# Integrative Medicine Directions Report

A report commissioned by the National Institute of Complementary Medicine

2009

Highlighting complementary medicine research

NICM is an Australian Government initiative, supported by the NSW Government and hosted by the University of Western Sydney



www.nicm.edu.au

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### **Foundation partners**

The National Institute of Complementary Medicine was established in June 2007 with seed funding from the Australian Government through the Department of Health and Ageing and the NSW Government through the Office for Science and Medical Research, Department of Industry and Investment to provide leadership and support for nationally coordinated and strategically directed research into complementary medicine and translation of evidence into clinical practice and relevant policy to benefit the health of all Australians. Hosted by the University of Western Sydney at its Campbelltown campus, our role includes working with national and international partners to identify and develop sources of accurate information on complementary medicines and practices, including evidence of safety, efficacy and cost-benefits.

## **Table of Contents**

Executive summary	2
Recommendations	5
Introduction	6
Definitions	8
Models of integration	9
International initiatives promoting integration	11
Policies & guidelines	13
Outcome measures & minimum data sets	16
Lessons from national & international experience	25
References	27

Appendices Appendix 1: Contact list

#### **Resources**

The following resources are available on the NICM website Links to databases and agencies Outcome measurement tools & data sets National & international policies & guidelines National & international reports

32

### **Executive Summary**

There is growing interest by government, clinicians and the public in the health and economic benefits offered by the combined use of mainstream and complementary medicine (integrative care). This interest has been stimulated in part by concern about our ability to effectively manage chronic disease and escalating health costs in the context of an ageing population.

Whilst some documented examples exist, there is no current profile of integrative care initiatives in Australia, nor is information collected on a regular and agreed basis to enable trends to be monitored and comparisons of health and cost benefits to be made. Yet this information is required to inform both clinical practice and research. This is increasingly important given the known high rate of mixed use, with some 35% of patients who use Chinese herbal medicine co-utilise pharmaceuticals and 84% of breast cancer patients under conventional medical care use complementary medicines for reasons relevant to their disease.

Integrative care raises significant policy issues for government and other stakeholders, not least of all around ensuring optimal care and safety of patients, improved referral and communication pathways, capturing data and managing information and development of clinical guidelines, practitioner regulation and funding options.

As part of its remit, NICM developed a scoping paper and undertook preliminary consultations in mid 2008 to identify key strategies that would assist in understanding the baseline of integrative care activity and appropriate pathways forward. For example, it is known that while some mainstream health and support settings have policy guidelines on the use of complementary medicine, little is known about their content; the extent to which they cover key sectors and the extent to which they are followed. NICM commissioned a directions paper to take stock of models of care and current issues and activities.

The integrative healthcare landscape is rapidly evolving. It is hoped this report and associated resources will both prompt and inform future activity in this important part of our healthcare system.

#### Definitions

Integrative healthcare (or integrative medicine (IM) for the purposes of this report was taken to mean the use of mainstream or orthodox western medicine with complementary, alternative and traditional medicine (TCAM), with TCAM being broadly construed to include health and medical systems, practices and products not currently recognised a part of conventional or mainstream western medicine practiced by medical practitioners, nurses and allied heath professionals and includes indigenous medicines and practices. The term Traditional Medicine acknowledges that for some Australians, including Indigenous Australians, these therapies are neither complementary nor alternative.

#### Categories & models of integration

Both in Australia and abroad, the setting, models and styles for IM services are varied, with virtually every combination in operation in primary and secondary settings. There are only a handful of evaluations of IM clinics reported in the literature. Most of this research focuses on institutions and publicly funded initiatives. Many of these practices ultimately fail due to a lack of funding or a poor business model. Australia, like many countries has a strong primary care TCAM and IM presence in the private sector. There is however no reliable information that maps or describes IM services in Australia.

#### International initiatives promoting integration

The review identified the following initiatives:

- A handful of active organisations and foundations in the UK, Europe and USA supporting research and implementation of IM. These include the Consortium of Academic Health Centers USA, The Princes Foundation for Integrative Health UK, and The European Congress for Integrative Medicine.
- International government strategies for integrating TCAM into the healthcare system (e.g. Malaysia, Cuba, China, Italy).
- IM projects where TCAM access is facilitated (e.g. GetWell UK, Impact, CHIP).
- A focus on patient centered outcomes when evaluating IM services, including an on-line data set for multicentre data collection (e.g. IN-CAM).
- A systematic review of IM being undertaken by the RAND Corporation.

#### **Policies and guidelines**

The World Health Organisation Beijing Declaration 2008 calls on member states to take steps to integrate Traditional Medicine into their national health systems. It recognises that for integration to be effective there must be national policies and guidelines for the regulation of TCAM therapies and therapists, along with adequate investment into research. A copy of the Beijing Declaration is included in the Resource Section.

Few Australian health agencies have guidelines and policies for IM. However, Australia is not alone in this respect and a similar picture is seen internationally. Where they exist, Australian guidelines demonstrate an inconsistent approach to integrating (or not integrating) TCAM by health care services and clinicians. The Department of Health and Aging includes complementary medicines in the context of the National Medicines Policy and Quality Use of Medicines.

The Australian Government Health Ministers have also now included Traditional Chinese Medicine practitioners in the National Registration and Accreditation Scheme for the Health Professions from 2012.

#### Outcome measures & minimum data-sets

The brief appraisal of IM clinics in Australia found little research activity, including minimal clinical audit and routine data collection measuring outcomes. Two IM initiatives of note where outcomes are measured and analysed were the Integrative Cardiac Wellness Program, Cardiothoracic Surgical Unit Alfred Hospital, Melbourne and SolarisCare Foundation Cancer Support Centre, Sir Charles Gardiner Hospital, Perth.

A Canadian survey of TCAM researchers identified 92 different specific outcomes covering physical, psychological, social, spiritual, quality of life and holistic domains. Just over 200 standardised outcome measurement tools are listed on the IN-CAM Outcomes Database, including generalised and disease specific tools. Identifying an appropriate data set for ongoing routine or ad-hoc collection which includes outcome measurement would help coordinate and standardise IM research across Australia and better inform clinical care. However, measuring IM outcomes presents challenges for health service research. TCAM interventions are often complex and it can be difficult to separate the contributions of individual components.

#### National and international lessons

The drivers for public funding of IM are complex. International experience and translational research demonstrates that simply focusing on the evidence for efficacy and effectiveness and even economic savings of TCAM and IM services does not necessarily equate to change and improved integration. There is a need for research into funding and payment options for IM in Australia, having regard to public and private practice, and assessment of impacts on a range of stakeholders.

The success factors identified from evaluations available include:

- Open-mindedness of administrators and an open-minded culture within the centre.
- Credible "champions" to conceive, advocate and manifest the IM clinic.
- High competency of TCAM and mainstream health care practitioners.
- Finding the right fit of practitioners and staff.
- Effective communication and trust between practitioners.
- Appropriate physical space to house the clinic.
- Economically sustainable environment.
- Time and resources for evaluations, audits and service development.
- Ability to match the unique needs of the community and market.

### **Recommendations**

Recommendations from this review focus on the next steps in evaluating and developing successful integrative healthcare in Australia, and provide a framework for engaging more broadly with stakeholders. Whilst the following are a mix of specific and general recommendations based on this preliminary review, it is also intended that NICM and other relevant agencies be actively involved in supporting research that helps define the role Integrative Medicine may have in creating sustainable solutions for public health problems and improving the health and wellbeing of all Australians.

- Undertake a more comprehensive search, map and develop a database of Integrative Medicine practitioners, services and clinics in Australia including information about the location, setting, staff mix, model and style of IM offered (including Australian Indigenous medicine). This process should also identify gaps in information resources; international linkages; service provision and unmet needs for TCAM education, clinical guidelines, business support, research support and governance.
- 2. Create an Australian IM research support network linked to international counterparts for interested services and practitioners, providing guidance and practical assistance with developing funding and undertaking relevant research.
- 3. Undertake a consultative process in Australia similar to that commissioned by the King's Fund's review of *Clinical Governance for TCAM in Primary Care* to develop an Australian strategy for relevant integration of TCAM into the healthcare system.
- 4. Building on available national and international resources, work with relevant stakeholders, including Australian and state Government health and research agencies, professional associations, clinical networks, disease foundations and consumer groups to review and develop TCAM guidelines for use in the Australian health care system, including primary, secondary and tertiary care in both the public and private sectors.
- 5. Establish a strategy and process to develop a minimum data set to monitor and evaluate IM clinical practice in Australia.
- 6. Support and encourage research, both qualitative and quantitative, that explores the drivers, use and integration of TCAM by Australian consumers, GPs and specialists in public and private settings, and influence on referral and care patterns; and encourages the incorporation of health service evaluation and research into newly formed services

### Introduction

There is growing interest by government, clinicians and the public in the health and economic benefits offered by the combined use of mainstream and complementary medicine (integrated care). This interest has been stimulated in part by concern about our ability to effectively manage chronic disease and escalating health costs in the context of an ageing population. In Australia these concerns are reflected in the establishment and reports of the National Health and Hospitals Reform Commission and Preventative Healthcare Taskforce.

Whilst some documented examples exist, there is no current profile of integrative care initiatives in Australia, nor is information collected on a regular and agreed basis to enable trends to be monitored and comparisons of health and cost benefits to be made. Yet this information is required to inform both clinical practice and research. This is increasingly important given the known high rate of mixed use, with some 35% of patients who use Chinese herbal medicine co-utilise pharmaceuticals and 84% of breast cancer patients under conventional medical care use complementary medicines for reasons relevant to their disease.<sup>1,2</sup>

Integrative care raises significant policy issues for government and other stakeholders, not least of all around ensuring optimal care and safety of patients, improved referral and communication pathways, capturing data and managing information and development of clinical guidelines, practitioner regulation and funding options.

As part of its remit, NICM developed a scoping paper and undertook preliminary consultations in mid 2008 to identify key strategies that would assist in establishing a baseline of integrative care activity and appropriate pathways forward. Subsequently, NICM:

- Established a seed funding grants program to support integrated care projects and associated data collection, to demonstrate safety, clinical efficacy and cost-effectiveness of integrative care.
- Commissioned this directions paper describing integrated care initiatives and models.

Commissioning a directions paper was identified as an important first step to take stock of models of care; issues and activities. For example, it is known that while some mainstream health and support settings have policy guidelines on the use of complementary medicine, little is known about their content; the extent to which they cover key sectors and the extent to which they are followed. NICM was not positioned to undertake an exhaustive review, instead focusing on setting the broad landscape, building on available papers and literature reviews describing models of integrated care.

The landscape is rapidly evolving, and there have been a number of developments even in the short space of time when this work was commissioned. However, it is hoped this report and associated resources will both prompt and inform future activity in this important part of our healthcare system.

Dr Jennifer Hunter was contracted by NICM to undertake this review. Dr Hunter is a practising Integrative Medical Practitioner and General Practitioner in Sydney. Other relevant experience includes a Masters in Public Health, three years as a Registrar in Public Health in London and has published review articles about Integrative Medicine (IM) in primary care.

Information gathered for this report consisted of initial networking and consultation with experts, followed by literature searches. The initial list of contacts was augmented through a networking process. Published references were sourced from PubMed (February 2009).<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Search terms included Integrative Medicine, Complementary Medicine, outcomes, measurement, assessment, guidelines, government publications, the last names of key researchers and the names of outcome measurement tools. MeSH categories included Integrative Medicine, Complementary Therapies (classification, economics, legislation and jurisprudence, methods, organization and administration, standards, statistics and numerical data, trends, utilization), Outcome and Process Assessment (Health Care), Quality of Health Care, Guideline [Publication Type], Primary Health Care and Outpatient Clinics Hospital. Search results were narrowed down by combining search terms. Unfortunately, with the limited time available. Grey literature was sourced directly from contacts and through internet searches aimed at sourcing specific publications mentioned by academics and IM services.

### Definitions

Integrative medicine (or integrative healthcare) for the purposes of this report was kept purposefully broad and taken to mean the use of mainstream or orthodox western medicine with complementary, alternative and traditional medicine (TCAM), with TCAM being broadly construed to include health and medical systems, practices and products not currently recognised as part of conventional or mainstream western medicine practised by medical practitioners, nurses and allied heath professionals and includes indigenous medicines and practices. The term Traditional Medicine acknowledges that for some Australians, including Indigenous Australians, these therapies are neither complementary nor alternative.

What is 'complementary' can vary across location and time. For example, acupuncture is part of mainstream medicine practiced in China, and is a growing part of western general medicine practice in Australia.

#### **Complementary Medicine**

A formal definition of complementary medicine is contained on the NICM website, and is taken to encompass traditional as well as complementary and alternative medicine (www.nicm.edu.au). However, the World Health Organisation endorses the title Traditional, Complementary and Alternative Medicine (TCAM) as the most appropriate and inclusive description. Traditional medicines are those practised in their countries of origin and in countries by which they have been "exported" and are regarded as part of a traditional heritage rather than complementary or an alternative to western biomedical medicine. Traditional medicine includes Indigenous Australian medicine.<sup>3</sup>

#### Integrative Medicine

The term Integrative Medicine (IM) is often loosely used to describe the bringing together of biomedicine and TCAM. An IM practitioner can refer to a medical practitioner who uses both conventional medicine and one or more TCAM therapies through a TCAM practitioner working in an IM setting. Similarly, an IM clinic can range from clinics where medical and TCAM practitioners provide independent services under the one roof, through to clinics that consciously integrate TCAM and medical aspects of patient care.<sup>4-8</sup>

The Consortium of Academic Health Centers for Integrative Medicine is an American organisation whose membership currently includes 42 academic medical centres. They define IM 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>

### Models of Integration

Consumer driven integration is the main factor for institutions and community based private enterprise providing IM services and TCAM therapies.<sup>10</sup> It is common for the patient to decide when to seek biomedical or TCAM care and how this will be integrated.<sup>11-14</sup> However, medical practitioners' attitudes and knowledge of TCAM can strongly influence the style of IM practiced.<sup>15, 16</sup> The tendency in developed nations is for conventional medicine to dominate by incorporating TCAM "into" orthodox medicine rather than truly integrating the therapies.<sup>16, 17</sup> This may be less so if the medical practitioners working in the clinic have undertaken TCAM training.<sup>16</sup> The setting, models and styles for IM clinics are varied, with virtually every combination in operation.

#### International models

The RAND Corporation is undertaking a systematic review of IM practices covering around 12,000 references. IM programs are different with regard to their business models, institutional locations/relationships, professions involved, clinical models and definition of IM (personal communication, JH). Many of the reviewed institutional groups have unsustainable business models and often only survive if funded by philanthropy. Very little is known about private enterprise IM clinics.

The review has identified international examples of both hospital based and community based services, which may be grouped as follows:

- Within hospital programs there are inpatient, outpatient or combined clinics. The practitioners may be medical, TCAM or combined. The services offered may be wellness, disease or therapy based, or a full service providing care for patients not responding to biomedicine or who request IM on admission. A large 2003 USA hospital survey, identified five distinct models of integration.<sup>10</sup> The 'virtual' model (also known as 'the clinic without walls') was found in 75% of IM examples where-in existing staff provide TCAM services (e.g. a physiotherapist also provides therapeutic massage). In this model, the hospital has little internal restructuring and the costs are low.
- The 'consultatory' model relies on the medical officer referring the patient to an in-house TCAM provider. In this model the referring doctor maintains responsibility for the patient.
- The least common model is a primary care/outpatient IM clinic. Patients may be referred or self refer. This places the IM/TCAM providers in direct competition with hospital medical officers.
- A fitness or wellness centre.
- An increasingly popular model provides TCAM services in a retreat-like environment. It caters to high-end customers who are willing to pay out of pocket for expensive packages.

International community or primary care clinics are located within hospitals grounds, university campus grounds or independent sites. The practitioners may include doctors or alternatively offer a service where doctors refer patients for TCAM therapies. The focus may be wellness, disease or therapy based.

Funding arrangements range from government, insurance, philanthropy, patient or a combination of sources.

#### **Integrative Medicine in Australia**

The attitude of Australian GPs towards integrating TCAM is changing,<sup>18</sup> with an increasing number of GPs considering many TCAM therapies as highly effective and safe.<sup>19</sup> However, most GPs may be using TCAM with little formal training.<sup>19</sup>

The internet has a number of commercial databases that list Australian medical practitioners who use TCAM or describe themselves as holistic or integrative. However, compared to the findings from GP surveys, this must only represent a very small number of doctors using TCAM. The process for how Australian GPs make clinical decisions to prescribe TCAM and integrate this within their clinical practice has not been explored in detail.

The majority of IM clinics within Australia are private enterprise primary care services. They are either solo or small group practices of general practitioners (some or all of whom use one or more TCAM therapies) or clinics housing general practitioners (with or without TCAM experience) working in a team or alongside TCAM practitioners. Patients may seek limited reimbursement of out-of-pocket expenses from private health insurance. Eligible patients may claim a limited amount from Medicare for Chiropractic and Osteopath services under the Enhance Primary Care initiative.<sup>21</sup>

One 'virtual' IM service was identified where medical, allied-health and TCAM practitioners are brought together on an ad-hoc basis to provide holistic, individualised drug and alcohol programs. Only one clinic indentified was currently involved in research, although the research consisted of clinical trials and did not include an evaluation of the IM clinic.

There is a growing interest by Australian hospitals (mostly private) to provide TCAM services, especially for cancer patients. Although many seem to be in the planning phase, at the time of this review only one example of an integrative cancer service was found to be in operation: SolarisCare, Perth which has two centres in operation. The Cardiothoracic Surgical Unit, Alfred Hospital, Melbourne, is providing IM peri-operative cardiovascular care. The Jean Hailes Foundation for Women's Health, Clayton, Victoria is a multidisciplinary clinic providing specialist gynaecology and endocrinology, primary care, allied health and TCAM services.

Only one example of an Indigenous Australian healing centre was identified.<sup>21</sup> Sponsored by the Yothu Yindi Foundation, the *"Dilthan Yolngunha: respite and healing, Yolngu way"* is a community respite and rehabilitation service at Gulkula, North East Arnhem Land. It is not clear whether this is a standalone service or integrated with other health services in the region.

#### Recommendations

1. Undertake a more comprehensive search, map and develop a database of Integrative Medicine practitioners, services and clinics in Australia including information about the location, setting, staff mix, model and style of IM offered (including Australian Indigenous medicine). This process should also identify gaps in information resources; international linkages; service provision and unmet needs for TCAM education, clinical guidelines, business support, research support and governance.

### International Initiatives Promoting Integration

#### World Health Organisation

Following on from the World Health Organisation (WHO) Traditional Medicine Strategy,<sup>22</sup> the Beijing Declaration 2008, calls on member states to take steps to integrate traditional medicine (TM) into their national health systems.<sup>23</sup> It recognises that for integration to be effective there must be national policies and guidelines for the regulation of TCAM therapies and therapists, along with adequate investment into research.

#### The Prince's Foundation UK

In the UK, The Prince's Foundation for Integrative Health appears to be the most active not-for-profit organisation promoting IM. It provides information for the public and health professionals. It takes an active role in creating a platform for the integration of TCAM into the NHS.

#### The King's Fund UK

In 2003 the King's Fund commissioned an extensive consultative process and submitted a final document to the Department of Health in Oct 2004: *"Clinical Governance for Complementary and Alternative Medicine in Primary Care"*. The document provides a summary of the findings from six working groups (seminars and Delphi process); a survey across the UK of NHS funding of CAM by the Primary Care Trusts; a more detailed review of integrated CAM provision by 16 primary care clinics in London; background information and recommendations.

#### IM services in the UK

Through the UK Government's New Deals for Communities program started in the late 90's, a small number of IM projects were funded and reviewed (e.g. Get Well UK, Impact, CHIP). Whilst reporting positive outcomes for patients, referring medical practitioners and cost savings, none have secured ongoing National Health Service (NHS) funding. Some projects have secured temporary funding through the Local Health Authorities (e.g. in Glastonbury, Newcastle, Londonderry, Dublin).

#### IM in Italy

The public healthcare programs in Tuscany, Italy, began a process of integrating various types of "non-conventional" medicine in 1996. The process has included regional laws governing the practice of complementary medicine by doctors, dentists, veterinarians and pharmacists. The aim is to integrate therapies which are supported by a sufficient level of evidence and can thus be termed "complementary medicine".<sup>24 25</sup>

#### IM in Germany

The Institute for Social Medicine, Epidemiology and Health Economics, Charité University Medical Center, Berlin has undertaken focused TCAM research for ten years and now has three TCAM chairs. The institute focus is on research methods appropriate for TCAM; health services research and effectiveness studies.

#### IM in Malaysia and Cuba

Both the Malaysian and Cuban governments have formally endorsed the integration of TCAM. Cuba has established a large integrative clinic / hospital. Malaysia has three traditional medicines, Malay, Chinese and Indian which it aims to better integrate into the Malaysian healthcare system. Focusing on policy and guidelines for accreditation, education and training, responsible advertising and research, the government has set the goal of implementing integration into the hospital system by 2010 and community health centres by 2015.

#### IM in the US

In the USA the Consortium of Academic Health Centers hosts regular scientific conferences and there are several examples of privately funded hospital integrative care centres.

#### **Recommendations**

- 2. Create an Australian IM research support network linked to international counterparts for interested services and practitioners, providing guidance and practical assistance with developing funding and undertaking relevant research.
- 3. Undertake a consultative process in Australia similar to that commissioned by the King's Fund's review of *Clinical Governance for TCAM in Primary Care* to develop an Australian strategy for relevant integration of TCAM into the healthcare system.

### Policies & Guidelines

There is a paucity of well constructed guidelines for the use, practice and integration of TCAM, with only a handful of clinical guidelines <sup>26-31</sup> and health services guidelines <sup>32-37</sup> on the use of TCAM identified. The following provides a summary of major reports and guides identified in the course of the project.

#### World Health Organisation

The WHO Beijing declaration on Traditional Medicine expresses "the need for action and cooperation by the international community, governments, and health professionals and workers, to ensure proper use of traditional medicine as an important component contributing to the health of all people, in accordance with national capacity, priorities and relevant legislation".<sup>23</sup>

The WHO also published a set of guidelines in 2004 for providing reliable consumer information that set out a series of questions to guide users through the decision making process for the use of TCAM.<sup>38, 39</sup>

#### United States

A survey of USA hospitals with IM services found few guidelines or policies. Those that did exist were inconsistent and failed to cover all relevant areas<sup>40, 41, 42</sup>

The White House Commission on Complementary and Alternative Medicine Policy (2002) was established to provide the President with a report containing legislative and administrative recommendations to ensure public policy maximises the potential benefits of complementary and alternative medicine (CAM).<sup>45</sup> The Commission was asked to address the coordination of research to increase knowledge about CAM products, education and training of health care practitioners in CAM, provision of reliable and useful information about CAM practices and products to health care professionals, and guidance regarding appropriate access to and delivery of CAM.

#### United Kingdom

In the UK, the King's Fund and the Department of Health commissioned an extensive consultative process to provide guidance on issues for TCAM Clinical Governance.<sup>43</sup> The Princes Foundation also offers practical advice on what to consider when developing guidelines for TCAM and IM clinics.<sup>44</sup> The Scottish Executive briefly states that Health Boards and doctors should consider providing TCAM services and referring patients for TCAM therapies and outlines where responsibilities lie.

During the consultative work on TCAM clinical governance in 2003-04 for the King's Fund, the need to develop clinical guidelines was recognised, and the first set of clinical guidelines on the treatment of lower back pain including TCAM were released by the UK National Institute of Clinical Excellence in May 2009.<sup>48</sup>

#### Australia

Currently, there appears to be no single agency or policies that specifically and systematically address the use and integration of TCAM.

The Department of Health and Aging (DHA) includes CAM within the context of the National Medicines Policy and Quality Use of Medicines. In May 2003, the Australian Government established the Expert Committee on Complementary Medicines in the Health System (the Expert Committee). The Expert Committee was asked to *"consider the regulatory, health system and industry structures necessary to ensure that the central objectives of the National Medicines Policy are met in relation to complementary medicines."* The committee's report and Government response focus on practitioner and product regulation; information and education needs; research; safety; product claims and restoring consumer confidence following the PAN pharmaceutical recall.<sup>46</sup> Integrative healthcare is not specifically addressed.

In February 2009, the Australian Government announced a new structure to advise government on the *Quality Use of Medicines Policy*, which provides the framework for medication access, safety and quality in Australia. The structure includes a National Medicines Policy Committee, which includes a member with expertise in complementary medicines. New health committees were established by the National Health and Medical Research Council in 2009, however, no members with specific expertise in TCAM were appointed to any of the committees or Council. In 2009, the Australian Health Ministers Council announced the inclusion of Traditional Chinese Medicine Practitioners into the National Registration and Accreditation Scheme for health professionals from 1 July 2012. The change in status may provide an impetus for improved communication and interaction between TCAM and medical practitioners.

2009 also saw the release of major reports on reforming the Australian healthcare system, specifically aimed at increasing focus on prevention, early intervention and self-care. These include reports from the National Health and Hospitals Reform Commission (NHHRC), Primary Health Care Reform Australia and the Preventative Health Taskforce. There is virtually no reference to complementary medicine in any of the reports.

This project did not allow for systematic enquiries to be made to area health services, community centres or hospitals. Among the network of those consulted, the "*NSW Wentworth Area Health Service: Complementary Medicine / Therapy Policy and Procedures 8 April 2004*" is the only known set of guidelines covering both TCAM therapists and medicines.

The Wentworth document is comprehensive, with clearly defined terms and guiding principles. It covers a wide range of circumstances; addresses clinical governance and credentialing; and is congruent with, and refers to existing non-TCAM Area Health guidelines and policies. However, the document cited is a final draft written in 2004 by the then Wentworth Area Health Service Complementary Therapies Committee and at the time of compiling this report it was unclear if the document has been endorsed by the now Sydney West Health Service.

The Therapeutic Goods Administration (TGA) within DOHA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard. The Council of Australian Therapeutics Advisory Groups (CATAG) and its respective state groups have made some efforts to write guidelines for the use of TCAM in hospitals. Unfortunately, activities to date have not been coordinated.

The Victorian TAG (VicTAG) group published its guidelines in 2005, including appendices for a CAM self administration medication chart, CAM use against medical advice statement for inpatients, proposed content for a patient information brochure and a flowchart for the use of CAM in hospital. In 1999, the NSW CATAG discussion paper on CAM in hospitals was adopted by NSW Health Department (Information Bulletin 99/18). It briefly covers topics such as regulation, quality, safety and efficacy of medicines, as well as practical issues such as medication history, therapeutic choice, documentation, supply, storage and patient consent. The document sets the agenda for NSW hospitals to write their own more comprehensive guidelines.

The Australian Medical Association (AMA) has a Joint Position Statement (204) with the Australian Integrative Medicine Association (AIMA) on Complementary Medicine), recognising the high rate of use of complementary medicine, stressing the importance of evidence as the key principle for integration and calling for more research and information about TCAM.<sup>47</sup> 2010 will see the start of the first Integrated Medicine Fellowship program available through the Royal Australian College of General Practitioners.

#### Recommendations

4. Building on available national and international resources, work with relevant stakeholders, including Australian and state Government health and research agencies, professional associations, clinical networks, disease foundations and consumer groups to review and develop TCAM guidelines for use in the Australian health care system, including primary, secondary and tertiary care in both the public and private sectors.

### **Outcome Measures & Minimum Data-Sets**

Integrative Medicine is significantly under-researched. The brief appraisal of some IM clinics in Australia found no examples of routine data collection and outcome measurement. Identifying an appropriate set of data for ongoing routine or ad-hoc collection which includes outcome measures would help coordinate and standardise IM research efforts across Australia and underpin evidence-based clinical care. A coordinated approach would not only create consistency of data collection between centres but also offer the potential for pooling resources and expertise.

However, in addition to developing appropriate tools and measures, there is a need to proactively support clinical research in this field. IM clinics also need support to undertake high quality research and data collection. Models could be drawn from other initiatives aimed at encouraging research in primary care such as the RACGP research grants and the Primary Health Care Research, Evaluation, and Development program.<sup>69</sup>

#### Clinical collections, Australia

Two IM initiatives where identified in Australia that are already collecting and analysing data on outcomes: the Integrative Cardiac Wellness Program, Cardiothoracic Surgical Unit Alfred Hospital, Melbourne and the SolarisCare Foundation Cancer Support Centre, Sir Charles Gardner Hospital, Perth.

The Cardiac Wellness Program is monitoring the outcomes of a newly established IM service providing perioperative care to cardiac surgery patients. It follows on from clinical trials conducted in the same hospital. The outcomes measured include patient characteristics, biochemical measures used in routine clinical care (e.g. serum treponin, ECG), length of stay, post operative rehabilitation participation, quality of life, patient satisfaction. Funding for data analysis comes from the hospital and research grants.

SolarisCare is a free drop-in centre for patients to access information and support. Volunteer therapists provide selected complementary therapies for cancer patients and their families. Patient demographics are recorded and standardised questionnaires measure quality of life, improvements in symptom distress (e.g. breathing, bowel, appetite problems, pain, insomnia, nausea and fatigue), and reduction in depression and anxiety. Funding for data analysis comes from philanthropic and other grant sources.

#### **Outcome measures**

Measuring health related outcomes in essential for determining the efficacy and effectiveness of interventions and health care services. Outcomes may be specific to a disease or general quality of life and wellbeing measures.

Finding and choosing appropriate outcome measurement tools can be difficult and time consuming.<sup>55, 56</sup> Standards for the development and evaluation of outcome tools have been proposed.<sup>57-63</sup> The Scientific Advisory Committee (SAC) of the Medical Outcomes Trust released a helpful document that lists eight key attributes to consider for health related outcome measurement tools (Table 1). Table 2 provides a list of some standardised measurement tools that have been used in the TCAM and IM research settings.

#### Table 1: Attributes of Outcome Measurement Tools Source Scientific Advisory Committee, Medical Outcomes Trust<sup>64</sup>

- 1. The concept or attribute to be measured should be clearly defined and match its intended use.
- 2. Reliability is the reproducibility of the results and the measurement error caused by chance.
- 3. Validity is capacity to measure the attribute is aims to measure.
- 4. Responsiveness is the ability to detect change over time.
- 5. Interpretability is ability to understand the results from the measurement tool.
- 6. Burden considers practical aspects such as such as time, effort and other demands placed on the respondent and administrators.
- 7. Alternative means of administration includes self-report, intervieweradministered, computer assisted and comparability of results using different means.
- 8. Cultural and Language adaptations or translations of the tool and its subsequent validity and reliability.

#### Table 2: Examples of Non-Disease Specific Standardised Measurement Tools

•	Arizona Integrative Outcomes Scale (AIOS)	•	Measure Yourself Medical Outcome Profile (MYMOP)
•	Catastrophizing (Coping Strategies)	•	Medication Change Questionnaire
•	Daily Stress Inventory		(MCQ)
•	EQ-5D – EuroQol	•	Patient Health Questionnaire-15
•	HAM-D sleep	•	Psychological Outcome Profile
•	Hospital Anxiety and Depression		(PSYCHLOPS)
•	I-Med Index	•	Recent Life Changes
•	Life Orientation Test-R	•	SF-36 & SF-12
•	Measure Yourself Concerns and	•	The Patient Enablement Instrument
	Wellbeing (MYCaW)	•	The Perceived Stress Scale

Standardised measurement is required to ensure validity and reliability of the results.<sup>49, 50</sup> There appears a trend toward using patient-centred outcomes for evaluating IM services including measures of patient preference, patient empowerment and health care practitioner satisfaction.<sup>43</sup>

A specific challenge is the complex, whole practice nature of TCAM interventions. Individual components may be inseparable in their effects. For example, focusing only on the active ingredients of the IM system could be misleading. Whole systems research (WSR) with mixed methodologies using both qualitative and quantitative methods be utilized may be appropriate. <sup>53, 54</sup>

The Canadian Interdisciplinary Network for CAM Research (IN-CAM) identified the need for easy access to a wide range of outcome measures. They surveyed the views of 164 Canadian CAM researchers, practitioners and students about outcome measures currently used, outcome measures' assessment criteria, sources of information, perceived barriers to finding outcome measures and outcome domains of importance. Ninety-two different outcomes were identified covering physical, psychological, social, spiritual, quality of life and holistic domains. Measuring unique patient-centered outcomes and the context and process of healing were also important. Barriers experienced were the accessibility of instruments and that outcome measures for many health concepts do not exist.<sup>51</sup>

IN-CAM proposed a framework of outcome domains ranging from specific to general (Table 3). Two of the domains, the process and context of healing, may not be considered classic health related outcomes. However, they were identified as important for TCAM and IM research and in need of construct development.<sup>52</sup>

The IN-CAM Outcomes Database lists over 200 standardised outcome measurement tools, including generalised and disease specific tools. Not all the tools listed have been used in TCAM or IM research. However, the reviewers have judged them as potentially appropriate tools for use in these settings. For each tool, information is provided that includes a brief and detailed description, the authors, year created, cost, domain classification and references including any publications of TCAM evaluations.

The King's Fund report reviews several areas to consider when measuring IM outcomes, including patient related outcomes, health care service outcomes and wider social outcomes (Table 4). The report notes the challenge (and customary need) for effectiveness studies as a precursor to undertaking economic evaluations. They propose exploring alternative economic methodologies such as Conjoint Analysis that assesses a patient's preferences and willingness to pay.<sup>43</sup>

The King's Fund report also discusses IM health service data collection and included a list of Performance Indicators for use in the NHS (Table 5).<sup>43</sup> This list highlights some important areas to consider in addition to measuring patient characteristics, health service use and outcomes. These include practitioner job satisfaction; targeting problems areas in orthodox care such as waiting times, effectiveness gaps and expensive treatments; safety and adverse events; consideration of local demographic and prevalence rates; equity and patient access; a focus on 'process' and not just outcomes; and national health priorities.

#### Table 3: Outcome Domains for TCAM & IM Source: IN-CAM

#### Context of the Intervention

Context is the set of circumstances within which an intervention takes place, which may include the patient provider relationship and patient and provider characteristics and the health care system.

#### Process of the Intervention

A process is a series of actions, changes, reactions or functions that happen over time as an individual moves from one state of health to another. Where an outcome measure can determine if change happened specific to a particular symptom, process focuses on not only whether change occurred, but how the change occurred. Some common examples include unsticking and transforming.

#### Holistic

The holistic domain includes health outcomes related to the interaction between mind, body, spirit and the individual patient context, and therefore considers the whole person perspective. Holistic health outcome measures do not distinguish between specific domains as they provide a global measure of an individual's overall sense of well being.

#### Health-Related Quality of Life

The health-related QOL domain includes outcomes that are related to an individual's experience and appraisal of their current health state in relation to their health-specific goals, expectations, standards and concerns. They often assess multiple health outcome domains, such as those listed above.

#### Spiritual

The spiritual domain includes health outcomes related to meaningful connections with the self, others, the environment and a higher power. These can be experienced as: faith, beliefs and spiritual/soulful practices AND/OR interconnectedness (with others and the environment). Some common examples include spiritual wellbeing, awareness and self-transcendence.

#### Psychological

The psychological domain includes health outcomes related to cognitive and emotional status, and a sense of being. Some common examples include coping, hope, stress, anxiety and depression.

#### Physical

The physical domain includes health outcomes related to physical function, from the ability to carry out daily self care tasks to activities that require a greater degree of mobility, strength and endurance. Some common examples include disability, activity levels (related to work, leisure, etc), sleep, energy (as experienced physically) and pain. Physical health outcomes are separate from biological markers (e.g., cortisol levels, blood pressure) which are directly measurable and therefore are not included in this database.

#### Social

The social domain includes health outcomes related to a sense of participation and belonging in various social relationships, and development of personal potential within those roles. Some common examples include attachment, family relationships, friendship, work-related relationships, and community-oriented relationships.

#### Individualized

# Table 4: Developing methods for the economic evaluation of primary<br/>care CAM43 Source: King's Fund Report

#### 1. Measuring patient related outcomes

1.1 Health states; symptom relief and dis-benefits of side effects

**1.2** Wellbeing; empowerment, emotional wellbeing, coping strategies and patients feeling good about themselves (despite some impairment)

**1.3** Process utilities i.e. what patients value; empathy, the pleasure of receiving treatment, touch, & the time that is taken

**1.4** Health behaviours i.e. changes in patient knowledge, behaviour and understanding of their health e.g. changing attitude to health, taking greater responsibility, healthy eating & exercise

1.5 Patient identified outcomes commonly associated with CAM interventions (modality specific and

condition / symptom specific – including levels of pain and mobility/disability) as well as more general gains e.g. satisfaction, perceived value of safe, non-invasive modalities, and of the personal locus of control remaining with the patient etc

1.6 Patient satisfaction

 $\ensuremath{\textbf{1.7}}$  Cost to the individual e.g. loss of earnings, cost of medical equipment and interventions

**1.8** Wellbeing, empowerment, emotional wellbeing coping strategies and patients feeling good about themselves (despite having some impairment)

1.9 Patient choice evaluated as an outcome / benefit

#### 2. Measuring Primary Care Trusts (PCT)/NHS related outcomes

2.1 Impact on PCT's ability to address local targets (e.g. access, waiting lists)

**2.2** Impact on demand (and cost) for other services e.g. primary and secondary referrals (using study group data as well as PACT data)

2.3 Impact on PCT drugs bill (reduced prescribing)

2.4 Impact on national clinical priorities (e.g. NSFs)

2.5 The health promotion and preventative impact of CAM interventions (as this is part of the PCT remit)

2.6 Impact on conditions for which there are gaps in provision and demand within the PCT2.7 Impact on related PCT employment issues e.g. absenteeism and workforce efficiency,

GP stress and recruitment and retention issues

#### 3. Measuring wider social outcomes

**3.1** Social services, welfare and business related costs e.g. early return to work, claims for sickness and mobility benefits, welfare benefits to support individuals separated due to impact of ill health, need for social services involvement and care, disability services, occupational health. (N.B. Incorporate the concerns of the new Care Trusts as they have unified budgets and will become increasingly relevant)

**3.2** Long-term community health gains – (when health becomes a driver for change & there is continuity and cohesion over generations)

**3.3** Wider benefits to the patient, their carer(s), family and family life (including family cohesiveness and related costs e.g. need for carer to stop work to provide care, separation)

#### 4. Costs and other related outcomes and considerations

4.1 Related cost implications of side effects of conventional option.

**4.2** An assessment of the whole service as well as different aspects of the service (i.e. not just comparing different types of therapeutic intervention and not just focusing on individual patient outcomes) i.e. Calculate total cost savings (may be cost neutral)

4.3 A breakdown of the costs for treatment of individual patients (CAM and orthodox pathways)

**4.4** Calculate the whole set-up costs for services including; overheads, salaries, training, informing referrers to the service, time for meeting and resources for communication, provision of patient information, systems for regulation, supervision, audit and other clinical governance activities

5. Appropriate methodologies (see also pilot studies suggested below)

5.1 Conventional outcome measures relative to health states; general health (EQ5D, SF36) or specific condition related scales

5.2 Cost utility analysis (orthodox i.e. QALYs)

**5.3** Develop a new model for evaluating effectiveness based on the example of NICE guidelines on infection control. As RCT evidence wasn't available NICE based the guidelines on best practice and expert opinion. A CAM version could incorporate both these aspects as well as the holistic care angle

5.4 Cost Benefit analysis (conventional methodology)

5.5 Cohort studies: contemporary care control groups versus CAM integrated intervention group

5.6 Cost effectiveness analysis (e.g. conjoint analysis)

5.7 Cost minimisation (conventional methodology)

**5.8** Longitudinal studies (e.g. including comparative studies)

5.9 Early intervention studies e.g. delayed use of medication

5.10 Develop 'tools' to measure the four domains of benefit: health states, wellbeing, process utilities and health behaviours

5.11 Programme Budgeting and Marginal Analysis

5.12 Gap analyses - local orthodox services to identify provision and demand

5.13 Measures used in the field of occupational health and employment e.g. workforce efficiency measures

6. Research considerations

**6.1** Make sure that any evaluation fulfils the information requirements of the PCT (especially those specified by a commissioning panel)

6.2 Ensure evaluations incorporate PCT and patient expectations and requirements

6.3 Define measures of analysis very clearly e.g. measuring outcomes for complex conditions; costs of maintenance, support, remedial care

6.4 Consider whether the focus should be on an individual therapy or package model of delivery (i.e. assessing the overall model of delivery or the individual therapies within it)

6.5 Consider whether to measure individual gain to individual patients, or system gains to the whole PCT

**6.6** Consider where economic analysis fits with patient choice and factors that determine their decisions to chose CAM as treatment option

6.7 Consider which aspects of economic analysis determine commissioning decisions.

6.8 Be creative and think about outcomes of the service in new and expansive ways

# Table 5: Provisional guidance for developing Performance Indicators(PIs) in the NHS43Source: Kings Fund Report

1. Recommended areas for PI development
1.1 Safety 1.1.1 Adverse Events 1.1.2 Risk Assessment 1.1.3 Health and safety procedures
<ul> <li>1.2 Effectiveness</li> <li>1.2.1 Health outcomes for specific conditions</li> <li>1.2.2 Health outcomes for non-specific conditions</li> <li>1.2.3 Functional Improvement</li> <li>1.2.4 Wellbeing</li> <li>1.2.5 Patient enablement in chronic disease</li> <li>1.2.6 Patient feedback and satisfaction</li> <li>1.2.7 Patients ability to cope</li> <li>1.2.8 Impact on patient's family life</li> <li>1.2.9 Patient expectation versus outcome</li> <li>1.2.10 Symptomatic relief</li> <li>1.2.11 Patients' personal productivity</li> </ul>
<ul> <li>1.3 Delivery</li> <li>1.3.1 Closing the gap between patient need and access</li> <li>1.3.2 Access (focus on equity and equality)</li> <li>1.3.3 Acceptability</li> <li>1.3.4 Patient choice</li> <li>1.3.5 Patient feedback and satisfaction</li> <li>1.3.6 Demand management and capacity issues (from the PCTs perspective)</li> <li>1.3.7 Referral rates to primary and secondary care services (including impact on GP referral rates)</li> <li>1.3.8 How well patient care was liaised, co-ordinated and communicated</li> <li>1.3.9 GP satisfaction</li> <li>1.3.10 Availability</li> <li>1.3.11 Appropriateness</li> <li>1.3.12 Impact on conventional services – pressure/demand</li> <li>1.3.13 Waiting times</li> </ul>
<ul> <li>1.4 Value for money</li> <li>1.4.1 Reduction of primary and secondary care referrals</li> <li>1.4.2 Population health gain or individual QALYs gained</li> <li>1.4.3 Prescribing costs</li> <li>1.4.4 'Knock on costs' such as number of days patients take off work due to illness</li> </ul>
<b>1.5</b> Target particular NHS problem areas within orthodox care e.g. long waiting times, effectiveness gaps, expensive surgery
2. Factors that need to be taken account of in developing PIs
<ul> <li>2.1 PIs should be relevant and useful to patients</li> <li>2.1.1 Impact on GP consultation rates</li> <li>2.1.2 Time lost from work</li> <li>2.1.3 Cost of treatments</li> <li>2.1.4 Complaints</li> <li>2.2 PIs should take account of local patient demographics</li> <li>2.3 PIs should take account of local prevalence rates for specific conditions</li> <li>2.4 PIs should relate to national targets/initiatives (e.g. NSFs)</li> <li>2.5 PIs should also be developed around the 'process' and not just outcomes</li> </ul>

3. Individuals/organisations that need to be involved in deciding PIs:

3.1 Complementary Practitioners (CPs 95)

3.2 PCT /StHA representatives

3.3 Patients

3.4 Expert patients and patient representatives/advocacy groups

3.5 GPs

- 3.6 Community nurses
- 3.7 Educationalists (in the fields of CAM and research/evaluation)
- 3.8 Public health representatives

3.9 Regulatory bodies

4. Individuals /organisations to sign up to the PIs

4.1 Clinical governance teams (PCTs)

- 4.2 Complementary Practitioners
- 4.3 General Practitioners
- 4.4 Members of the PCT Professional Executive Committee (PEC)
- 4.5 Regulatory bodies

5. Implementation and development

5.1 Conduct a pilot project to develop a range of PIs

5.2 Circulate suggested PIs to all relevant stakeholders to ensure buy-in

5.3 Regular reviews of progress and relevance of PIs

- 5.4 Develop a standardised questionnaire to help establish benchmarks
- 5.5 Establish local PI working groups (online)
- 5.6 Local PI groups should work with interested PCTs
- 5.7 Local PI groups should develop partnerships with other PI groups nationally

5.8 Audit used to measure if PIs are being achieved and sustained

#### **IM Data Sets**

A minimum data set collects longitudinal health service data, providing information about patient characteristics, health service use, outcomes and performance indicators. It can be used to monitor a health care service, compare services, and combine data from different services.

The use of a minimum dataset by different IM clinics allows comparisons to be made between clinics and enables multicentre collaborations. However, the disadvantage is that IM clinics specialising in different clinical areas may not collect enough specific information about patient characteristics and outcomes. Recognising that a minimum dataset is just that, it should be used to provide a baseline that standardises data collection common to all IM clinics and research projects. Each clinic or research project would then add specific data collection and measurement of outcomes. If comparisons between orthodox and IM service delivery are also to be made, then their datasets must be compatible.

When formulating a dataset, the purpose for collecting the information must be clearly defined. Logistical considerations for how the data will be collected and analysed, including funding, must be well thought out. Much data is already routinely collected by health care services which could potentially be included or built upon when establishing a minimum dataset.

Two operational IM datasets (international) were identified in the course of the project, one collecting patient characteristics and health service use (ABC electronic coding) and the other collecting information about patient characteristics and outcomes (PROCAIM).

Minimum data sets such as the ABC electronic coding system include TCAM codes for treatment episodes. Data is entered by the service provider. This system is used by some health insurance organisations in the USA and now also Dubai Healthcare City.

PROCAIM collects data on patient reported health and outcomes.<sup>65</sup> Developed by the UCLA Center for Neurobiology of Stress, it is a Web-based system collecting information from patients of participating IM clinics. Patients enter information about their demographics, symptoms, general health, mood, spirituality/religiosity and life orientation. Following this, patients complete 9 different standardised questionnaires at set intervals. Collectively the questionnaires provide information about thoughts and feelings, stress, early childhood experiences, daily stresses, pain perceptions, sleep, vitality and symptom relief. The aim of the database system is to facilitate large scale, multi-site studies in effectiveness research, hypothesis-driven research, clinical management and clinical trials.

Other initiatives include the RAND group toolkit for evaluating IM in the military (USA). As part of the project, they will review and develop outcome measures along with a template for program evaluation. The National Institutes of Health (NIH) in the US funded Patient-Reported Outcomes Measurement Information System (PROMIS) is developing ways to measure patient-reported symptoms, such as pain and fatigue, and aspects of health-related quality of life across a wide variety of chronic diseases and conditions. It is not clear whether they are also assessing outcomes specific to TCAM and IM.

#### **Recommendations**

5. Establish a strategy and process to develop a minimum data set to monitor and evaluate IM clinical practice in Australia.

### Lessons from national & international experience

Understanding the safety, efficacy and cost-effectiveness of TCAM and IM interventions are major components of appropriate and effective use. However, simply focusing on the evidence for these factors will not necessarily equate to change and better integration of relevant evidence-based healthcare options. It is important also to understand the spectrum of drivers and success factors for policy implementation and service access, use and provision of integrated care.

The National Prescribing Service has undertaken reviews of the TCAM information requirements of consumers, general practitioners and pharmacists.<sup>78</sup> These reports provide important guidance about the information needs and gaps of these groups. However, little is known about what influences GPs to use or refer patients for TCAM<sup>16</sup>. What happens at the coal face between patients and their doctor's influences the way TCAM is practised, and the nature and degree of integration.

Although there are only a handful of evaluations of IM clinics reported in the literature, the success factors found for an IM clinic appear reasonably consistent.<sup>44, 66, 67</sup> These are:

- Open-mindedness of administrators and an open-minded culture within the centre.
- Credible "champions" to conceive, advocate and manifest the IM clinic.
- High competency of TCAM and mainstream health care practitioners.
- Finding the right fit of practitioners and staff.
- Effective communication and trust between practitioners.
- Appropriate physical space to house the clinic.
- Economically sustainable environment.
- Time and resources for evaluations, audits and service development.
- Ability to match the unique needs of the community and market.

For many developing countries facilitating TCAM access is culturally appropriate and has the potential benefits of contributing to preventative health and chronic disease management. In Australia however, integration of TCAM needs to be negotiated in an already complex health funding system. The interwoven nature of private and public health service provision in Australia adds to the complexity of issues to consider when reviewing and planning IM services.

Survey interviews with a random sample of NHS Primary Care Organisations responsible for commissioning local health services found that a small number were developing area-wide TCAM and IM services. Positive influences were identified as: existing services, local enthusiasm and expertise, patient demand, a willingness to consider the wider evidence-base for CAM, and a perception that complementary therapies could help them meet national NHS targets. Negative influences included: the cost of ensuring equitable access to services, a perception that CAM lacks the credibility required for public funding, the need to prioritize services and the need to direct funding towards meeting national and local health objectives.<sup>70</sup>

The statistics for the use of TCAM by German doctors is impressive: around 25% of primary care doctors use acupuncture, 5,000 doctors are registered homeopaths, 10,000 are registered naturopaths and many more "unqualified" doctors prescribe phyto-medicine and supplements. Private health insurers generally pay for IM and TCAM. The statutory insurance companies would also like to provide TCAM to their customers; however the German government restricts this without sufficient evidence of effectiveness. This requirement initiated the funding of a large multicentre effectiveness study on acupuncture. Since 2008, results have started to be published and led to statutory insurers now funding acupuncture to treat chronic lower back pain and OA of knee.

The German government's requirement for evidence before funding TCAM and IM is a common theme among decision makers. However, the intention for evidence-based medicine to use the *best available* evidence, blended with clinical experience.<sup>43, 73, 74</sup> It is unrealistic to expect every decision, be it clinical or service based, to have an RCT to back it. Consistency of expectations for TCAM with mainstream medicine is also important, with estimates that an average 37% of interventions are supported by RCTs, and an average 76% of interventions are supported by some form of compelling evidence.<sup>79</sup> Other types of qualitative data and evidence can also be used to inform the decision making process, for example information about patient preference and wider benefits to the community.<sup>75, 76</sup>

For many years now, acupuncture provided by Australian medical practitioners attract a Medicare rebate. In 2004, the Australian DHA included Osteopaths and Chiropractors on the Allied Health Practitioner (AHP) list for Enhanced Primary Care (EPC) Medicare rebates. The DHA states that the purpose of the EPC program is for GPs to formulate and enable comprehensive evidence-based management plans for chronic diseases. However, it is not clear how the evidence-base of practices chosen for funding have been determined. The Enhanced Primary Care also limits a total of 5 Allied Health Practitioner visits per year.<sup>1,77</sup> Although this decision may have been based on research, it might not always equate with the evidence for TCAM effectiveness (e.g. the UK National Institute for Health and Clinical Excellence clinical guidelines for lower back pain include offering a course of manual therapy including spinal manipulation up to 9 sessions for a period of up to 12 weeks).<sup>48</sup>

More holistic and comprehensive research is needed on funding and payment options for TCAM within the Australian health system, having regard to the benefits and impacts of measures for a range of stakeholders, including consumers, practitioners and the broader community, who ultimately fund these options.

#### **Recommendations**

6. Support and encourage research, both qualitative and quantitative, that explores the drivers, use and integration of TCAM by Australian consumers, GPs and specialists in public and private settings, and influence on referral and care patterns; and encourages the incorporation of health service evaluation and research into newly formed services

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