An initiative of NSW Clinical Pharmacologists & Pharmacists
Funded by the NSW Department of Health

COMPLEMENTARY MEDICINES IN PUBLIC HOSPITALS: A DISCUSSION PAPER

Prepared by a Working Group of the NSW Therapeutic Assessment Group Inc.

March 1999
Revised
August 1999

This work is copyright of the NSW Therapeutic Assessment group Inc and NSW Health department. Apart from any use as permitted under *The Copyright Act 1968*, no part of this information may be reproduced by any process without written permission.

Whilst the information contained in this document has been presented with all due care, and the information is considered to be true and correct at the date of publication, changes in circumstances after publication may impact on the accuracy of the information.

This document represents expert consensus opinion and should not be relied upon as professional advice other than in this context. The information provided should not be regarded as a substitute for detailed expert advice in individual cases. NSW Therapeutic Assessment Group Inc will accept no responsibility for any loss, claim or damage suffered or caused by any person acting or refraining from action as a result of any material in this document.

1. INTRODUCTION

This paper has been prepared at the request of the NSW Therapeutic Assessment Group to assist public hospitals in formulating local policy on the use of complementary medicines (CM). The current State Health Department documentation relating to medication in hospitals [NSW Health Department Circular 95/37. Guidelines for the Handling of Medication in New South Wales Public Hospitals] was not written with CM in mind but this document may be considered for referencing when 95/37 is updated. The issues regarding the use of pharmaceuticals in a non-conventional manner (off-label use) and illicit drug use are not addressed here.

'Local policy' refers to hospital policy developed by the local Drug and Therapeutics Committee not policy drawn up at a ward or unit level.

2. DEFINITION

The term complementary medicine (CM) encompasses a wide range of disciplines of alternative practices.[1] These include herbal, homoeopathic, essential oils (aromatherapy), nutritional (vitamins and minerals) and some health food supplements.

The Therapeutic Goods Administration (TGA) consider a CM to be a product for oral, dermal, rectal or inhalational use containing active substances with a complementary or traditional use associated with maintenance of health or prevention of disease. 'Traditional use' is use which has been well documented, or otherwise established, and which represents accumulated experience of many practitioners over an extended period of time. Preparations, dosage, purpose, methods of use as well as identity should be well established. 'Complementary use' refers to a regimen for the prevention or alleviation of a disease or ailment, or for the maintenance of health, and which does not necessarily rely on the evidence of efficacy based on Western current medical practice.

3. BACKGROUND

Community surveys in Australia indicate that half the population have taken a complementary medicine in the last year.[2] Only 20% of users consult a CM practitioner and approximately 70% do not inform their doctor they are taking these alternative therapeutic agents.[2,3] A recent survey confirmed that CM is used because of dissatisfaction with mainstream medicine, the desire for autonomy over health decisions and a general belief that "natural" remedies are more compatible with health.[4]

4. REGULATION

Australian products for human medicinal use must be recorded on the Register of Therapeutic Goods under the Therapeutic Goods Act of 1989 in one of two categories:

4.1 Listed Goods

Formulations containing substances which have been accepted as being of low public health concern and have indications consistent with the Therapeutic Goods Advertising Code can be 'listed' on the Register for a small fee. [This code generally restricts wording of claims to those that may responsibly be directed to the public (eg "relief of symptoms" rather than "treat" or "cure").] The products have to be manufactured by a TGA licensed manufacturer and the same labelling and standards apply as for registered products. Quality and safety are the key criteria considered for listing of products. Proof of efficacy is not required. Instead the sponsor / manufacturer is expected to hold efficacy data (which will not necessarily be clinical trial data) on file and this can be audited at any time. At present there are some 4500 herbal products approved for marketing in Australia.

4.2 Registered goods

Full registration is required for products containing herbs and other substances included in schedules of the Standard for the Uniform Scheduling of Drugs and Poisons, those for which efficacy claims are more substantial and those which are specified by the TGA as being of some health concern. Registration involves submission of appropriate documentation outlining clinical trial work to the Complementary Medicines Evaluation Committee (CMEC) which first convened at the end of 1997 and replaced the Traditional Medicines Evaluation Committee (TMEC) which was established in 1991. This process is more expensive and fewer than five products have been evaluated in this way.

Australia has more regulatory controls for complementary medications than many countries. The majority of these preparations however do not have to go through the pre-marketing process that prescription and scheduled proprietary medicines undergo.

5. QUALITY, SAFETY AND EFFICACY

Adverse drug reactions to CM products can result from a number of extrinsic effects that are unrelated to the intended ingredients but relate to the quality of products. Examples include contamination with heavy metals (eg lead, arsenic) or microorganisms and adulteration with undeclared pharmaceuticals.[5-7] Others result from the intrinsic effects of the intended ingredients[8] or from the effects of other ingredients which are unavoidably associated with the intended active ingredients. In many cases the product is not analysed leaving uncertainty as to whether the adverse drug reaction was associated with an intrinsic or extrinsic effect.[9] When assessing the safety of CMs it may be necessary to differentiate between manufactured products carrying an Aust L or Aust R number whose safety has already been assessed by the TGA and those that are individually (or extemporaneously) prepared by CM practitioners.

CM products have also been referred to as "unproven remedies" in the literature because their use is often based on accumulated empirical experience. The argument that these remedies have stood the 'test of time' does not hold up when they are used in combinations or doses

outside the bounds of their traditional (or past) use or concurrently with mainstream medicines.[10] There is, however, a considerable amount of research carried out on plant components and there may be information available to assist health professionals in their discussions with patients about CM use.[11] Information can be accessed via hospital pharmacy departments and associated drug information services, allied health professionals eg dietitians and libraries.

6. LOCAL POLICY DEVELOPMENT

Community use of CM is so widespread that it must be considered as part of a patient's total management and local protocol should be developed to assist individual health professionals working in the hospital environment in dealing with the issues that arise.
'Seamless care' dictates that it may not be appropriate to simply recommend all CM use be deferred until a patient leaves hospital. Indeed this approach has resulted in problems when patients have been stabilised on medication in hospital and resume taking their CM when discharged eg a patient stabilised on warfarin who resumed taking high dose vitamin E after discharge resulting in increased effects of warfarin.

A number of institutions have already developed local hospital policy. Approaches tend to be based on regulation and supply and they range from disallowing all CM in hospital to treating CM as "patient's own" medication or non-formulary items unless individually approved for inclusion in the formulary by the local Drug and Therapeutics Committee.[12]

The following points found in existing hospital policies and publications are highlighted for consideration when developing new local policy:

6.1 Medication history

Complementary medicines need to be routinely included in a patient's medication history in order to make a full assessment of patient management and identify adverse drug reactions or interactions. Patients are unlikely to volunteer this information for a number of reasons; there is a popular conception that "natural" products differ from pharmaceuticals and are safe and that medical practitioners disapprove or are not interested in knowing about the use of such products. Hence patients have to be actively prompted for the information by asking if they take any products bought in a health food store or pharmacy for their general health. A neutral approach has to be maintained in order to encourage this disclosure.[13] The need to include CM as part of the medication history is now included in recent APAC Guidelines [Australian Pharmaceutical Advisory Council. National guidelines to achieve the continuum of quality use of medicines between hospital and community. January 1998].

6.2 Therapeutic choice

Patients who are already using, or considering using, CM products should be encouraged to openly discuss risks and benefits with their doctor or therapeutic team to ensure:

(a) that the patient can distinguish between approaches that may be helpful and those that may be harmful
(b) that there is no interaction with their primary treatment
(c) that the patient is aware of any potential adverse effects
(d) the dose is appropriate
(e) the patient understands that quality control is not guaranteed with all CMs in the same way as for pharmaceuticals.[14]

Health professionals may need to seek information in order to have an informed discussion (see “efficacy” earlier). Consumer medication information (CMI) leaflets are available for some products bearing an Aust L number.

6.3 Documentation

Any discussion with the patient should be fully documented in the medical notes including any advice given.

Any decision which results in nursing staff (or ‘persons responsible’ eg parents) being required to administer CMs should be made by medical staff and they should prescribe the CM on the medication chart in the usual manner.

6.4 Supply

All therapeutic substances used in hospital are generally supplied by the pharmacy department. This poses problems with CMs since the quality of CMs cannot be guaranteed from product to product (and even from batch to batch) necessitating that same brand be used consistently by a particular patient. Also supplies cannot be purchased through the usual pharmaceutical wholesalers and large quantities of CM products have to be ordered from CM wholesalers.

If health professionals are to administer CMs to patients in hospital (eg prescriber-initiated CM use or use for a non-competent or incapable patient) they should be supplied by the pharmacy. This approach can be restricted to allow only manufactured products bearing an Aust L or an Aust R number (indicating that they are listed or registered on the Australian Register of Therapeutic Goods).

If the decision is made to allow a patient to continue taking their own CM supply (in accordance with the patient’s wishes), it is prudent to mandate that the product be clearly labelled with contents and dosage instructions.

6.5 Storage

Products should be stored appropriately to prevent injury to others. This is the hospital’s duty of care as well as the patient’s responsibility.

6.6 Discharge

Open discussion with patients about CM use in hospital should prevent the occurrence of potential problems mentioned previously. A complete discharge medication summary should include all known CM use.

6.7 Patient acknowledgment

A hospital's duty of care requires it to take reasonable care (and therefore steps) to avoid foreseeable risk of harm to patients. This risk may be considered 'foreseeable' should a patient bring CMs into hospital about which there is no or insufficient information as to quality, safety or efficacy (including potential interactions with approved medications) or where there is evidence that potential adverse reactions may occur if the CM is taken concurrently with prescribed medication.

In cases where the therapeutic team considers a CM has or may have potential adverse effects on a patient under their care, it may be appropriate to ask the patient to sign a written acknowledgment which informs them of the potential adverse effects, reminds them that the therapeutic team does not endorse their CM use and requests that the patient does not take the CM during their admission.

In circumstances where there is no or insufficient information about a CM, the issues should still be discussed with the patient and in appropriate cases this discussion may need to be documented in the patient record.

6.8 ADR reporting

The response from the government to the last TGA review (April 1997) recommended that the role of ADRAC, the Adverse Drug Reaction Advisory Committee, be extended to actively monitor adverse drug reactions from CM as well as orthodox medical products. Hence adverse drug reaction or interactions involving CM should be forwarded to ADRAC on the blue cards in the usual manner.

6.9 Ethical aspects

Disallowing CM use in hospital does create a potential paradox. Whilst outside hospital, patients can freely take products / preparations with the aim of improving health or well being at their own expense (potentially relieving burden on the social health system). However, in hospital, duty of care takes precedence.

The complex ethical issues relating to CM use have been broken down for consideration in a number of ways;

They can be broadly considered under the four ethical principles autonomy, beneficence, non-maleficence and justice. Autonomy encompasses both the patients' rights and the clinicians' rights, beneficence / non-maleficence balance risk and benefit

(“to do good” / “to do no harm”) and justice refers to the fair distribution of resources (or funding) from institutional and societal perspectives.[†]

Alternatively the issues can be broken down separately for competent, capable patients and non-competent or incapable patients.[15]

6.10 Policy implementation

Once the local policy has been drawn up and approved by the Drug and Therapeutics Committee it is important that it is implemented appropriately. This entails an education process for all medical and allied health staff and should also extend to undergraduate or pre-registration training.

CM PRACTICE IN HOSPITAL

A number of health professionals choose to train in a discipline of complementary medicine. The NSW Nurses’ Association policy on complementary therapies in nursing practice states that “the practice of complementary therapies must be supported by written policies and protocols endorsed by the employing facility”. This point may need to form the content of a separate policy to that relating to CM use by hospital patients.

Prepared by NSW TAG CM Working Group, March 1999.
Revised August 1999.

REFERENCES

1. Barnes J. Complementary medicine; other therapies. Pharm J 1998;261(7013):490-493.

2. MacLennan AH, Wilson DH, Taylor AW. Prevalence and cost of alternative medicine in Australia. Lancet 1996;347(9001):569-573.

3. Kristoffersen SS, Atkin PA, Shenfield GM. Use of alternative medicines on Sydney's North Shore. Aust J Hosp Pharm 1997;27(5):367-372.

4. Astin JA. Why patients use alternative medicine: results of a national study. JAMA 1998;279(19):1548-1553.

5. Ko RJ. Adulterants in Asian patent medicines [letter]. N Engl J Med 1998;339(12):847

6. Hufnagel TJ, Schein OD. Suppurative keratitis from herbal ocular preparation [letter]. Am J Ophthalmol 1992;113(6):722-723.

7. Drew AK, Myers SP. Safety issues in herbal medicine: implications for the health

professions. Med J Aust 1997;166(10):538-541.

8. Sheikh NM, Philen RM, Love LA. Chaparral-associated hepatotoxicity. Arch Intern Med 1997;157(8):913-919.

9. Adverse Drug Reactions Advisory Committee. An adverse reaction to the herbal medication milk thistle (Silybum marianum). Med J Aust 1999;170(218-219.

10. Ernst E, de Smet PAGM, Shaw D, Murray V. Traditional remedies and the 'test of time'. Eur J Clin Pharmacol 1998;54(2):99-100.

11. Newall CA. Anderson LA, Phillipson JD (eds). Herbal Medicines; A Guide for Health-Care Professionals. London: The Pharmaceutical Press, 1996.12.

12. Beal LCDRFC. Herbals and homeopathic remedies as formulary items. Am J Health Syst Pharm 1998;55(12):1266-1267.

13. Eisenberg DM. Advising patients who seek alternative medical therapies. Ann Intern Med 1997;127(1):61-69.

14. Anti-Cancer Council of Victoria. Making choices; unproven remedies. 1996.

15. Hunter Area Health Clinical Ethics Working Group on Complementary Medicine. Use of Complementary Medicines. 1-13. 1998.

[†] Notes from Maria Kelly and Peter Dwyer available upon request.

Appendix 1 Working Group Members:

Megan Cadman	Deputy Chief Pharmacist, Pharmaceutical Services Branch, NSW Health Department
Dr Terry Campbell (Chair)	Professor of Medicine, University of NSW, St Vincent's Hospital
Anna Drew	Director, Hunter Drug Information Service, Newcastle Mater Hospital
Margaret Duguid	Director of Pharmacy, Royal North Shore Hospital
Peter Dwyer	Barrister, St James Hall; Adjunct Assoc. Professor (Law & Ethics), Postgraduate Studies Programme in Drug Development, Faculty of Medicine, University of NSW
Karen Kaye	Executive Officer, NSW Therapeutic Assessment Group
Maria Kelly	Director of Pharmacy, Concord Repatriation Hospital

Appendix 2

NSW Hospitals with Policies Related to Complementary Medicines Handling (as at March 1999)

John Hunter Area Health Service
Lismore Hospital
Neringah Hospital
New Children's Hospital
Royal North Shore Hospital