

Australian Paediatric Surveillance Unit
PROTOCOL SHEET- ADVERSE EVENTS ASSOCIATED WITH THE USE OF
COMPLEMENTARY OR ALTERNATIVE MEDICINE (CAM)
January 2001

Background to study

Complementary medicine refers to a group of therapeutic and diagnostic disciplines that exist largely, but not exclusively, outside the institutions where conventional health care is taught and provided. These disciplines are sometimes labelled "alternative" but this implies that they are used instead of conventional therapies which is not always the case. Some experts have adopted the term "complementary or alternative medicine" (CAM) as an acceptable way to define the area of practice.

It is known that CAM is extensively used in the Australian community. In fact, it is estimated that annual expenditure on CAM exceeds the budget for the Pharmaceutical Benefits Scheme. Paediatricians are aware that CAM is being used in children, both in those with common childhood conditions (eg. the use of Echinacea for the common cold) and in those with serious or chronic conditions (eg the use of a wide range of complementary therapies in children with cancer). It is the impression of the investigators and their colleagues that the use of CAM in children has increased considerably in the last five years.

Some types of CAM are practised in a well-regulated environment (eg. Osteopathy), but many are not. It is likely that many forms of CAM are good therapies with important potential roles in health care. Some will be ineffective but harmless, while others will be dangerous. There is a good case for improving the regulatory framework within which CAM is practised in the interest of public safety. This is particularly the case for the use of CAM in children given that they do not seek these forms of therapy for themselves and rely on the quality of decisions made by others.

There is no known incidence/prevalence data for adverse events associated with the use of CAM in children in Australia, nor for that matter anywhere in the world to our knowledge.

Objectives

- To provide data on the incidence of major adverse events associated with the use of CAM in children in Australia
- To provide information for paediatricians and other health practitioners about specific adverse events associated with the use of particular forms of CAM
- To help inform policy makers on the magnitude of this potential problem. Government and professional bodies (eg. the Paediatric Division of the RACP), require this information to decide if further investigation or action is required

CASE DEFINITION AND REPORTING INSTRUCTIONS

*Please report any **adverse events**, suspected or confirmed, to be associated with the use of **CAM**, occurring in children up to 15 years of age.*

Note:

- An "**adverse event**" is any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease associated with the use of CAM, whether or not confirmed to be related to the therapy.
- "**Complementary or Alternative Medicine (CAM)**" includes any health care practice other than one intrinsic to the current conventional system.

Examples of adverse events associated with the use of Complementary or Alternative Medicine

1. A patient develops cellulitis following the use of needle acupuncture
2. A patient has an anaphylactic reaction following the use of a compound containing royal jelly
3. A patient has an adverse effect following interaction between a prescribed medication and a herbal therapy

Severity of adverse events may be graded as follows:

Mild	an adverse experience which is easily tolerated by the patient, causing minimal discomfort and not interfering with everyday activities (eg. a minor rash).
Moderate	an adverse experience, which is sufficiently discomforting to interfere with normal everyday activities (eg. nausea and vomiting requiring time away from school).
Severe	an adverse experience which is incapacitating and prevents normal everyday activities and/or requires therapeutic intervention (eg. use of a prescription drug or hospitalisation).
Life threatening	the patient was perceived to be at risk of death from the event as it occurred (eg. an anaphylactic reaction).
Fatal	the patient died.

Examples of Complementary or Alternative Medicine

Naturopathy; Homeopathy; Herbal therapy; Traditional Chinese Medicine; Kinesiology; Colour Therapy; Chiropractic; Hypnotherapy; Osteopathy; Reiki; Therapeutic Massage; Acupuncture; Moxibustion; Alexander Technique; Acupressure; Reflexology; Ayurveda; Aromatherapy; Therapeutic Touch; Yoga (detailed definitions of these and other CAM therapies can be found at our web-site, www.CAM-study.org).

Follow up of notifications

Clinicians who notify a case will receive a two-page questionnaire requesting further details.

Investigators

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The full application, more detailed definitions of the various forms of CAM, and facilities for contacting the investigators can be found at our study web-site:

www.CAM-study.org.