Public Consultation on the Complementary and Alternative Medicine Resource for Clinicians

Submission to the
National Health and Medical Research Council

Highlighting complementary medicine research

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

NICM
THE NATIONAL INSTITUTE OF COMPLEMENTARY MEDICINE
www.nicm.edu.au

ABOUT THE NATIONAL INSTITUTE OF COMPLEMENTARY MEDICINE (NICM)

Hosted by the University of Western Sydney, the National Institute of Complementary Medicine (NICM) has provided leadership and support for strategically directed research into complementary medicine since its bipartisan establishment in 2007. NICM advocates for the translation of scientific evidence into complementary medicines policy and practice to benefit the health of all Australians.

NICM has undertaken initiatives including seed funding research and data collection to help develop the evidence base for integrative care (mainstream and complementary medicine) in areas including cancer, cardiac surgery, reproductive health and general practice medicine. NICM is also working on improving ways of communicating information about the evidence base of complementary medicines to consumers and clinicians.

PUBLIC CONSULTATION ON THE COMPLEMENTARY AND ALTERNATIVE MEDICINE RESOURCE FOR CLINICIANS: NICM SUBMISSION

Questions for professional bodies/networks/administrators/educators:

1. Would the information contained in these two documents be of use or interest to your members?
2. Do you have any comments on *Talking about Complementary and Alternative Medicine – a Resource for Clinicians* (eight page document)?
3. Do you have any comments on *Talking to your patients about Complementary and Alternative Medicine* (one page document)?
4. Would your organisation be interested in distributing these two documents to your members? If so, what is the best way to distribute them? For example print, email, newsletter etc.
5. Do you have any suggestions for how this information could be distributed to clinicians?
6. Would your organisation be interested in incorporating the two documents into training or professional development programs?

NICM response:

1. Would the information contained in these two documents be of use or interest to your members?

The National Institute of Complementary Medicine (NICM) aims to be a destination of choice for accurate, balanced communications on complementary medicine (CM). While NICM does not have members, NICM would be interested in assisting in the dissemination of accurate information to clinicians and consumers. It is important that clinicians actively seek information regarding a patient's use of CM. This discussion may be prompted by completing a formal medication history in line with the Australian Pharmaceutical Advisory Council guidelines.[i]

Nonetheless, the tone of the resource for clinicians on CM produced by the NHMRC is judgmental, placing too much responsibility on patients to provide answers and failing to provide adequate support to clinicians who need to help guide patients with accurate and relevant information. The NHMRC may consider the more informative 'toolkit' approach of the US NCCAM Research for Healthcare Providers.

2. Do you have any comments on Talking about Complementary and Alternative Medicine – a Resource for Clinicians (eight page document)?

NICM commends the NHMRC on releasing a document that encourages clinicians to communicate openly and respectfully about the evidence for and against the benefits and harms of CM use.

Please provide comments for each section:

a. Information on CAM (pages 1-3)

General comments

The term complementary and alternative medicine (CAM) is outdated and justified only by a linguistic, even theoretical, definition that serves no real purpose. A simpler, more broadly (internationally) accepted umbrella term is complementary medicine (CM). The Australian Medical Association (AMA) uses the term CM in their position paper, the Australian Therapeutic Goods Administration adopts CM as the defined term in the *Therapeutic Goods Regulation* 1990 and this is also used by the National Institute of Complementary Medicine (NICM) and the National Prescribing Service (NPS). The proposal to use 'CAM' by the NHMRC is out of step with all relevant key organisations in the CM sector.

Page 2
Specific comments on the text

- What is the difference between 'practices' and 'therapies'? We recommend that one of these terms be removed.
- The definition of CAM (second paragraph) is not important for this fact sheet.
- 'Information on CAM': The main point to make is that the sources of information on CM are of variable quality and relevance to consumers. This gap has continued to exist for many years, despite the growth in use of CM. The first 2 paragraphs (CHF and NPS conclusions) do not add much to this main point and consume more space. The 3rd paragraph regarding non-disclosure to doctors is important. Again the last sentence on this page does not add substance to this resource.

b. Questions on CAM (boxes page 3)

Specific comments on the text

- Breakout box 'CAM use': Very few people 'grow their own'; we recommend this be removed.
- Breakout box 'Details of the CAM products': The dosage and active ingredient should be confirmed by the practitioner. While the dosage is usually simple enough to understand, the active ingredient is not.
- Breakout box 'Details of the CAM practitioners: The first three questions are precisely the kind of challenges/negative statements that have the effect of discouraging disclosure by patients to clinicians and may make the patient uncomfortable with their choices. What is the relevance and appropriateness

of asking about cost? Will this be compared to the medical consultation costs incurred, including the Medicare portion, and the patient and PBS costs for related medicines? Is the reason for asking about costs to create some crude assessment of relative cost-benefit of interventions?

c. Information on discussions about evidence (page 4)

General comments

NICM is advocating for more research funding to be directed to the development of an evidence-based CM sector in Australia. In the interim, NICM agrees that patients should seek to be as informed as possible about CM use. Nonetheless, NICM asserts that the line of questioning promoted in this section places an unrealistic burden upon patients in terms of seeking and reviewing scientific evidence about CMs, particularly where such evidence may be difficult to find; does not consider that patients may be using CM where conventional treatments may be expensive, inadequate or have significant side effects; and asks questions of CM treatment where such questions may not be asked of conventional treatments (such as the costs per session or qualifications of the health professional).

It is considered that this line of questioning be replaced with one where the clinician can show patients where to obtain information about CM use in an easy to read, lay guide (such as the University of Maryland's Complementary and Alternative Medicine Guide, which is available online, or other such relevant sites). Clinicians should also be encouraged to acknowledge the reasons why patients seek CM treatments, which may go some way to encouraging patients to provide further information about their CM use.

Specific comments on the text

- First paragraph under 'Discussions about evidence': That the TGA does not evaluate Listed medicines for their effectiveness is not quite true. In fact, many traditional use medicines are permitted for use because they have accepted histories of use for particular conditions. The reference texts that support these uses are identified and prescribed by the TGA. The label wording is specifically designed to communicate that the product claim is based on established traditional use. Some products have had evidence of effectiveness evaluated, including those that have been routinely audited and those that have been evaluated for Registrable claims, and been granted lesser claims (for whatever reason).

d. Questions on discussing evidence and reliability of information (box page 4)

General comments

NICM is concerned about the appropriateness of assigning the patient the responsibility of knowing and understanding the nature of scientific evidence about CM, the principles of peer review and publication of evidence. It would be preferable if this resource encouraged GPs to keep up to date on the evidence base in the same

way they would for other treatments, and that they were encouraged to look into the evidence base as needed. NICM is committed to assisting with this and most of the other guides to clinicians take this approach.

Specific comments on the text

- Breakout box 'Discussing evidence': The question 'How do you know that the CAM treatment works' and whether it provides sufficient clinical progress could be asked of any conventional or non-conventional intervention. It may be better to frame the question in a non-judgmental way (e.g. how do you know if any of your treatments are working?). Let the patient state what role each form of intervention represents for him/her and the relative benefits of each. It will be challenging enough for the patient to respond honestly to the prescriber of one class of treatment only. The questions that follow this one are equally judgmental of the patient's choice. The patient would be unlikely to be able to answer these questions for any treatment they are undergoing.
- Breakout box 'Discussing reliability of information': These questions assume a level of scientific knowledge among patients that is unrealistic and should only be asked if equally posed about all (CM and mainstream) interventions. As framed, the questions also appear unduly critical of CMs. If asked these questions, a patient might understandably firstly feel embarrassed at not knowing enough and second be led to believe that most or all evidence relating to CM is funded by companies that produce them. NICM endorses Cancer Care Australia's stance that: "Encourages healthcare providers to routinely discuss the use of CM therapies with all cancer patients and survivors in an open and non-judgmental manner."
- The NHMRC may consider a further question: 'Would you like me to look into this for you?' This would encourage the GP to develop the necessary knowledge base, given so many Australians are using CM. This is also consistent with the Australian Medical Association position that medical practitioners should have access to education about CM in their undergraduate, vocational and further education to provide advice to patients. They should be informed of the level of scientific evidence for both benefits and adverse reactions, including potential interactions with other medicines.

e. Information on discussing effectiveness (page 5)

General comments

NICM is advocating for more research funding to be directed to the development of an evidence-based CM sector in Australia. However, NHMRC funding for CM research has been 0.2% of total funding from 2003-12, despite high levels of usage by the Australian public and despite being acknowledged as a major health issue in successive NHMRC Strategic Plans.[ii] In the interim, NICM agrees that patients should seek to be as best informed as possible about CM use.

It is well established that few CM treatments have undergone the same level of multi-centre, RCT investigation as pharmaceuticals medicines. However, this does not mean they won't be effective for the individual. The same problem regarding

lack of evidence also commonly arises in other treatment categories including cancer care.

Where it is unclear whether a particular treatment is safe and efficacious, a co-managed period of treatment with the patient involving agreed upon outcomes and timeframes is a sensible step forward which allows for respect of patient autonomy, patient-centred care and shared decision-making. If the patient responds, even if there is no mainstream evidence supporting use, a discussion on continuing use should be encouraged and the clinician should be encouraged to keep a record of the positive indications.

Information on discussing potential risks (page 5)

General comments

NICM acknowledges that certain CM treatments, like pharmaceutical treatments, may have potential risks associated with their use. Nonetheless, it is unclear why the NHMRC has chosen to single out Echinacea and St John's Wort, where there are several other substances which have associated safety issues and which may be of more relevance e.g. interactions with Warfarin and those inducing Type A adverse effects.

NICM believes that clinicians should become familiar with the potential benefits and risks associated with the CMs most commonly used by the population they serve. When clinicians are uncertain about safety issues, they should refer to additional material. An informed discussion can proceed only when interpreting potential safety issues in the context of the potential benefits of the CM treatment and the particular interests of the patient.

Specific comments on the text

NICM notes that there are some inaccurate statements regarding herbal safety in this section:

- "*Echinacea, which is sometimes used as a CAM treatment for the common cold, may trigger an allergic response or exacerbate symptoms when used by asthma patients.*" This is an extremely rare, idiosyncratic occurrence and not a Type A adverse reaction that can be expected to occur more commonly. This should be stated as such. A 2013 overview of systemic reviews of the adverse effects of herbal medicines concluded that only minor adverse effects were noted for Echinacea.[iii] A systematic review of the safety of herbal products derived from Echinacea species concluded that while 'spontaneous reporting schemes seem to support the possibility of allergic problems with Echinacea in a minority of cases… determination of causality is variable..' but suggestive. It further states that 'in about a quarter of cases, Echinacea had been administered intravenously or intramuscularly.'[iv] In Australia, Echinacea is not administered in these ways. The herb is contraindicated in people with allergies to the *Asteraceae (Compositae)* family of plants (e.g. chamomile, ragweed).[v]

- There are many other such examples of rare, idiosyncratic reactions to herbs. It is unclear how useful it is to present information about rare adverse events in this document. Including such information could lead the reader to over-estimate the incidence of serious adverse events to over the counter herbal medicines. If specific examples are to be included, clinicians may find a list of commonly used herbal medicines with their most common adverse reactions more useful.
- The statement "*St John's Wort can reduce the therapeutic effects of many pharmaceutical medicines including anti-depressants*" is not supported by scientific evidence. St. John's Wort has an SSRI-like effect (selective serotonin reuptake inhibitor) and when used together with another SSRI has the potential to induce serotonin syndrome unless used under professional supervision.[vi] A 2013 overview of systematic reviews investigating adverse effects of herbal medicines concluded that only minor adverse effects were noted for St John's Wort.[iii] It is considered extremely safe when used as a standalone treatment and better tolerated than standard pharmaceutical antidepressants. Sixteen post-marketing surveillance studies with such preparations, based on a total of 34,804 patients, recorded an incidence of adverse events (AEs) among patients between 0% and 6%. Of these studies, the four large-scale surveillance studies with a total of 14,245 patients recorded a rate of AEs ranging from 0.1% to 2.4% and a drop-out rate due to AEs of 0.1-0.9%. This is at least ten-fold lower than that recorded with synthetic antidepressants.[vii]
- Any reference to a drug interaction and St John's Wort mediated by cytochromes or p-glycoprotein should be qualified by the statement "St John's Wort products containing hyperforin." This is because low-hyperforin containing St John's Wort extracts have not demonstrated the same drug interactions under clinical trial test conditions. The hyperforin constituent is responsible for the induction effects.[vi]

NICM has discussed this section with the Clinical Oncology Society of Australia and acknowledges their assistance in providing references and information where required.

f. Information on regulation of CAM in Australia (page 6)

No comment.

g. Further information for clinicians and patients (page 7)

NICM has provided a list of other useful references that could be considered for inclusion in the NHMRC publication (in alphabetical order).

- *About Herbs, Botanicals & Other Products*
  Evidence-based information about CAM products from the Memorial Sloan-Kettering Cancer Center.
  http://www.mskcc.org/cancer-care/integrative-medicine/about-herbs-botanicals-other-products

- *Australasian Integrative Medicine Association (AIMA)*
  A peak medical body promoting the practice of evidence-based integrative medicine, research and education as the gold standard for optimising wellbeing, prevention and management of disease in Australasian health care systems.
  (www.aima.net.au)

- *Cancer Council Australia position statement on alternative and complementary therapies*
  The statement considers the evidence, risks and benefits associated with these therapies and makes considered recommendations for cancer patients and health practitioners.
  http://wiki.cancer.org.au/prevention/Position_statement_-_Complementary_and_alternative_therapies

- *Clinical Oncology Society of Australia (COSA) position statement on use of complementary and alternative medicine by cancer patients*
  A comprehensive position statement released by the COSA Complementary and Integrative Therapies Group in 2013. The purpose of this document is to provide guidance for clinicians involved with the treatment of cancer patients who are using or wish to use CM.
  (https://www.cosa.org.au/)

- Medical Board of Australia. Good Medical Practice: A Code of Conduct for Doctors in Australia.

- *Natural Standard*
  High quality, evidence-based information about complementary and alternative medicine including dietary supplements and integrative therapies.
  http://www.naturalstandard.com/

- *National Institute of Complementary Medicine (NICM)*
  NICM is the premier national academic research centre dedicated to CM. It was established to provide leadership and support for strategically directed research into complementary medicine and translation of evidence into clinical practice and relevant policy to benefit the health of all Australians.
  www.nicm.edu.au

- Olver I, Robotin M (Eds). Perspectives On Complementary And Alternative Medicine. Imperial College Press London 2012.

- Phelps K, Hassed C. General Practice - The Integrative Medicine Approach. Churchill Livingstone Publishers 2011. It is designed to mee the needs of healthcare professionals practising in Australian and New Zealand.

- Braun L, Cohen M. Herbs and Natural Supplements- an Evidence Based Guide, 3rd edition. Churchill Livingstone Publishers, 2010.

NPS concluded it as one of the few 'quality resources' for CM information. It is designed to meet the needs of healthcare professionals practising in Australian and New Zealand.

3. Do you have any comments on Talking to your patients about Complementary and Alternative Medicine (one page document)?

Please see our comments in section 2a above, with regards the use of the term 'CAM'. The first reasons for patients not disclosing their CM use may be extended to: 'anxiety that it will evoke their clinician's disapproval, including a concern that their clinician will fail to understand their reasons for use'.

a. Do your patients know...whether their CAM is effective?

This section fails to acknowledge at the outset that there might even occasionally be good reasons for using a CM category medicine. In addition, this section encourages patients to review scientific evidence to determine whether their CM is effective. As noted throughout this submission, NICM considers it inappropriate for a variety of reasons to place the onus on patients to determine the evidence basis for the CM intervention that they are using. For example, there may be limited relevant information on the CM that the patient is using. Referring patients to peer-reviewed journals also assumes a level of access to such journals and critical scientific understanding which many patients may not have. It may be preferable for the clinician to provide advice to the patient on their CM use or if not, refer the patient to sites where information is easily accessible.

It may not be true that the effectiveness of most CMs has not been evaluated by the TGA. NICM is not aware of hard data on proportions of traditional use claims, audited products, compared to products on the market, etc. See the comments above in section 2c.

b. Do your patients know...the potential risks of CAM use?

NICM agrees that it is important for patients to consider the potential risks of CM use. NICM notes that over 40% of CM use in Australia is for chronic medical conditions,[viii] where conventional medicine is expensive, inadequate or has significant side effects. As a result, it may be misplaced to consider that patients are using CM in place of proven and effective conventional medicine, which may itself have side effects. Hence, this statement may fail to recognise the potentially well informed decisions by patients.

4. Would your organisation be interested in distributing these two documents to your members? If so, what is the best way to distribute them? For example print, email, newsletter etc.

NICM would be prepared to include this information upon its website for access by clinicians subject to the concerns above being addressed.

5. **Do you have any suggestions for how this information could be distributed to clinicians?**

NICM does not represent clinicians as a peak body. It is expected, however, that the NHMRC could liaise with medical colleges, national clinician bodies and patient advocacy groups to promote the dissemination of these resources.

6. **Would your organisation be interested in incorporating the two documents into training or professional development programs?**

Subject to addressing the concerns raised above, NICM would support further dissemination of these documents within training or professional development programs.

---

[i] Australian Pharmaceutical Advisory Council (2005) Guiding principles to achieve continuity in medication management. Canberra.
[ii] NHMRC Research Funding Datasets 2003-2012.
[iii] Posadzki P, Watson LK, Ernst E. Adverse effects of herbal medicines: an overview of systematic reviews. *Clin Med* 2013 Feb;13(1):7-12.
[iv] Huntley AL, Thompson CJ, Ernst E. The safety of herbal medicinal products derived from Echinacea species: a systematic review. *Drug Saf* 2005;28(5):387-400.
[v] Braun L, Cohen M. *Herbs and Natural Supplements - an Evidence Based Guide*. 3 ed. Sydney: Churchill Livingstone, Elsevier; 2010.
[vi] Borrelli F, Izzo AA. Herb-drug interactions with St John's wort (Hypericum perforatum): an update on clinical observations. *AAPS J* 2009 Dec;11(4):710-27.
[vii] Schulz V. Safety of St. John's Wort extract compared to synthetic antidepressants. *Phytomedicine* 2006 Feb;13(3):199-204.
[viii] Australian Bureau of Statistics. (2006) *Household Expenditure Survey, Australia* 2003-04, cat. no. 6530.0, ABS, Canberra.