



**Joint Submission to the NHMRC Public Consultation**

## **Complementary and Alternative Medicine Resource for Clinicians**

**Clinical Oncology Society of Australia and Cancer Council Australia**

**September 2013**

The **Clinical Oncology Society of Australia (COSA)** is Australia's peak multidisciplinary society for health professionals working in cancer research, treatment, rehabilitation and palliative care with over 1600 members. COSA is an advocacy organisation whose views are valued in all aspects of cancer care. COSA provides high-level clinical advice to Cancer Council Australia.

COSA members formed the **Complementary and Integrative Therapies (CIT) Group** to respond to a broad range of issues associated with use of complementary and alternative medicines in Australia, including the need for information, guidelines for practice, specific issues in oncology and management of unconventional treatments.

**Cancer Council Australia (CCA)** is the nation's peak, non-government, cancer control organisation. Cancer Council Australia advises the Australian Government and other bodies on practices and policies to help prevent, detect and treat cancer and advocates for the rights of cancer patients for best treatment and supportive care.

***Note:***

**The COSA position statement on the use of complementary and alternative medicine by cancer patients (released May 2013) is provided as supplementary reference material to this submission.**

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## Questions for clinicians

### 1. Do your patients require prompting to discuss their use of CAM?

The majority of patients require prompting to discuss their use of CAM. In order to identify and avoid CAM induced adverse effects and CAM drug interactions, COSA recommends that health professionals actively seek information regarding a patient's use of CAM. COSA recommends health professionals prompt the discussion of CAM with cancer patients by completing a formal medication history in line with the Australian Pharmaceutical Advisory Council guidelines.<sup>1</sup>

### 2. Do you currently have access to resources that assist you in discussing the effectiveness and evidence base of CAM use with your patients?

**If yes, please provide details.**

In light of the high use of CAM amongst cancer patients and the potential for physical and financial harm to individual patients, COSA developed a position statement on the use of complementary and alternative medicine by cancer patients (released May 2013).<sup>2</sup> A multidisciplinary national working party chaired by Dr Lesley Braun, Monash University, developed the position statement for health professionals confronted by the scenario of when a cancer patient chooses to use complementary and alternative medicine (CAM). It is aimed at the large number of speciality medical and allied health disciplines typically involved in several aspects of care for cancer patients.

The guiding questions for the COSA position statement were as follows:

- What approach should a conventional health care provider take in the case of a patient who has decided to use a non-medical therapy as an alternative to medical cancer treatment and seeks the involvement of a conventional health care provider in this process.
- What approach should be taken by a conventional health care provider in the case of a patient who has decided to use a non-medical therapy to complement medical cancer treatment and seeks the involvement of a conventional health care provider in this process in the case of therapies:
  - which are unlikely to do harm but where there is evidence of potential benefit
  - for which the evidence either for or against the treatment is equivocal
  - for which there is no available scientific evidence indicating it may be of benefit or present potential harm
  - which are likely to do harm
- What are the moral and legal responsibilities of a conventional health care provider when faced with these issues in a medical setting.

The document is posted on the COSA website (<https://www.cosa.org.au/>) and plans are currently underway to submit the COSA position statement in full to the Asia-Pacific Journal of Clinical Oncology. We would ask that the NHMRC also consider referencing the COSA position statement<sup>2</sup> in their resource for clinicians.

**3. Is the information and questions included in Talking about Complementary and Alternative Medicine – a Resource for Clinicians (eight page document) useful and relevant?**

It is most appropriate for the NHMRC to release a document encouraging health professionals to communicate openly and respectfully about the evidence for and against benefits and harms of CAM use.

**Please provide comments for each section:**

**a) Information on CAM (pages 1-3)**

No comments.

**b) Questions on CAM (boxes page 3)**

The questions should include asking patients about any adverse effects experienced with CAM products they have used (e.g. CAM side-effects, CAM + CAM interactions or CAM + conventional drug interactions).

**c) Information on discussions about evidence (page 4)**

In discussions about evidence, it is also important to determine whether patients distinguish explicitly between conventional treatments and CAMs or perceive these as interchangeable options.

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

It would be difficult for a patient to answer these questions about evidence. In the consultation process for the COSA position statement<sup>2</sup>, the opinion was expressed that patients have trouble answering these questions about the conventional medicines they take so this would be just as difficult, if not more so, when discussing CAM.

**e) Information on discussing effectiveness (page 5)**

Whilst decisions should be informed by evidence, they should also be informed by the patients' wishes, involve shared decision making and a respect for patient autonomy.

It is well established that few CAM treatments have undergone the same level of multi-centre, RCT investigation as pharmaceutical 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 palliative care and with other populations.

As suggested in the COSA position statement<sup>2</sup>, if something is demonstrated as safe but efficacy is unclear, a co-managed trial with the patient involving agreed outcomes and timeframes is a sensible step forward. This allows for respect of patient autonomy, patient centred care and shared decision making. Also, if the patient responds, even if there is no evidence, they will be able to safely use the treatment.

**f) Information on discussing potential risks (page 5)**

It is unclear why NHMRC have chosen to single out Echinacea and St John's Wort when there are several other substances which have associated safety issues which may be of more relevance (e.g. interactions with Warfarin and those inducing Type A adverse effects).

It would be worthwhile making the general recommendation that physicians become familiar with the potential benefits and risks associated with the CAMs most commonly used by the population they serve and refer to resources when they are uncertain about safety issues. Only when interpreting potential safety issues in relation to potential benefits and patients interests can an informed discussion proceed.

There are some inaccurate statements regarding herbal safety in this section which is a major concern.

- Whilst the *"National Asthma Council Australia warns that 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 frequently. A note should be made to this effect.

A 2013 overview of systematic reviews investigating adverse effects of herbal medicines concluded that only minor adverse effects were noted for Echinacea species<sup>3</sup>. A systematic review of the safety of herbal products derived from Echinacea species concluded that whilst "spontaneous reporting schemes seem to support the possibility of allergic problems with Echinacea in a minority of cases ... determination of causality is variable". It further states that "in about a quarter of cases, Echinacea had been administered intravenously or intramuscularly"<sup>4</sup>. 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).<sup>5</sup>

- There are many other such examples of rare, idiosyncratic reactions to herbs. It is unclear how useful it is to present information in the NHMRC resources about rare adverse events. Including such information could lead the reader to over-estimate the incidence of serious adverse events to OTC herbal medicines. If specific examples are to be included, a list of commonly used herbal medicines with their most common adverse reactions may be more useful to physicians.
- The statement *"St John's Wort can reduce the therapeutic effects of many pharmaceutical medicines including anti-depressants"* is another incorrect statement which is not supported by the scientific evidence. It has an SSRI-like effect and when used together with another SSRI (selective serotonin reuptake inhibitor) has the potential to induce serotonin syndrome unless used under professional supervision<sup>6</sup>.

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<sup>3</sup>. It is considered extremely safe when used as a stand-alone treatment and better tolerated than standard pharmaceutical antidepressants. Sixteen post-market surveillance studies with such preparations, with 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% to 0.9%. This is at least ten-fold lower than that recorded with synthetic antidepressants<sup>7</sup>.

- 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" because low-hyperforin containing St John's Wort extracts have not demonstrated the same drug interactions under clinical trial test conditions. This is because the hyperforin constituent is responsible for the induction effects<sup>6</sup>.

**g) Information on regulation of CAM in Australia (page 6)**

No comments.

**h) Further information for clinicians and patients (page 7)**

Other useful references that could be considered for inclusion in the NHMRC publication are listed below (in alphabetical order). Of particular relevance are the position statements developed by Cancer Council Australia and COSA, as well as the resources available on the National Institute of Complementary Medicine website. As a minimum we would recommend that the Council should include these 3 references in the NHMRC documents.

- *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 optimizing wellbeing, prevention and management of disease in Australasian health care systems.  
([www.aima.net.au](http://www.aima.net.au))
- *Braun L, Cohen M. Herbs and Natural Supplements – an Evidence Based Guide, 3<sup>rd</sup> edition. Churchill Livingstone Publishers, 2010.*  
NPS MedicineWise concluded this is one of the few "quality resources" for CAM information. It is designed to meet the needs of health care professionals practicing in Australia and New Zealand.

- *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](http://wiki.cancer.org.au/prevention/Position_statement_-_Complementary_and_alternative_therapies)
- *Cancer Council NSW guide on understanding complementary therapies*  
This resource for patients and their families provides an overview of the role of complementary therapies in cancer care.  
<http://www.cancercouncil.com.au/1303/b1000/complementary-therapies-40/understanding-complementary-therapies/>
- *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 health professionals involved with the treatment of cancer patients who are using or wish to use CAM.  
(<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 CAM. 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](http://www.nicm.edu.au)
- *Phelps K, Hasted C. General Practice - The Integrative Medicine Approach. Churchill Livingstone Publishers 2011.*  
It is designed to meet the needs of health care professionals practicing in Australia and New Zealand.

**4. Is the information included in Talking to your patients about Complementary and Alternative Medicine (one page document) useful and relevant? If so, how would you use this document?**

The one page summary document adequately covers the key messages that clinicians could focus on when discussing CAM use with their patients, although some further

distinction between complementary as opposed to alternative therapies is important. Clinicians need to establish whether patients are taking these therapies as alternatives to standard treatments or in conjunction with them, as well as their expectations of the treatment (preventative, curative or supportive). It would also be worth highlighting that the Australian government pays for open access to the Cochrane library ([www.thecochranelibrary.com](http://www.thecochranelibrary.com)), thereby providing all Australians with access to high quality lay summaries of reviews.

**5. Is the information in the eight page document and one page document provided in a clear, logical, and user-friendly format?**

The NHMRC documents are excellent contributions for the area of CAM use in Australian health settings and provide the information in a clear, logical, and user-friendly format.

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

The NHMRC Resource for Clinicians should encourage clinicians to take into account benefit versus risk when considering CAM use. As discussed in the COSA position statement<sup>2</sup>, sometimes there is a low risk CAM option which should not be dismissed, especially if the patient is interested in trying it. While many CAM options won't have the high level RCT evidence to the same extent as pharmaceutical treatments, there may still be some well documented benefits. A therapeutic trial co-managed by the physician and patient is a sensible option which respects patient autonomy and determines whether the treatment is safe and effective for the individual.

COSA also strongly recommends that NHMRC undertake an evidence review before including any specific statements regarding herbal safety. Statements should be referenced with up-to-date, primary citations rather than using secondary sources like the National Asthma Council document.

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

No further comments.

**8. Once these two documents are published, what is the best way for you to receive them? For example, print, email, editorial in a relevant journal, health professional organisational newsletter, e journal etc.**

Along with the usual NHMRC promotional mechanisms, the Council could also directly inform all health jurisdictions, medical colleges, national health professional bodies and peak medical disease related NGO's (non-governmental organizations).



## Questions for professional bodies/networks/administrators/educators

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

The NHMRC resources developed for clinicians on complementary and alternative medicines are likely to be of interest to COSA members, particularly those in the Complementary and Integrative Therapies (CIT) Group.

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

Please see the information provided under Questions for Clinicians (Q3 and Q6).

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

Please see the information provided under Questions for Clinicians (Q4).

**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.**

COSA's focus is to promote our own position statement on the use of complementary and alternative medicine by cancer patients<sup>2</sup>. COSA could however reference the NHMRC documents (once finalized) in our position statement. Members may also access additional materials under the "Resources" section of the COSA website, and we would see value in posting the NHMRC documents in that location.

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

Please see the information provided under Questions for Clinicians (Q8).

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

As a society COSA does not conduct training or professional development programs. This would be more relevant for institutions and educators.

## Acknowledgements

COSA and Cancer Council Australia thank the review panel for the opportunity to make this submission to the National Health and Medical Research Council.

We would also like to thank the members of the COSA Complementary and Integrative Therapies (CIT) Group Executive for contributing their time and expertise to the development of this submission.

## References

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