: [www.racgp.org.au/whatisgeneralpractice](http://www.racgp.org.au/whatisgeneralpractice) [accessed 27th August 2011].

<sup>2</sup> Integrative Medicine Statement. See Statement Chapters in RACGP Curriculum for Australian General Practice. <http://www.racgp.org.au/scriptcontent/curriculum/pdf/integrativemedicine.pdf> [accessed 27th August 2011].

<sup>3</sup> Brown J, Morgan T, Adams J, Grunseit A, Toms M, Roufogalis B, Kotsirilos V, Pirota M, Williamson M. Complementary Medicines Information Use and Needs of Health Professionals: General Practitioners and Pharmacists. National Prescribing Service, Sydney, December 2008. [http://www.nps.org.au/\\_data/assets/pdf\\_file/0020/66620/CMs\\_Report\\_-\\_HP\\_-\\_Apr\\_09.pdf](http://www.nps.org.au/_data/assets/pdf_file/0020/66620/CMs_Report_-_HP_-_Apr_09.pdf) [accessed 27th August 2011].

<sup>4</sup> Williamson M, Tudball J, Toms M, Garden F, Grunseit A. Information Use and Needs Of Complementary Medicines Users. National Prescribing Service, Sydney, October 2008.

## Authorship of these guidelines

The Australasian Integrative Medicine Association (AIMA) is constituted by a body of registered medical practitioners around Australia who integrate various forms of complementary medicine (CM) and holistic approaches into their medical practices.<sup>5</sup> In recent decades there has been a steady and strong revival of interest in the general and medical communities for more holistic and natural forms of medicine. Many doctors seeking greater options to provide for their patients are safely and successfully integrating CM into their practices. AIMA formed as a non-profit organisation in 1992 to make submissions to relevant government and medical authorities regarding the appropriate use of IM by medical practitioners. AIMA has developed practice guidelines (Appendix 2) for medical practitioners integrating CMs.

AIMA was a key player in producing the Integrative Medicine statement for the RACGP Curriculum in general practice.<sup>22</sup>

### BEST PRACTICE FOR INTEGRATIVE MEDICINE IN AUSTRALIAN MEDICAL PRACTICE

#### 1. Preamble

The Australasian Integrative Medicine Association (AIMA) recognises that medicine is not only guided by evidence and science but is also informed by tradition and experience. Current standards allow a wide degree of latitude in medical practitioners' exercise of their professional judgement and do not preclude the use of any methods that are reasonably likely to benefit patients without undue risk. Furthermore, patients have a right to seek any kind of care for their health problems but it is the responsibility of the medical practitioner to help those decisions to be effective, safe, ethical and informed. It is also recognised that a full and frank discussion of the risks and benefits of all medical practices is in the best interest of patients.

##### 1.1. Introduction

Medical practitioners, like all healthcare professionals, have a duty not only to avoid harm but also to do good - that is, to act in the best interests of patients. Because of the increasing interest in and use of CM, and the integration of these therapies into medical practice, professional colleges such as the RACGP and Australian Medical Board have a responsibility to assure that medical practitioners utilise IM in a manner consistent with safe and responsible medicine. In response to widespread use of CM in Australia and the growing number of medical practitioners utilising IM, the authors undertook an initiative in August 2005 to develop a safe and responsible model for the Australian medical profession and medical boards. This document has a particular focus on medical practitioners who:

- (1) use CM in their practices,
- (2) need to help patients make informed decisions with regard to CM,
- (3) and/or those who co-manage patients with CM providers.

The intention is to provide principles that are clinically responsible and ethically appropriate. These principles are designed to be consistent with what the Australian Health Practitioners Registration Authority and Medical Board of Australia generally consider to be within the boundaries of professional practice and accepted standard of care.

<sup>5</sup> Australasian Integrative Medicine Association <http://www.aima.net.au/> [accessed 27th August 2011].

##### 1.1.1a. Potential benefits of IM

Evidence based IM therapies offer many potential benefits, as they may provide safe and effective therapies that can be used to:  
Treat conditions that conventional medicine cannot treat

- Avoid or reduce the use of potentially harmful medicines.
- Enhance the effectiveness of conventional medicine.
- Enhance physical and psychological health.
- Provide symptomatic relief.
- Prevent disease.
- Involve patients in their own healthcare.

##### 1.1.1b. Potential risks of IM

The use of IM therapies is however not free of risk. Decisions about the use of these therapies should be based on an assessment that the potential benefits outweigh the potential risks. These risks are varied and are not restricted to the direct effects of the therapy but include denying and not informing the patient of appropriate conventional care.

(Refer to Section 3.5.)

##### 1.1.2. International guides to the use of IM

There are currently no documents which adequately address the issue of practice principles for IM in Australia. The British Medical Association has moved towards resolving this problem<sup>6</sup> but more work is required. The United States has developed 'Model Guidelines for the Use of Complementary and Alternative Therapies in Medical Practice (A Policy Document of the Federation of State Medical Boards of the United States, Inc.)' which form part of these guidelines.<sup>7</sup> What follows here is most likely the beginning of a longer evolutionary process. In keeping with the dynamic nature of the field it will need regular revision to keep it as up-to-date and accurate as it can be, in response to changing community needs, research evidence and clinical experience.

#### 1.2. Definitions

##### 1.2.1. Conventional Medicine/orthodox medicine

Conventional/orthodox medical practices refer to those medical interventions that are taught extensively at Australian medical schools, generally provided at Australian hospitals, or meet the requirements of the generally accepted standard of care as determined by professional colleges such as the RACGP. All general practice is by nature holistic, dynamic and continuously changing, guided by evolving science and experience.

##### 1.2.2. Complementary Medicine (CM)

CM is a fluid concept that has been defined differently by various organisations and groups. For the purposes of these principles, the Committee has chosen to use the term CM as defined by the National Center for Complementary and Alternative Medicine (NCCAM). The authors acknowledge that some therapies deemed CM today may eventually be recognised as mainstream over time, as further evidence accumulates.

NCCAM<sup>8</sup> defines complementary medicine as, 'a group of diverse medical and health care systems, practices, and products

<sup>6</sup> British Medical Association. Complementary medicine. New approaches to good practice. Oxford University Press, 1993.

<sup>7</sup> Model Guidelines for the Use of Complementary and Alternative Therapies in Medical Practice. A Policy Document of the Federation of State Medical Boards of the United States. Copyright 2002 by the Federation of State Medical Boards of the United States, Inc., PO Box 6,19850 Dallas, TX 75261-9850. [http://www.fsmb.org/pdf/2002\\_grpol\\_Complementary\\_Alternative\\_Therapies.pdf](http://www.fsmb.org/pdf/2002_grpol_Complementary_Alternative_Therapies.pdf) [accessed 27th August 2011].

<sup>8</sup> National Center for Complementary and Alternative Medicine (NCCAM), 2002. What is Complementary and Alternative Medicine (CAM)? May 2002, USA. Last Modified: 21 October 2002. <http://nccam.nih.gov/health/whatiscam/>.

that are not presently considered to be part of conventional medicine’.

### 1.2.3. Integrative Medicine (IM)

The term Integrative Medicine refers to the blending of conventional and evidence-based natural/complementary medicines and/or therapies along with lifestyle interventions and a holistic approach – taking into account the physical, psychological, social and spiritual wellbeing of the person – with the aim of using the most appropriate of all available modalities.

IM also describes a style of clinical practice and can also be defined as “the practice of medicine that reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, healthcare professionals, and disciplines to achieve optimal health and healing”.<sup>9</sup>

Many medical practitioners offer complementary health care as a part of the total services available to their patients. For some practitioners it constitutes the bulk of their work. For others, a single modality such as acupuncture is available as an adjunct to their routine practice. Patients are likely to perceive them to be ‘doctors who offer complementary healthcare’ rather than ‘complementary health practitioners who happen to be doctors’. It is for this reason the term Integrative Medicine is appealing as it implies the medical practitioner will chose whichever treatment, be it orthodox or CM that is appropriate and suitable to the patient.

### 1.2.4. Alternative Medicine

Alternative Medicine is a less used term now. It implies that a particular non-conventional therapy will be used as an alternative to a conventional one. Sometimes doctors and the public can take the term Alternative Medicine to encompass an alternate healthcare system implying a rejection of conventional healthcare. Doctors who practise IM will often discuss the merits of various alternatives with regard to the management of a condition, and would not support the notion of rejecting conventional healthcare.

### 1.2.5. Holistic Medicine

Holistic Medicine is an approach to healthcare which includes attention to physical, psychological, social, spiritual and lifestyle elements as a part of illness prevention or management, and is often associated with CM and doctors practising IM. It should be said, however, that many GPs practise in a very holistic way and the philosophy and training of GPs through the Royal Australian College of General Practitioners (RACGP) emphasises the importance of the holistic approach. Further, many practitioners who utilise complementary therapies do not necessarily practise in a holistic way and so ‘Holistic Medicine’ can be a very poor demarcation between medical practitioners and CM practitioners.

### 1.2.6. Natural Medicines

Natural Medicines or natural products usually refer to herbal medicines (also known as botanicals), vitamins, minerals, amino acids, and other “natural products” such as dietary products, glucosamine, probiotics and fish oils.

## 2. Modalities

Modalities will generally be classified under one particular domain but sometimes the modality can overlap with other domains so the following classification is open to interpretation.

For example, a philosophical system like Ayurveda also include herbs, mind-body, manual and bio-energetic therapies.

The NCCAM classifies natural, complementary and alternative medicines into five categories, or domains:

### 2.1. Alternative (or philosophical) Medical Systems

Alternative medical systems are built upon complete or integrated systems of theory and practice such as homoeopathic and naturopathic medicine, traditional Chinese medicine and Ayurveda. They will often incorporate many of the elements referred to above in holistic medicine but will also be underpinned by a particular philosophy as a way of explaining the mechanisms underpinning the approach.

### 2.2. Mind-Body Interventions

These interventions, which work with the intimate interconnectedness of the mind-body nexus, include yoga, patient support groups, meditation, prayer, spiritual healing, and therapies that use creative outlets such as art, music, or dance. The evidence-base in this area is growing but still scarce for some of the modalities mentioned. Some would also include more conventional psychological therapies such as psychotherapy and cognitive therapies in this category when one looks at them from the perspective of the physical health benefits which often accompany the psychological therapy.

### 2.3. Biologically (or medicinally) Based Therapies

These therapies focus on the administration of a compound and include the use of herbs, foods, vitamins, minerals, and dietary supplements.

### 2.4. Manipulative (or manual) and Body-Based Methods

These methods involve physical movement or manipulation and include chiropractic or osteopathic manipulation, massage, Alexander Technique and Feldenkrais. Some elements of Yoga and Tai Chi would also fall under this domain.

### 2.5. Energy (or bio-energetic) Therapies

Energy therapies involve the use of energy fields. They are of two types: (a) Bio-field therapies such as qi gong, Reiki, and Therapeutic Touch, and (b) Bio-energetic therapies involving the use of electromagnetic fields, such as pulsed fields, magnetic fields, or alternating-current and/or alternating and direct-current fields. Sometimes acupuncture is also classified here because it works on the principles of energy flow around the body. The presence and nature of bio-fields has been among the most challenging for biomedical science to measure and define.

## 3. Professional decision making in IM

The medical practitioner may offer the patient a conventional and/or CM treatment pursuant to a documented treatment plan tailored to the individual needs of the patient by which treatment progress or success can be evaluated with stated objectives, such as pain relief and/or improved physical and/or psychosocial function. Such a documented treatment plan shall consider pertinent medical history, previous medical records and physical examination, as well as the need for further testing, consultations, referrals or the use of other treatment modalities. Clear documentation is essential, in accordance with the RACGP Standards for General Practice.

<sup>9</sup> Integrative Medicine definition. Developed and adopted by The Consortium of Academic Centers for Integrative Medicine, May 2004. Edited May 2009 and November 2009. <http://www.imconsortium.org/about/home.html> [accessed 27th August 2011].

The treatment offered should:

- not delay or preclude any other necessary or more effective evidence based treatment, e.g. the need for surgery or antibiotics in emergency situations,
- have a favourable risk/benefit ratio compared to other treatments for the same condition,
- be based on the best available evidence to support its effectiveness,
- be based upon a reasonable expectation that it will result in a favourable patient outcome, including preventive practices,
- be based upon the expectation that a greater benefit will be achieved than that which can be expected with no treatment,
- be provided for a trial period and observation undertaken for a therapeutic clinical response during this time. If there are no clinical benefits obtained compared with the risk of trialling the therapy, then the treatment should be abandoned.

### 3.1. The decision-making process

When deciding on any course of treatment there are many factors that must be considered which can be encapsulated in the PEACE mnemonic.<sup>10</sup> These include acknowledgement and respect for the Personal preferences of both the practitioner and the patient, the strength of the available scientific Evidence, the range of possible Alternatives, the associated Costs and risks versus the potential benefits of a proposed treatment, as well as aspects of Expedience such as availability, accessibility and immediacy of treatment.

These factors are summarised below.

|                             |
|-----------------------------|
| Personal preferences        |
| Evidence                    |
| Alternatives                |
| Costs and risks vs benefits |
| Expedience                  |

Every decision about therapeutic interventions must include acknowledgement and respect for the personal preferences of both the practitioner and the patient. Every practitioner brings their own unique personal, ideological, religious, ethical, cultural, educational and philosophical biases that influence the types of treatments that are thought to be appropriate to either receive or to practice. These biases must be acknowledged and respected although the doctor may not always advise the course of action preferred by the patient if for example it is deemed to be detrimental to the patient or against the practitioner's own culture or principles. Informed consent and the respect for patient autonomy are amongst the highest ethical principles in medicine. Thus practitioners have an ethical (and possibly legal) obligation to declare their own limitations and biases and to fully inform their patients about the range of possible treatment as well as their associated risks. Furthermore, practitioners must respect the rights of their patients to make their own informed decisions as to the type of healthcare they wish to have. As such as all patients have a responsibility to become more informed and to be active participants in the decision making process. Recently, this approach has started to receive much attention and is widely discussed as 'evidence-based, patient-centred care'. Equally, it is important for medical practitioners to obtain informed refusal, and to document this in their notes about any other potential mainstream treatments.

As expected of those medical practitioners using conventional medical practices, medical practitioners providing CM therapies

are encouraged to stay up to date with best evidence. Becoming informed about different healthcare options generally means becoming aware of the strengths and weaknesses of the available scientific evidence. This includes regular review of the evidence of safety and efficacy for the therapies under consideration as well as the importance of understanding the inherent limitations of the available evidence and its relevance to a specific situation.

In addition to reviewing the evidence for a particular therapy there may be a range of therapeutic alternatives that may be used together, or in isolation. Thus, it may be necessary to review the evidence for a number of different therapies and to weigh the evidence for one against others. This weighing up of evidence generally involves an assessment of the costs and risks versus the potential benefits. As such, a treatment that is risky or comes at high cost generally needs to be balanced by a large potential benefit before it is utilised, whereas a treatment that poses little risk and has a low cost may be used even if the potential benefits are not so pronounced.

Further, some practitioners may wish to engage in the clinical research of new CMs and other therapies as part of their professional interests and responsibilities. Researchers shall be expected to conform to the same ethical standards as govern other clinical general practice research. It is expected that any such research will conform to the National Ethics Application Form (NEAF) from the National Health and Medical Research Council. The NEAF standards have been adopted by the RACGP Ethics committee.

A further consideration when deciding on a therapeutic option is expedience. In order to utilise a particular treatment, the treatment must be available for use and readily accessible to the intended individual. If a particular therapy is appropriate but unavailable due to government regulations or some other restrictions, or if it is inaccessible due to financial, geographical, logistic or other restrictions, then this must be taken into consideration. Furthermore, the timing and immediacy of treatment needs to be considered. Treatment received at the roadside or at a country clinic may be considerably different to treatment received at a tertiary teaching hospital. Thus if a condition demands urgent treatment then the range of potential treatments is naturally limited to those that are immediately available, whereas less urgent conditions may wait until a wider range of treatments can be accessed.

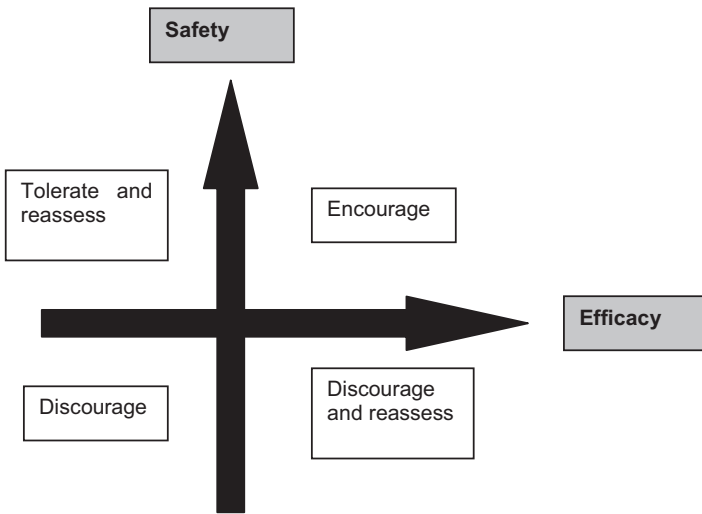
The principles described above apply across all therapeutic modalities and should be applied to considerations of both conventional and complementary therapies. Furthermore, it is clear that of all the factors that must be considered when making treatment choices, individual factors are at least as important as the scientific evidence. When patients are sympathetic to the management plans being offered there is a greater chance of efficacy or compliance and good communication makes this more likely. Evidence however does play a special role. It represents the accumulated wisdom and experience of humanity and this is being continually updated and refined as our collective experience expands. As such, it is clear that medical decision-making needs to be based on the best available evidence and informed decision-making on behalf of both practitioners and patients. It is also clear that it is up to each individual practitioner and patient to seek out and find the necessary information they require and to interpret this evidence in light of each individual situation.

The following diagram helps to represent some of the considerations which need to be taken into account when making clinical decisions- taken from Renella and Fanconi (2005) and adapted from Cohen and Eisenberg (2002).<sup>11,12</sup>

<sup>11</sup> Renella R, Fanconi S (2006) Decision-making in pediatrics: a practical algorithm to evaluate complementary and alternative medicine for children. *European Journal of Pediatrics* 165(7), 437–41.

<sup>12</sup> Adapted from Cohen MH, Eisenberg DM (2002) Potential physician malpractice liability associated with complementary and integrative medical therapies. *Ann Intern Med* 136:596–603.

<sup>10</sup> Adapted from Cohen M. 2006.



### 3.1.1. Where evidence is strong

Where the evidence for a particular therapy is strong (level I or II), then it should be considered as first line treatment or be used alongside conventional approaches if the risk of interactions between therapies is considered to be low.

### 3.1.2. Where evidence is limited

Where evidence is more limited (level III or IV), such as that from smaller or less rigorous trials, or where there is a long history of traditional use suggesting efficacy and safety, there could be a good case for offering such a treatment as one of a range of options. A number of therapies for which evidence is still equivocal could also fall into this category.

Explaining the level of evidence to patients is important as is discussing the conventional therapies available and the merits of each therapy offered. Where evidence for a conventional therapy strongly supports it being safer and more effective then it would be incumbent on the practitioner to recommend this as first line. Documenting well the therapies offered and their potential adverse events in the notes and the questions and responses of patients would be a sound approach. Also documenting the clinical response to treatment, including any adverse events and any informed refusal of conventional medicine are equally important.

### 3.1.3. Where evidence is absent

This is a difficult area for decision-making but is thankfully becoming a smaller category as the evidence-base around CM grows. The practitioner needs to make the lack of evidence for the therapy clear to the patient and outline their reasons for offering it above any other conventional therapy. Obviously support for such therapies would be far more questionable where valid conventional therapies are available, where there is a significant risk of adverse effects, or where costs to the patient in terms of money or time might be significant. As outlined above, clear documentation is important in the clinical notes.

### 3.1.4. Where evidence is negative

The offering of therapies where evidence has clearly and consistently been shown to be negative in terms of efficacy or harm would be of a concern to professional bodies and potentially medico-legal organisations. This category is where concerns are most significant with regard to patients being directed away from safe and effective conventional therapies, patients being taken advantage of and disreputable therapists. Doctors would need to be cautioned from using such therapies.

## 3.2. Diagnostics and Testing

An area of concern with relation to cost effectiveness has to do with the ordering of pathology tests. The ordering of pathology tests by integrative medical practitioners often differs from their mainstream general practitioners colleagues. Very different patterns of the initiation of pathology under the Medicare Benefits Scheme may lead to a Medicare Australia audit and investigation, and a possible referral to the Professional Services Review.

It is incumbent on the GP to ensure that there are clear and valid clinical indications to order any tests and to be able to justify and document that clinical decision for patient care supported by available evidence. Documentation in the clinical record of the reasons for such testing is essential to defend any unusual patterns of initiation.

If practitioners choose to order pathology which is outside the spectrum of what is considered by the majority of practitioners to be typical practice, then private pathology ordering should be considered.

## 3.3. Safety

This initiative focuses on encouraging the medical community to adopt consistent standards, ensuring public health and safety by facilitating the proper and effective use of both conventional and CM treatments, while educating medical practitioners about the adequate safeguards needed to ensure these services are provided within the bounds of acceptable professional practice. The authors believe that the adoption of principles based on this model will protect legitimate medical uses of CM while avoiding unacceptable risk. It is recognised that these risks can be difficult to identify, especially where there is treatment initiated, and oftentimes driven by patient autonomy.

## 3.4. Costs

The potential for patients to be taken advantage of financially remains a significant concern for all healthcare providers, not merely for Integrative Medicine practitioners. With billing practices, patients need to be given the opportunity to make an informed decision about the treatments available and the cost implications to them.

Cost issues in relation to IM needs to be addressed in three parts, the first is the cost of complementary medicine and/or therapies which are not covered by the Pharmaceutical Benefits Scheme or Private health cover, the second is the cost of the longer consultations which are typically associated with IM Practice. The final issue relates to costs of investigations particularly pathology tests which are outlined in Section 3.2.

It is imperative that patients are advised of the range of issues in relation to these costs and are then able to make an informed choice as to which diagnostic and treatment options they are willing to accept.

### 3.4.1. Costs of complementary therapies

Medical practitioners have a responsibility to outline any increased cost associated with complementary medicines to their patient. This allows patients to make an informed decision about treatment options that could potentially involve a higher cost, or that are not covered by the Pharmaceutical Benefits Scheme.

The decision making in regards to the financial costs of complementary therapies for patients can be potentially complicated by inappropriate advertising. Therapies that would cause the most risk are those:

- for which the financial outlay is high,
- for which the outlays are over a considerable period of time,



- where less expensive but efficacious treatments are available particularly conventional options available under the Pharmaceutical Benefits Scheme and Medicare Benefits Scheme,
- where the doctor has a potential financial interest in the therapy.

#### 3.4.2. Costs of extended consultations

Longer consultations do often demonstrate positive outcomes for patients (please refer to Appendix 5). However, medical practitioners have a responsibility to openly discuss and advise patients of the potential for higher consultation fees to allow them to make an informed choice as to whether they are willing for a longer consultation to occur.

### 3.5. Risks associated with CM

#### 3.5.1. Types of risks

##### • Intrinsic and Extrinsic risks

Risks associated with CM include **intrinsic** and **extrinsic** risks related to CM products.

**Intrinsic risks** include Type A reactions that can be predicted based on the pharmacological activity of the product. Such reactions include predictable side effects and interactions with pharmaceutical drugs. Intrinsic risks also include Type B reactions which are unpredictable and idiosyncratic such as allergic responses.

**Extrinsic risks** are risks not related to the product itself, but result from the failure of good manufacturing practice. These risks may be due to misidentification of materials, lack of standardisation, contamination, substitution, adulteration, incorrect preparation or dosage and inappropriate labelling or advertising.<sup>13</sup>

##### • Risks linked to practice

Risks associated with CM use also include risks related to practice.<sup>14</sup> These may include:

- recommendation from practitioners that patients defer or withdraw from appropriate medical therapy,
- failure to detect serious underlying disease and/or failure to refer on resulting in delay of diagnosis and appropriate treatment,
- mental trauma,
- unsubstantiated claims of therapeutic benefit.

There are other potential dangers associated with the integration of CM. The Federation of State Medical Boards of the United States<sup>10,10</sup> summarises potential harm in three possible ways:

**3.5.1.1. Economic harm.** The promotion of complementary medicines often occurs directly to the public, for example through advertising and testimonials in the press, the internet, television and through multi-level marketing. Australia is a world leader in the regulation of complementary medicines. The Therapeutic Goods Administration (TGA) and government's expert advisory committee have produced guidelines stipulating what evidence is required by the industry when claims are made for these products (refer to Section 13). The TGA and Australian Competition and Consumer Commission (ACCC) are increasing the reprimand of companies for unjustifiable and unreasonable claims made.

When profits are made by the seller, this may involve a direct conflict of interest when the seller is also representing themselves

as a health professional, for example a medical practitioner, allied health professional, e.g. physiotherapist, and alternative practitioners, e.g. naturopaths, herbalists, and chiropractors.

#### Declaration of financial interest

Declaring to your patients your professional and financial interest in any product you might endorse or sell from your practice, and not making an unjustifiable profit from the sale or endorsement. If a practitioner has a financial or other interest in promoting a particular complementary medicine treatment, practitioner, clinic or product then this must be disclosed to patients. Failure to do this may contravene the Trade Practices Act, and be considered misleading or deceptive conduct, and lead to possible referral to the Medical Board of Australia.

#### 3.5.1.2. Direct harm

Overall, most CMs tend to be safe and have relatively low side-effect profiles. Direct harm may nevertheless result from the complementary medicine itself. For example there is a documented reaction to the herb Black cohosh (*Cimicifuga racemosa*) that is linked to liver impairment. Harm may also arise from herb–drug interactions (e.g. St. John's Wort and Selective Serotonin Reuptake Inhibitors), or a physical adverse outcome from the complementary therapy itself, e.g. a needle penetrating the lung during acupuncture or manipulation of the spine aggravating a disc problem. Although such adverse events tend to be rare particularly in the hands of experienced practitioners, they can occur and so a similar standard of care to that expected of practitioners using conventional medicines would be expected.

#### 3.5.1.3. Indirect harm

This results from the delay of appropriate treatment for a medical condition, due to misinformation about unrealistic treatment of a condition. This can sometimes be seen with cancer treatments. Indirect harm could also include:

- mental and emotional harm associated with unrealistic patient expectations of the treatment,
- social harm such as where the person might become geographically or emotionally dislocated from family and friends in the process of pursuing a therapy,
- negative impact of the time taken to undertake a particular therapy,
- failure to adequately diagnose a condition before prescribing complementary therapy,
- certain therapies that involve touch for therapeutic purposes that have the potential in some cases to be interpreted as “inappropriate touching”. The practitioner needs to be aware and respectful of patient's boundaries, look at body language and signals. Health practitioners should always request patient permission before touching them, like a physical examination, and be sensitive and respectful with their response.

#### 3.5.2. Balancing risks and benefit

Therapies can also fall into a range of categories with regard to the balance of risks and benefits as indicated by reliable evidence.

##### 3.5.2.1. Low risk vs. high benefit

This category is not problematic and is a good case for recommending the particular therapy in question, for example relaxation therapies for anxiety or a high fruit and vegetable intake for a cancer patient.

<sup>13</sup> Myers SP Cheras PA. The other side of the coin: safety of complementary and alternative medicine. *MJA* 2004;181(4):222–225.

<sup>14</sup> NSW Health Regulation of Complementary Health Practitioners – Discussion Paper September 2002. NSW Health Department [http://www.health.nsw.gov.au/pubs/2002/pdf/compmed\\_paper.pdf](http://www.health.nsw.gov.au/pubs/2002/pdf/compmed_paper.pdf) [accessed 27th August 2011].

### 3.5.2.2. Similar risks and benefits

These therapies also tend not to be problematic and patient preference, cost, availability and practitioner experience will have a significant effect on the final therapy chosen.

### 3.5.2.3. High risk and low benefit

Therapies in this category are obviously problematic and there would have to be a strong reason for recommending or using such a therapy such as strong patient preference even in the face of informed refusal of other safer therapies. An example of a therapy that fits into this category includes intravenous ozone therapy, where little or no evidence of benefit exists and there is a potential for harm to the patient. Such therapies should be strongly discouraged. Careful documentation, monitoring and cessation of the therapy in the face of adverse events would be a minimum requirement in this area.

### 3.5.2.4. Inadequately studied but safe

For some therapies there is insufficient evidence to say much about clinical efficacy, but reasonable evidence to suggest relative safety. This evidence could also include, at least in part, a long history of traditional use. Informed consent, documentation and exploration of alternatives are again important.

## 4. Communications and relationships

There is strong supporting research on the importance of communications and relationships between the various parties involved in the provision of healthcare for patients and their families/carers.

There are ethical and legal issues at the interface of CM and conventional medicine as addressed in a 2004 article in the *Medical Journal of Australia*.<sup>15</sup> The authors of this paper summarise that doctors should be:

- honest with patients direct questioning about CM,
- establish patients understanding of CM and why they use it,
- take into account the burden of illness and provide documentation on patients expressed preferences,
- discuss the risks and benefits of both CM and conventional treatment,
- adequately inform patients about available CM that has been shown to be safe and effective, and if relevant those that are shown to be ineffective,
- become familiar with qualified and competent CM therapists (both medical and non-medical) to whom referrals are made,
- maintain ongoing, therapeutic and supportive relationships with patients, continuing to monitor their health throughout therapy,
- maintain open and respectful communication with patients.

### 4.1. Doctor – Patient

Effective communication is obviously important for any medical discipline and CM is no different. A full, honest, unbiased and clear exchange of information about therapies and clinical experience is vital. Various ethical principles underline the importance of the relationship such as respect for patient autonomy, informed consent, confidentiality, beneficence and non-maleficence.

The doctor–patient relationship of doctors who practise more holistically and also use a range of CMs is often one of the most valued aspects of the therapeutic relationship because the consultations are often long, a wide range of topics are explored, and patient empowerment is positively encouraged.

Ongoing contact and open communication is particularly vital so that the patient will keep the doctor informed about the therapies they are using which will also make it easier for the doctor to ensure that any potential interactions or misinformation might be avoided.

## 4.2. Doctor – Doctor

### 4.2.1. General Practitioners

Many GPs will refer suitably inclined patients within the practice to a doctor within the same or another practice who uses one or more CMs. This is rarely problematic but adequate referral notes, direct communication and ongoing monitoring by the referring doctor would be seen as important.

### 4.2.2. Specialist

Few medical specialists practice or integrate CM. Nevertheless, all the same requirements that normally apply for such referrals, and particularly those mentioned above, would apply. In this case the specialist will be accountable for their actions as is the GP.

## 4.3. Cultural issues

Many cultures readily integrate a range of CMs into their healthcare and do not find this at all problematic. The Chinese, for example, will quite easily use a range of traditional and conventional therapies. Any medical treatment, CM or otherwise, should always take into account the patients cultural background.

## 4.4. Referrals

The medical practitioner may refer the patient as necessary to achieve treatment objectives and this may include referral to a medical practitioner integrating CM, an accredited or otherwise state-regulated non-medical health care practitioner with the requisite training and skills to utilise the CM therapy being recommended (please refer to Section 15 for a list of professional organisations with details regarding their codes of practice, training and CPD requirements). It is important to be familiar with qualified and competent CM therapists (both medical and non-medical) to whom referrals are made.

The medical practitioner should encourage the patient to attend followup appointments to monitor their progress with periodic reviews scheduled to ensure adequate progress of their condition.

## 4.5. Accessing information

In order for medical practitioners to ensure that they are well informed and to allow them to assist patients to navigate their way around the breadth of medical information available, they should be acquainted with where to find quality sources of information from medical databases to popular websites. It will often be prudent for a practitioner to defer giving an opinion about a therapy they are unacquainted with until they do access a reliable source of information.

## 5. Special areas

The following areas cover patient groups where there may be issues of consent and who may be vulnerable when decisions are made about the use of complementary medicine.

### 5.1. Minors

As is their right and duty, parents generally make the healthcare decisions for their children. Parents who use CM are far more likely

<sup>15</sup> Kerridge J. McPhee. Ethical and legal issues at the interface of complementary medicine and conventional medicine. *Medical Journal of Australia* 2004;181:164–166.

to recommend CM for their children. Approximately 50% of children with chronic health conditions, including conditions like cancer, will have used CM. It would obviously be under extreme circumstances where such choices would be taken out of parent's hands. Particular care needs to be taken where extreme diets are recommended with potential detrimental impacts on the nutritional status of children or where the safety of a particular therapy is unknown for children.

### 5.2. Mental illness

Important issues for this group can include an impaired competence and ability to give informed consent, the potential for making unsafe choices to use or reject a treatment, and potential vulnerability to coercion or exploitation.

### 5.3. End of life issues and life-threatening illness

It is well documented that many CMs can be of significant benefit in symptom control for patients such as acupuncture to treat chemotherapy induced nausea and pain in cancer patients and some therapies particularly the lifestyle therapies may help to prolong duration and quality of life. There is however the significant possibility of exploitation, particularly where expensive treatments with dubious claims to efficacy are offered to vulnerable patients and their families. Concerns can arise not only from the health, emotional and financial effects of these therapies but also from the potential for patients to refuse efficacious conventional therapies.

### 5.4. Continuity of care in hospital

Communication and continuity of care between hospital and GPs is often not optimal and even more so where CM is involved. Patients could be using CMs but many, intentionally or unintentionally, will not inform staff such as nurses and pharmacists and their treating doctors in hospital. This may lead them to no longer having access to these therapies, or for them to be having therapies which can potentially interact with hospital-based medical and surgical treatments. Such therapies should be asked about as a matter of course in the care of all patients who attend or are discharged from hospital.

### 5.5. Indigenous groups

Indigenous, and indeed many other cultural groups, have a high prevalence of use of traditional remedies which they combine freely with conventional healthcare. Many indigenous people may in fact have a significant mistrust of conventional healthcare, sometimes to their detriment. Clear, effective and culturally sensitive communication is vital in these situations as is the need for the health practitioner to seek information about therapies which are unknown to them.

### 5.6. Exotic Practice

Some less common and less evidence-based therapies are sometimes called 'exotic' and also classified as complementary therapies despite the fact that they might be used by an extremely small percentage of healthcare practitioners. As previously mentioned, documenting informed consent and refusal, not making false or misleading claims, including advice on conventional therapies, weighing the scientific evidence and any risks, and being mindful of how such a therapy would be viewed by wider medical opinion, are vitally important in such circumstances. Particular concerns arise when such exotic therapies are expensive or potentially harmful.

It should be noted that Medicare Australia does not fund therapies that are not supported by the general body of peers. Only when treatments become accepted by the general body are MBS or PBS benefits able to be claimed. For new and emerging therapies, peers require clinical trial evidence. Medicare is specifically not to be used to fund experimental or for clinical trial purposes.

## 6. Medico-legal issues

### 6.1. Medical Indemnity Cover

It is recommended that medical practitioners contact their insurer directly to clarify any concerns about their particular area of practice. When making a clinical decision, it is important the doctor weigh the choice of treatments, assesses the scientific evidence (efficacy), any risks associated with the therapy, the clinical outcome (effectiveness) and costs associated with the treatment, and inform patients appropriately. Doctors should discuss with their current or intended indemnity provider for their position on CM practice (see Appendix 3 for list of Australian Indemnity insurers).

In general, most policies do not specifically mention CM and medical practitioners need to ensure they are practising in a professional, safe and competent manner regardless of whether they are practising CM or conventional medicine. Under the Insurance Contracts Act (1984), any person who purchases insurance has a duty to disclose any relevant matter to their insurer. This duty of disclosure applies when doctors renew, extend, vary or reinstate an insurance contract.

### 6.2. Medical Board of Australia (MBA)<sup>16</sup>

Medico-legal issues relate to unsafe standards of care and lack of competency. Regardless of whether medical practitioners are using conventional treatments or CM in their practices, they are responsible for practising good medicine by complying with professional standards and regulatory mandates. In consideration of the potential harms, the MBA will evaluate whether or not a medical practitioner is practising safe, appropriate medicine according to a body of professional peers. If the MBA received a notification about a medical practitioner, it would base any decision on the practitioner's professional conduct, health or performance on the specific facts of the event that precipitated the investigation. The MBA would measure the practitioner's conduct, performance or health against the accepted standards of the day. This would include taking into account "Good Medical Practice: A code of Conduct for Doctors in Australia", any published MBA policies current at the time of the alleged conduct as well as other professionally accepted standards.

The MBA is obligated to protect the public's health, safety and welfare and recognise that the standards used in evaluating health care practices should be consistent (whether such practices are regarded as conventional or CM).

The New South Wales Medical Council's Policy on Complementary Health Care (Policy Number PCH9) is attached as Appendix 4.

### 6.3. Medical records

In terms of best practice, any complementary medicine treatment offered by a medical practitioner should occur in person and with a full and complete medical history of the patient being taken prior to treatment and consultation notes should adequately reflect the Medicare benefit schedule requirement for use of the appropriate item numbers used. Prior to

<sup>16</sup> Medical Board of Australia. <http://www.medicalboard.gov.au/>.

offering any recommendations for conventional and/or CM treatments, the medical practitioner shall conduct an appropriate medical history and physical examination of the patient as well as an appropriate review of the patient's medical records. This evaluation shall include, but not be limited to, conventional methods of diagnosis and may include other methods of diagnosis as long as the methodology utilised for diagnosis is based upon the same standards of safety and reliability as conventional methods, and shall be documented in the patient's medical record. Diagnosis may be based on long time traditional methods of diagnosis, as happens in Traditional Chinese medicine and Ayurvedic medicine.

Additional investigation may assist the care of the patient that may be considered unconventional but supported by a body of evidence and peer recognition. The medical practitioner is required to have training in this area and practice according to the relevant standards. The benefit of open communication and informed decision-making is well recognised to reduce the incidence of complaints made by patients.

Doctors should be diligent in their documentation of medical records which should conform to current RACGP Standards for General Practice and ideally include:

- the medical history and physical examination,
- diagnostic, therapeutic and laboratory results,
- diagnosis and differential diagnosis,
- results of evaluations, consultations and referrals,
- treatment objectives,
- discussion of risks and benefits,
- appropriate informed consent,
- appropriate informed refusal of treatment,
- treatment(s) and possible treatment options,
- medications (including date, type, dosage and quantity prescribed),
- instructions and agreements,
- periodic reviews.

The medical record should also document:

- what medical options have been discussed, offered or tried, and if so, to what effect, or a statement as to whether or not certain options have been refused by the patient or guardian,
- that proper referral has been offered for appropriate treatment,
- that the risks and benefits of the use of the recommended treatment to the extent known have been appropriately discussed with the patient or guardian,
- that the medical practitioner has determined the extent to which the treatment could interfere with any other recommended or ongoing treatment,
- that the evaluation of the patient happens in a clinical context of the individual patient, their individual circumstances, including the possible use of diagnostic tests and procedures. This provides the medical practitioner information in the context of the patient's needs and allows them to make an assessment.

## 7. Ethical issues

### 7.1. Patient autonomy, empowerment, paternalism and duty of care

These issues, probably more than any other ethical principle, underpin the rights of patients to choose the healthcare which they consider best for themselves. These factors drive much of the increasing medical and community interest in CM. Facilitated by increasingly easy access to health information and changing community attitudes, more patients are expecting their medical practitioners to be able to use or at least be able to advise about an

increasingly broad range of therapies. The right of the individual to make their own decisions on the type of care they wish to receive must always be predicated on best practice principles, including the provision of balanced and unbiased information upon which the patient can make an informed decision about any proposed treatment.

This level of patient autonomy obviously has to be tempered by a reasonable level of paternalism and the doctor's duty of care. When, for example, a GP considers that a patient's healthcare choices may be putting their health or wellbeing at significant risk then they will have a duty to be clear about their concerns and recommendations.<sup>17,18</sup>

### 7.2. Patient centred care

There is strong supporting research on the importance of patient centred care in the provision of quality, safe healthcare to patients and their families/carers.

### 7.3. Informed consent

Consent to any CM or medical therapy should always be based on quality information, delivered in a clear and appropriate manner. It is important when providing this information to patients to be mindful of what information would the reasonable patient attach significance to, and what information is required by the patient. This should include a discussion around financial costs of alternative treatments and investigations to ensure that the patient is fully informed. There may be occasions when the doctor also needs to document informed refusal when a patient wishes to forgo a conventional medical treatment on the basis of their choosing a complementary one.<sup>19</sup>

Also medical practitioners have a responsibility to outline any increased cost associated with complementary medicines to their patient. This allows patients to make an informed decision about treatment options that could potentially involve higher costs.

The RACGP Standards for General Practice recommend patients sufficient information about the purpose, importance, benefits and risks associated with proposed investigations, referrals or treatments to enable patients to make informed decisions about their health, tailored to the individual patient's needs, delivered in appropriate language.<sup>20</sup>

### 7.4. Beneficence and non-maleficence

At all times the wellbeing of the patient is the primary concern of the GP, providing benefit wherever possible and avoiding any foreseeable harm. Harms and benefits, as previously discussed, can be physical, emotional, social and financial. Discussion of these potential benefits and harms constitutes a significant part of informed consent.

### 7.5. Justice

Acting justly not only includes the doctor acting within the law and ethical constraints of the medical profession but also includes fair and equitable allocation of resources. Providing adequate

<sup>17</sup> Elizabeth Brophy, 'The GPs Duty of Care' (2009) 8(2) Journal of Complementary Medicine, 20.

<sup>18</sup> Elizabeth Brophy, 'Does a Doctor Have a Duty to Provide Information and Advice about Complementary and Alternative Medicine?' (2003) 10 Journal of Law and Medicine, 271.

<sup>19</sup> Elizabeth Brophy, 'Informed Consent and CM' (2003) 2(4) Journal of Complementary Medicine, 23.

<sup>20</sup> RACGP, Standards of General Practice, Criterion 1.2.2 Informed patient decisions <http://www.racgp.org.au/standards/thirdedition/122>.

access to healthcare for which a patient may have to pay out of pocket can cause some problems for patients who have less disposable incomes.

### 7.6. Privacy and confidentiality

As with any other medical treatment, patients have a right that their health information and choices remain their own private business unless that confidentiality needed to be breached to lessen or prevent a serious and imminent threat to an individual's life, health or safety, or there is a requirement under law to divulge the information. Potentially, issues can arise when patients wish their CM healthcare to remain confidential from their usual treating doctor and such confidentiality concerns need to be carefully balanced against safety concerns.

### 7.7. Accountability and responsibility

Doctors are held accountable for the advice and treatment they provide. They may also be held accountable for lack of follow-up or for the referrals they make to non-medically trained professionals where those referrals have put a patient's wellbeing at risk. The medico-legal boundaries have not as yet been clearly defined, and where a GP is concerned about a particular situation or patient they would be well advised to contact their medical defence organisation.<sup>21</sup>

### 7.8. Record keeping

Best practice involves the medical practitioner maintaining accurate and complete medical records (as documented in Section 6.3). Records should remain current and be maintained in an accessible manner, and remain readily available for review.

## 8. Long consultations

AIMA, together with the RACGP, supports the use of longer consultations especially in the management of chronic and complex health care problems, mental health problems, support of preventive health care and health promotion in all patients. The RACGP has provided evidence on the quality improvement outcomes arising from longer consultations in support for restructure of the current Medicare Benefit Schedule Attendance Items for General Practice. Complex care of chronic conditions often involves longer consultation times.

The full AIMA position statement on long consultations is included in Appendix 6.

Overall, the studies indicate that longer consultations lead to:

- improved therapeutic relationship – e.g. for trust and rapport,
- better health outcomes,
- better handling of psychosocial problems,
- less prescriptions,
- more lifestyle advice,
- less litigation,
- more patient and doctor satisfaction.

It is mandatory that written notes accurately and thoroughly reflect the comprehensive nature of assessments, that extensive notes are written for all aspects of the consultation-including the history, examination, diagnosis and management and hence fit the required criteria for documentation for longer consultation item

numbers. The Department of Health guidelines on long consultations are included in Appendix 5.

Practitioners whose services are eligible for Medicare rebates should acquaint themselves with all the requirements of the Medicare and Pharmaceutical Benefits Schemes including the explanatory notes.

## 9. Good Medical Practice: A Code of Conduct for Doctors in Australia

The Medical Board of Australia adopted the Code of Conduct.<sup>22</sup>

It is essential that medical practitioners be aware of the code of conduct of the Medical Board of Australia (MBA). The MBA has formally adopted the Australian Medical Council publication and has published it after making minor changes to reflect practitioners' obligations under the *Health Practitioner Regulation National Law Act* (National Law) as in force in each state and territory.

It is the responsibility of all doctors to be familiar with *Good Medical Practice* and to follow the guidance it contains. *Good Medical Practice* describes what the community and the medical profession believe constitutes proper and ethical conduct for a registered medical practitioner.

The topics covered in this document are universally relevant to any doctor and applicable to the practice of Integrative Medicine and include:

- Core ethical principles and qualities of good doctors.
- Good patient care.
- Shared decision making.
- Doctor–patient relationship.
- Good communication.
- Confidentiality and privacy.
- Informed consent.
- Children and other vulnerable patients.
- Openness and honesty.
- Respect for colleagues.
- Teamwork.
- Wise use of health care resources.
- Risk prevention.
- Adverse reactions.
- Conduct and performance of colleagues.
- Continuing professional development.
- Medical records.
- Advertising.
- Financial and commercial dealings.
- Conflicts of interest.

Specifically the Good Practice document makes comment about the importance of communicating with patients about CAM.

### 9.1. Effective communication

An important part of the doctor–patient relationship is effective communication. This involves:

- Listening to patients, asking for and respecting their views about their health, and responding to their concerns and preferences.
- Encouraging patients to tell you about their condition and how they are currently managing it, including any alternative or complementary therapies they are using.”

<sup>21</sup> Elizabeth Brophy, 'Referral to Complementary Therapists' (2003) 2(6) Journal of Complementary Medicine, 42.

<sup>22</sup> Good Medical Practice; A Code of Conduct for Doctors in Australia. <http://goodmedicalpractice.org.au/> [accessed 27th August 2011].

## 10. Australian Medical Association

The AMA position statement<sup>23</sup> on CM, endorsed in 2002, is provided in the appendices (see Appendix 7).

## 11. Medicare Australia

Medicare does not fund therapies that are not supported by the general body of peers. Only when treatments become accepted by the general body of peers, are MBS & PBS benefits able to be claimed. Specifically Medicare is not to be used to fund experimental or clinical trial purposes.

Doctors who practise CM have a tendency for longer consultations which places their Medicare profile outside their peers. Care of complex and chronic health conditions often involves longer consultation times. The reasons for this are addressed in the AIMA position paper on long consultations in Appendix 6.

The authors advise that doctors are at risk of Medicare investigation if their ordering of pathology testing is not in accordance with peer professional practice, and/or meets the definition of 'inappropriate practice' (please refer to Section 3.2).

Doctors should be diligent in their documentation of medical records and medical records should conform to current RACGP Standards for General Practice. The high standard of documentation ensures that any allegations of inappropriate billing or pathology testing can be defended.

## 12. Therapeutic Goods Administration (TGA) – regulation of CMs in Australia

### 12.1. The regulatory framework for complementary medicines in Australia

In Australia, medicinal products containing herbs, vitamins, minerals, and nutritional supplements, homoeopathic medicines and certain aromatherapy products are referred to as 'complementary medicines'. These are regulated as medicines under the Therapeutic Goods Act 1989 (the Act). Complementary medicines comprise traditional medicines, including traditional Chinese medicines, Ayurvedic medicines and Australian indigenous medicines.<sup>24</sup>

The overall objective of the act is to ensure the quality, safety, efficacy and timely availability of therapeutic goods, including medicines, supplied in or exported from Australia.

The TGA maintains the Australian Register of Therapeutic Goods (ARTG), a database that includes details of all therapeutic goods that are imported into, supplied in, or exported from Australia. It is a legal requirement that, unless specifically exempt or excluded, all therapeutic goods be included in the ARTG prior to their supply. Therapeutic goods cannot be included in the ARTG unless an application is lodged by a 'sponsor' who is the person or company responsible for the product.

### 12.2. Pre-market assessment

The TGA uses risk-based pre-market assessment procedures. In determining risk and the evaluation process to be applied to complementary medicines, a number of factors are taken into consideration.<sup>2727</sup> These include:

- the toxicity of the ingredients (itself a complex of factors);
- the dosage form of the medicine;

- whether the medicine is indicated for a serious form of a disease, condition or disorder, or for the treatment, cure, management or prevention of a disease, condition or disorder;
- whether the use of the medicine is likely to result in significant side effects, including interactions with other medicines; and
- whether there may be adverse effects from prolonged use or inappropriate self-medication.<sup>2727</sup>

Listed and Registered medicines are differentiated on the product label by the designation, 'AUST L' or 'AUST R' respectively, followed by a unique number.

### 12.3. Registered medicines

Medicines that are assessed to be of higher risk are individually evaluated for safety, quality and efficacy before they can be released onto the market.

Medicines that are assessed to be of higher risk are individually evaluated for quality, safety and efficacy. Higher risk products approved by the TGA are included on the ARTG as Registered medicines. Efficacy is usually assessed by examining data from controlled clinical trials. However, where adequate information is available on each active ingredient, and it is well described in standard textbooks/guidelines, this may be used to support efficacy.<sup>2727</sup>

If, following evaluation, they are approved by the TGA for use, they are included in the ARTG as Registered goods. Registered medicines include both prescription and non prescription complementary and conventional medicines.

### 12.4. Listed medicines

A different process is applied to low-risk medicines, which includes most complementary medicines. Low-risk medicines are included in the ARTG as 'Listed' medicines and most complementary medicines fall into this category. These medicines are not individually evaluated before they are released onto the market, but are checked to ensure they comply with certain legislative requirements. The process by which these medicines gain entry to the ARTG is via a rapid automated system.

Listed medicines are low risk medicines and are included on the ARTG via a low-cost and streamlined electronic application and validation process. Listed medicines may only contain ingredients that have been evaluated by the TGA to be low risk, must be manufactured by licensed manufacturers in accordance with the principles of Good Manufacturing Practices (GMP) and may carry indications only for health maintenance and health enhancement or certain indications for non-serious, self-limiting conditions. Most, but not all, complementary medicines included on the ARTG are Listed medicines.<sup>2424</sup>

The Australian Government set up the Expert Committee on Complementary Medicines in the Health System and "identified the need for the Australian regulator, the TGA, to ensure that appropriate standards for all ingredients used in CMs are legally enforceable". The supply of safe, high quality and efficacious complementary medicines, the quality use of and timely access to these medicines and the maintenance of a responsible and viable complementary medicines industry are important objectives for Governments, healthcare practitioners, consumers and industry.<sup>2727</sup>

## 13. Advisory Committee on Complementary Medicines (ACCM), TGA

The Advisory Committee on Complementary Medicines (ACCM) was formed in January 2010 to advise and make recommendations

<sup>23</sup> Australian Medical Association. Position paper on Complementary Medicine 2002 <http://ama.com.au/node/2214> [accessed 27th August 2011].

<sup>24</sup> Department of Health and Ageing. Therapeutic Goods Administration. Complementary Medicines. <http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm> [accessed 27th August 2011].

to the TGA on the inclusion, variation or retention of a complementary medicine in the Australian Register of Therapeutic Goods.<sup>25</sup>

ACCM may also provide advice to the TGA on any other matters concerning complementary medicines, and any other matters referred to it by the TGA (whether or not related to a complementary medicine).

ACCM supersedes the Complementary Medicines Evaluation Committee (CMEC) and has an increased focus on the advisory role within the regulatory framework of complementary medicines.

A major role for ACCM is to provide scientific and policy advice relating to controls on the supply and use of complementary medicines in Australia. The ACCM provides this advice with particular reference to the safety and quality of products and, where appropriate, efficacy relating to the claims made for products.<sup>28,28</sup>

### 13.1. Off label use of complementary medicines

It is well recognised that a significant number of conventional medications are used 'off label' that is prescribed for purposes other than for the approved indications, in the approved age groups, dosages or forms of administration. The same is true of complementary medicines.

Practitioners should be mindful of the safety and efficacy issues which are outlined throughout this document and be confident that they have provided adequate information to patients to ensure that they are able to make an informed choice should this situation arise.

The decision making process outlined in Section 3 with references to the PEACE mnemonic and the Renella and Fanconi diagram (2005) depicting safety and efficacy issues should be considered by practitioners when they are assessing whether to prescribe medications outside the approved indications, age groups, dosages or forms.<sup>14,14,15,15</sup>

## 14. Advisory Committee on the Safety of Medicines (ACSOM), TGA Reporting of adverse drug reactions for CMs

The Advisory Committee on the Safety of Medicines (ACSOM) was formed in January 2010 to advise and make recommendations to the TGA on the:

- safety of medicines and
- risk assessment and risk management of medicines.

ACSOM may also provide advice to the TGA on other matters related to the detection, assessment, understanding and prevention of adverse effects, known as pharmacovigilance, and any other matters referred to it by the TGA.

ACSOM supersedes and expands upon the role of the Adverse Drug Reactions Advisory Committee (ADRAC) with an increased focus on the safety aspects of medicine regulation and the detection, assessment, understanding and prevention of adverse effects.<sup>26</sup>

A major role for ACSOM is to provide advice on the quality and appropriateness of risk management plans which are designed to define and pro-actively manage risks relating to a medicine over its entire life cycle.<sup>22</sup> Adverse drug reaction reports should be submitted for the following medicines:<sup>29</sup>

- Prescription medicines (including vaccines).
- Over-the-counter medicines (medicines purchased without a prescription).
- Complementary medicines (herbal medicines, naturopathic and/or homoeopathic medicines, and nutritional supplements such as vitamins and minerals).

Medical practitioners are encouraged to report any adverse events associated with the use of any medicines to ADRAC, including CMs. This can be done using the blue card or electronically via the TGA website.<sup>29</sup>

### 14.1. Report an adverse reaction to a medicine

For prescription, over-the-counter and complementary medicines and vaccines, reports can be made:<sup>29</sup>

by post, fax or email using the 'Blue card'

- by phone, for consumers, to the Adverse Medicines Events line on 1300 134 237

This phone-in service, provided by the Mater Hospital, Brisbane, is available for members of the general public who suspect they have experienced an adverse medicine event. The service forwards reports of suspected adverse reactions to the TGA.

- online using TGA eBusiness Services:  
<http://www.tga.gov.au/safety/problem.htm#adr> [accessed 2 August 2011].

The level of adverse reporting for CMs is relatively low compared with pharmaceuticals, considering the widespread usage of CMs in Australia. There may be a number of factors contributing to this, other than having a relatively favourable safety profile (not necessarily efficacy), including significant under-reporting due to patients failing to communicate adverse events to their medical practitioner and CM and medical practitioners failing to report adverse events.

Australian TGA data from adverse events reported to the Australian Drug Reactions Advisory Committee (ADRAC) arising from the use of listed CMs from 2004 to 2008, shows that there were a total of 656 total reports where a CM was the sole suspected possible, probable or certain cause of an adverse patient reaction, with 7 possible death outcomes associated with a CM. During the same period there were 38,337 cases where a medicine (prescription, over the counter medication and other products registered on the Australian Register of Therapeutic Goods (ARTG) was the sole suspected possible, probable or certain cause of an adverse patient reaction, and there were 1014 possible death outcomes.<sup>33</sup> In many cases the contribution of the suspected medicine to the death is uncertain, however based on the information reported it is not possible to entirely exclude the possibility that the suspected medicine contributed to the fatal outcome.<sup>27</sup>

### 14.2. Medicine Safety Update

Medicines Safety Update provides practical information and advice on drug safety and information about emerging safety issues. It replaced the Australian Adverse Drug Reactions Bulletin in 2010.<sup>28</sup> Medicines Safety Update appears in each edition of Australian Prescriber.

<sup>25</sup> Department of Health and Ageing. Therapeutic Goods Administration. Advisory Committee on Complementary Medicines. <http://www.tga.gov.au/about/committees-accm.htm> [accessed 27th August 2nd 2011].

<sup>26</sup> Department of Health and Ageing. Therapeutic Goods Administration. Advisory Committee on the Safety of Medicines (ACSOM). <http://www.tga.gov.au/about/committees-acsom.htm> [accessed 27th August 2011].

<sup>27</sup> Statistics provided by the Office of Medicines Safety Monitoring at the Therapeutic Goods Administration. 25th March 2009.

<sup>28</sup> Medicine Safety Update in Australian Prescriber. <http://www.tga.gov.au/hp/msu.htm> [accessed 27th August 2011].

## 15. CM professional bodies

- 15.1. *Australian College of Nutritional and Environmental Medicine (ACNEM)*  
<http://www.acnem.org/>

ACNEM (Australasian College of Nutritional and Environmental Medicine) is a postgraduate medical college established in the early 1980s. It is independent of all governments, government agencies and other organisations and relies on no other body for funding. It is a non-profit organisation, funded from membership fees, subscriptions, courses and other programmes, book sales and donations. The College is set up as an incorporated association.

ACNEM training is designed for healthcare professionals, predominantly doctors, dentists, pharmacists, nurses, naturopaths, dieticians and other specialists who want to learn more effective ways of treating their patients. Content is evidence-based and strongly referenced, presented by leading medical and clinical experts, with practical tools to aid integration into clinical practice.

ACNEM is an accredited RACGP QI&CPD training provider. ACRRM, RNZCGP and other CPD/PDP/CME points may also be available.

- 15.2. *Australian Medical Acupuncture College (AMAC)*  
<http://www.amac.org.au/>

The Australian Medical Acupuncture College promotes acupuncture by medical practitioners as a safe, effective and unique modality of treatment within the framework of western medicine to achieve better health outcomes for all Australians.

The State branches run both introductory and advanced courses in acupuncture for medical practitioners and the Federal body conducts a Fellowship examination annually. One of the aims of the AMAC is to promote high standards of professional ethics, competence, conduct, qualifications and achievements among medical acupuncturists.

AMAC is an accredited RACGP QI&CPD training provider.

- 15.3. *Australian Association of Musculoskeletal Medicine (AAMM)*  
<http://www.musmed.com/>

The AAMM is a non-profit organisation that was formed by a group of medical practitioners in 1971 with the aim of promoting the education of doctors in the area of spinal pain disorders.

- 15.4. *Australian Medical Fellowship of Homoeopathy; Director, Australian Register of Homeopaths Ltd*  
<http://www.aroh.com.au/>

This is the umbrella body which provides education and support for doctors who practice homoeopathy.

- 15.5. *Medical Section of General Anthroposophical Society*  
[http://www.anthroposophy.org.au](http://www.anthroposophy.org.au/)

- 15.6. *Australian Ayurvedic Medical Council*  
<http://www.australiaamc.com>

## 16. Non medical CM professional bodies

Please refer to the weblinks below to find more information on the codes of ethics, registration criteria and continuing professional development expectations for each discipline.

- 16.1. *Australian Register of Naturopaths and Herbalists (ARONAH)*  
<http://www.aronah.org/>

- 16.2. *Australian Traditional Medicine Society (ATMS)*  
<http://www.atms.com.au/>

- 16.3. *Chiropractic and Osteopathic College of Australia (COCA)*  
<http://www.coca.com.au/>

- 16.4. *National Herbalists Association of Australia (NHAA)*  
<http://www.nhaa.org.au/>

## 17. Education and training

The RACGP has developed an Integrative Medicine Network within its National Faculty of Specific Interests for GPs. In future this Network may be able to offer an accreditation system and education standards for doctors practising in Australia under the umbrella of the RACGP.

## Conclusion

The authors recognise that legitimate standards of medical practice are rooted in competent and reliable scientific evidence and clinical experience. However, these standards are subject to continual change and improvement as advances are made in scientific research and analysis. In addition, standards of medical practice to some degree and the provision of medical services in individual circumstances in particular, are influenced by psychological, social, political and market forces. It is the responsibility of the Australian Medical Board to balance all of these considerations in fulfilling their mission of protecting the public through the regulation of the practise of medicine.

Public protection is carried out, in part, by ensuring medical practitioners in all practices, whether practising conventional or integrative medicine, comply with professional, ethical and practice standards and act as responsible agents for their patients. Accordingly, the authors encourage the Medical Board of Australia to consider these guidelines to assist educating and regulating medical practitioners who are (1) engaged in a practice environment offering conventional and/or CM treatments; and/or (2) engaged in cooperative therapeutic relationships for their patients with a non-medical (licensed or otherwise state regulated) health care practitioner offering CM.

All medical practitioners should ensure a balance between evidence-based medical practice and the art of medicine that informs and guides such practice, remaining compassionate and respectful of the dignity and autonomy of patients and themselves. This balance should also ensure informed consent and minimise the potential for harm.

AIMA reaffirms its commitment to cooperate with medical practitioners and professional, governmental and other organisations and agencies in supporting the further study of all health care practices that offer clinical benefits.

## Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at [doi:10.1016/j.aimed.2013.12.001](https://doi.org/10.1016/j.aimed.2013.12.001).