

COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM) USE AT SCHN

POLICY AND PROCEDURE[®]

DOCUMENT SUMMARY/KEY POINTS

- Complementary and Alternative Medicine (CAM) is broadly referred to within this policy as complementary medications (**CAM-medication**) and alternative therapies (**CAM-therapy**).
- Generally, SCHN does **NOT recommend** the use of CAM whilst the patient is an inpatient.
- There should, however, be **open communication** with parents/carers about any medications and/or treatments given to the patient.
- CAM use may be considered in *individual circumstances* (e.g. palliative care or chronic conditions) and *only with the express support from the treating Consultant*. In these instances, parents/carers may request a CAM to be used. If supported:
 - Parents/carers are responsible for the financial cost and supply of the CAM.
 - All discussions & outcomes are to be documented in the patient's medical record.
 - Parents/carers are responsible to administer CAM-medications unless it is dispensed from Pharmacy; in which case nurses may administer.
 - CAM-therapy practices must be documented in the patient's medical record.
 - Any adverse events relating to the CAM use must be documented in IIMs *and* an ADRAC form should be completed for CAM-medication adverse events.
- CAM (therapy or medication) that is deemed harmful by the Treating Team should not be administered to patients. If a CAM is used against medical advice, discussions and actions must be documented in the patient's medical record. Contact the Director of Clinical Governance if parents intend to administer a harmful CAM.
- SCHN staff may practice CAM on patients at SCHN **only** if it is written in their position descriptions *and* they are appropriately credentialed.
- Credentialed CAM practitioners practicing outside SCHN are **NOT PERMITTED** to practice within SCHN without specified authorisation from SCHN.

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1 st October 2015	Review Period: 3 years
Team Leader:	Network Manager Policy and Procedures	Area/Dept: Clinical Governance Unit

CHANGE SUMMARY

- Due for mandatory review. No changes made other than updating links.

READ ACKNOWLEDGEMENT

- The following staff should read this document:
 - Consultants and other medical officers in treating teams.
 - Allied Health staff working in clinical in-patient areas
 - Nursing staff working in clinical in-patient areas
 - Pharmacy staff

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

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Flowchart: CAM use at SCHN

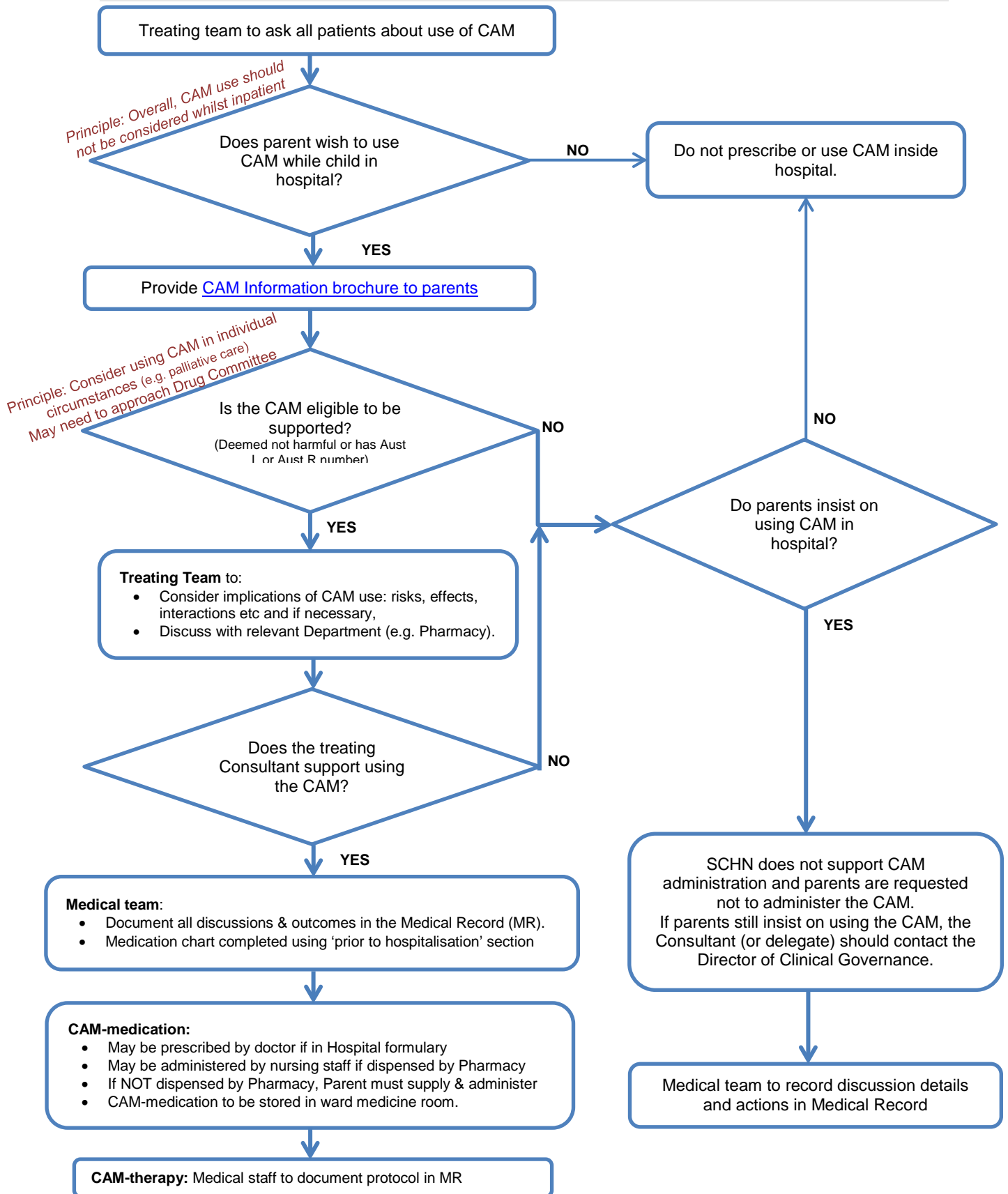


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1 Introduction

Complementary and Alternative Medicine (CAM) are becoming popular treatment options in the public domain. Parents/carers or patients sometimes self-determine medical treatments by using complementary medicines and/or alternative therapies. This is acknowledged by The Sydney Children's Hospitals Network (SCHN) and patients/carers are encouraged to openly discuss their CAM use whilst their child is an inpatient.

SCHN also has a duty of care to patients and staff to ensure a favourable risk/benefit relationship for all therapeutic goods and therapies used at the Hospitals. Therefore discussions should always be balanced with '*is there a risk of harm to the patient, other patients or to staff*'.

2 Purpose and Scope

The purpose of this policy is to provide staff at SCHN guidance on the use of CAM at the hospitals. The guidance applies to therapeutic products which are supplied from outside SCHN and are not listed on the hospitals formulary and also to unconventional therapies or treatments.

Generally SCHN is not in a position to assess the value or risks associated of CAM and therefore support for CAM use may be limited. This document however, outlines the framework within which CAM use may be considered if an individual circumstance presents (refer to the [Policy](#) section for more information).

3 Definitions

3.1 Complementary and Alternative Medicine

Complementary and Alternative Medicine (CAM) is a group of diverse medical and health care systems, practices, and products that are not presently considered to be a part of conventional medicine¹.

The National Centre for Complementary and Alternative Medicine (NCCAM)¹, the American lead agency for scientific research on CAM, groups CAM practices into five disciplines:

- 1. Biologically based practices:** include a variety of substances found in nature including herbs, vitamins, and foods. Some examples include dietary supplements, herbal products, and the use of other so-called natural but as yet scientifically unproven therapies (for example, using shark cartilage to treat cancer).
- 2. Whole-medical systems** are built on complete health systems based on theory and practice. Examples of whole medical systems that have developed in Western cultures include homeopathic medicine and naturopathic medicine.

3. **Manipulative and body based practices:** techniques based on the manipulation or movement of parts or the whole body. Some examples include massage, acupuncture and chiropractic manoeuvres.
4. **Energy medicine:** involves the use of energy fields, including biofield therapies (eg Reiki, gi gong and Therapeutic Touch) and bioelectric-magnetic therapies (e.g. pulsed fields, magnetic fields or alternating current fields).
5. **Mind-body medicine:** practices intended to affect body function through the capacity of the mind. Some techniques that were considered CAM in the past have become main-stream (e.g. patient support groups and cognitive-behavioural therapy). Other mind-body techniques are still considered CAM, including mental healing, and therapies that use creative outlets such as art, music, or dance.

Overall, CAM may be classified into 2 broad categories: *medications* (biological and whole-medical systems administered via oral, rectal, inhalation or topical routes) OR *therapies* (body manipulations, energy or mind-body medicine).

For the purposes of this policy, where CAM practices need to be differentiated, hereafter two categories '**CAM-medication**' and '**CAM-therapy**' will be used.

The **Therapeutic Goods Administration (TGA) Australia** defines CAM-medications (also known as "traditional" or "alternative" medicines) to include vitamins, minerals, nutritional supplements and herbal, aromatherapy and homoeopathic products². Traditional Chinese medicine would be included under the TGA definition.

3.2 Australian Therapeutic Goods Act, 1989³

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

(a) *Listed Goods (allocated with an Aust L number)*

Medicines which have been accepted as being of low public health concern and have indications consistent with the Therapeutic Goods Advertising Code are 'listed' on the Register. Listed goods include many vitamin, mineral, herbal and homoeopathic products.

(b) *Registered Goods (allocated with an Aust R number)*

Medicines that are assessed for safety, quality and efficacy and those which are specified by the TGA as being of some health concern. They include all prescription only medicines and many over-the-counter products.

3.3 Treating Team

Multidisciplinary team including staff from the Medical team, Nursing staff, Pharmacists and Allied Health staff.

4 Policy

SCHN has the responsibility for the safe administration of medications and therapies to patients whilst they are in our care. However, SCHN recognises that we cannot⁴:

- legally enforce removal of CAM brought into our hospital by patients, NOR
- effectively prevent medicines being brought into hospital by parents/carers, OR
- effectively prevent self-administration by patients or administration by parents/carers to their child, if they are determined to do so.

Policy Statement

SCHN encourages patients/parents/carers to **openly discuss** their CAM use with the Treating Team.

Overall, **SCHN does not recommend CAM (medication or therapy) to be used whilst the patient is an inpatient** because the impact of using a CAM is often unknown or it may be harmful to the patient or others around them.

Individual circumstances may present where a CAM may be considered for use (e.g. some chronic conditions or palliative care situations).

In these instances **and at the discretion of the treating Consultant**, CAM administration may be supported. The Consultant should document all discussions relating to the CAM use in the patient's Medical Record.

The treating Consultant may support a CAM so long as there are no contraindications and/or there are no risks to the patient and no risk or exposure to other patients or staff.

4.1 Considerations for the support of CAM-medication administration

Prior to supporting the use of a CAM-medication, the following points should be considered:

- CAM-medications that are *registered* with the Therapeutic Goods Administration (TGA) Australia (i.e. has an Aust R number) may be prescribed, supplied and administered as per [NSW Ministry of Health Policy Directive \(PD2013_043\) Medication Handling](#). **HOWEVER**, some CAM-medications may be registered as an Aust R with dose recommendations*. If the required dose falls outside these recommendations, the CAM-medication may be considered as unregistered (i.e. non-Aust R).
- Support for using CAM-medications that are TGA *unregistered* but TGA *listed* may be considered using the framework described in this document.*
- Support for using CAM-medications that are TGA unregistered *and* unlisted should be **considered with caution**. The Treating Team should work together to assess the safety and efficacy of the CAM-medication for that individual patient. If, with the information available at the time, the CAM-medication is deemed safe and efficacious it may be considered using the framework described in this document. *
- Substances that are prohibited or considered harmful **must not** under any circumstance be prescribed or administered to patients.
- If a CAM-medication cannot be identified (i.e. label not present, ingredients unknown), parents/carers should be encouraged to identify where they procured it and/or provide contact details. This information may assist the Treating Team in deciding if the CAM-medication is safe to use. If a CAM-medication remains unidentified, it should not be administered.

* Prescribing medications outside of the TGA approved doses may have legal implications.

4.2 Considerations for the support of CAM-therapy

CAM-therapies are diverse and like CAM-medication, obtaining reliable information about their safety and efficacy can be limited. Supporting the use of CAM-therapy, to a large degree, is beyond the scope of this document because the effect of the CAM-therapy is unknown. However, if the support of a CAM-therapy is being considered it should include:

- The CAM-therapy should be evaluated for safety and efficacy.
- The CAM-therapy **MUST NOT** be performed on patients if it is physically invasive or psychologically harmful or if reliable information about the CAM-therapy cannot be sourced.
- The CAM-therapy should not be intrusive to other patients in any way.

5 Procedure

5.1 At admission

At admission, staff should encourage open discussion with the patient and/or their parent/carer concerning the use of CAM (medication or therapy) whilst an inpatient: that is, in a neutral manner staff must actively ask if they currently use or intend to use a CAM. Document the CAM use in the patient's medical record.

1. The Attending Medical Officer (AMO) should discuss (in a neutral manner) the risks and benefits of the CAM use whilst an inpatient. Discussions should include asking what their concerns are and how to address the concerns using conventional treatment (if possible).
2. The patient/parent/carer should be advised of the SCHN policy and that they are responsible for the supply of the CAM (medication or therapy).
3. If the patient has an individual circumstance for the treating Consultant to consider supporting a CAM (e.g. palliative care or chronic condition), an assessment should occur noting the impact of the CAM on the patient and on others around them. *In all other circumstances CAM use whilst an inpatient should not be considered.*
4. The Treating Team may be able to assess the safety and efficacy of the CAM in question by discussion with the Ward Pharmacist or they may contact a Department listed below (Table 1) who MAY be able to provide guidance.
In either case, prolonged periods of time to gather the information is not encouraged as resources are limited and in many instances CAM information is not available.
 (see [Appendix 1](#) for brief information or [Additional Resources](#) for links to web pages)
 Parents may be encouraged to provide information.

Table 1: Contact Departments include (but are not limited to):

CAM-medications	CAM-therapies (integrated or alternative physical)
Pharmacy (the Drug Information Specialist Pharmacist) and/or	Physiotherapy or relevant Allied Health staff and/or
Poisons Information Centre and/or	Pain Medicine and Palliative Care
Nutrition & Dietetics	

5. All relevant information should be presented to the treating Consultant for consideration. It is at the **discretion of the treating Consultant to support the use of a CAM.** *There must be no contraindications and/or risks to the patient and no risk or exposure to other patients or staff to support using a CAM.*

6. For **CAM-medications** – If after reviewing the information, the Consultant feels:
- Strongly enough that a CAM-medication is appropriate or necessary for the patient, they should discuss their decision with the Chair of the Drug Committee to ascertain if the CAM-medication can be approved by the Drug Committee and therefore approved for administration (and supplied by Pharmacy) **OR**
 - The CAM-medication will *neither benefit nor harm* the patient; the Consultant may consider supporting the administration of a CAM-medication.
7. The Consultant should document all discussions and outcomes in the patient's medical record. (Refer to [CAM to continue whilst an inpatient](#))
8. If the impact of using the CAM on the patient (or on other patients or staff) is unknown or if it is considered harmful, the Treating Team should ask the patient/carer to stop the CAM or to suspend the CAM whilst they are an inpatient.

5.2 CAM suspended whilst inpatient

If the patient/parent/carer agrees to suspend the CAM but CAM-medication supplies have been bought to hospital, staff should encourage returning the CAM-medication to a relative for safe keeping or giving the CAM-medication to ward nursing staff for secure storage until discharge. The CAM-medication is not to be stored in the patient's personal belongings. Document all discussions in the patient's medical record.

Note: *When suspending (or ceasing) a CAM-medication, an investigation should occur if there is a known risk of harm from sudden cessation. Some CAM-medications have glucocorticoid effects and may need to be stopped gradually. Others may interact with other drugs (for example: warfarin, phenytoin or digoxin) resulting in increased or decreased levels when stopped. Increased drug monitoring to check levels may be required when ceasing CAM-medication.*

5.3 CAM to continue whilst inpatient

If a CAM is supported, the following **MUST** occur (also refer to [CAM use Flowchart](#)):

Supply

- The parent/carer shall be responsible for the provision and procurement of CAM (medication or therapy) used in hospital *unless* it is a CAM-medication that is available from the Hospital formulary. Where appropriate, the same brand CAM-medication should be used consistently by a particular patient.

Documentation

- CAM use *prior* to hospitalisation is to be documented in "Medications taken prior to Presentation to Hospital" section on the inpatient medication chart.
- All discussions and outcomes about the supported CAM are to be documented in the patient's medical record (from the time of admission through to discharge) and includes the requirements listed in Table 2. This is the responsibility of the treating Team.

Table 2

CAM-medication documentation	CAM-therapy documentation
Name/type of CAM-medication	Name/type of CAM-therapy
Name of Consultant supporting CAM-medication administration	Name of Consultant supporting CAM-therapy administration
Date	Date
Brief description of what is in the CAM-medication and expected outcomes	Brief description of expected outcomes
Brief description of how the CAM-medication is administered (e.g. topical/oral), the frequency and duration of administration.	Brief description of how the CAM-therapy is administered, frequency and duration of administration
How long has the patient been receiving the CAM-medication? (i.e. Has the patient been receiving the CAM-medication for a period of time or is it new?)	How long has the patient been receiving the CAM-therapy? (i.e. Has the patient been receiving the CAM-therapy for a period of time or is it new?)
Any side effects (if known)	Any side effects (if known)
The CAM-medication source (place of purchase). The identity of person supplying it (if applicable) and contact details.	Identity of person performing the therapy with contact details.
Any other relevant discussion details	Any other relevant discussion details

4. When a supported **CAM-medication is available from the Hospital formulary**:
 - i. Medical Officers should prescribe the CAM-medication on the inpatient medication chart for the indication as stated in the formulary.
 - ii. Nursing staff should document the administration of the CAM-medication on the patient's inpatient medication chart.
5. When a supported **CAM-medication is NOT available from the Hospital formulary**, medical staff are responsible to maintain current administration documentation in the patient's medical record.
6. Document in IIMs any adverse events relating to the CAM use and complete an [Adverse Drug Reaction Advisory Committee \(ADRAC\) Blue Card](#).

Administration

7. If the supported **CAM-medication IS dispensed from Pharmacy**, nursing staff may administer the CAM-medication. The CAM-medication is stored in the Ward medicine room.
8. If the supported **CAM-medication is NOT dispensed from Pharmacy**, parent/carers have the responsibility of administering the CAM-medication. The parent/carer also has the responsibility of storing the CAM-medication so their child or other patients cannot access the CAM-medication.
9. If a patient/parent/carer insists on using CAM *against medical advice*, discussions and actions must be documented in the patient's medical record. CAM (therapy or medication) that is deemed harmful by the Treating Team should not be administered to patients. The Consultant (or delegate) should *contact the Director of Clinical Governance for advice if patient/parent/carer intends to administer a harmful CAM*.

6 Responsibilities

6.1 Parent/carer or patient

- Notify Treating Team of any CAM the patient has been receiving prior to admission and those they intend to continue using during hospitalisation.
- Obtain explicit support from the treating Consultant to continue using the CAM during hospitalisation.
- Arrange the supply of the supported CAM (medication or therapy) for use at SCHN.
- Administer the supported CAM if the CAM-medication is NOT available in the Hospital formulary.
- Parents may supply information about the CAM for it to be recorded in the child's medical record.
- Report to the treating Medical Team any adverse effects noted prior and during hospitalisation.
- If requested, provide the contact details of where they obtained the CAM-medication or the CAM-therapy practitioner.

6.2 Treating Consultant

- Consider the potential risks and benefits of implementing or permitting the continued use of a CAM (medication or therapy) during hospitalisation. The Consultant (or delegate) should liaise with the relevant Department (e.g. Pharmacy) being aware there is often limited information available in the literature. During the process, weigh up other considerations as outlined in this document.
- Advise the patient/parent/carer of the support (or not) for the use of CAM during the admission.
- Document the advice in the patient's medical record.
- If the CAM is deemed harmful or remains unidentified, it should not be administered to patients. The Consultant should contact the Director of Clinical Governance if parents intend to administer a harmful CAM.
- When a treatment with a CAM-medication is deemed appropriate or necessary by the treating Consultant, he/she should discuss the decision with the Drug Committee Chair. In instances where the Chair concurs with the Consultants decision and approval is granted, the Pharmacy Department may supply the CAM-medication.
NOTE: *This process is no different from any other medication being introduced to the drug formulary; however approval should only occur when the CAM-medication is available from a reliable source and approval should be sought prior to prescribing the CAM-medication.*

6.3 Treating Medical Officer

- Request specific information regarding CAM use at admission and document these on the inpatient medication chart in the relevant section and inform the Consultant so they may consider ceasing or continuing the CAM. The information may need to be updated onto another chart as necessary.
- Provide the patient/parent/carer with available information regarding the relevant CAM in an objective manner.
- Provide the patient/parent/carer with a "[CAM Information for Parents](#)" brochure regarding the use of CAM during hospitalisation and discuss the issue with them.
- Ensure the patient/parent/carer is aware of the recommendations of the treating Consultant regarding the use of the CAM during hospitalisation.
- If available in the hospital formulary, prescribe the supported CAM-medication on the inpatient medication chart noting the name of product, dose, route and frequency of administration.
- Monitor the use of the CAM during hospitalisation for potential adverse effects and document in IIMs accordingly.
- If the CAM is deemed harmful by the treating Consultant or it remains unidentifiable, it should not be administered to patients. Contact the treating Consultant if parents intend to administer a harmful CAM and escalate to the DCG for appropriate action if not resolved.
- Communicate with the patient's General Practitioner regarding the use of CAM during hospitalisation, noting any adverse effects observed during the admission, details of the CAM the patient wishes to continue using after discharge and any follow up required post-discharge.

6.4 Ward Nursing staff

- If not already done so, request specific information regarding CAM use at admission and document these on the front of the inpatient medication chart in the relevant section.
- Ensure the patient/parent/carer has a "[CAM Information for Parents](#)" brochure regarding the use of CAM during hospitalisation.
- If the supported CAM-medication has been prescribed on the inpatient medication chart and it is available from the Hospital formulary, administer and record the CAM-medication on the patient's medication chart.
- Ensure the patient/parent/carer is aware of the procedure regarding the use of CAM (medication or therapy) during hospitalisation.
- If the CAM is deemed harmful by the treating Consultant or it remains unidentifiable, it should not be administered to patients. Notify the treating Consultant or After Hours Nurse Manager (AHNM) if parents intend to administer a harmful CAM.

6.5 Allied Health Staff

- If not already done so, request specific information regarding CAM use at admission. The Allied Health staff member must inform the Treating Team of any CAM use.
- Provide the patient/parent/carer with available information regarding the relevant CAM in an objective manner.
- Provide the patient/parent/carer with a "[CAM Information for Parents](#)" brochure regarding the use of CAM during hospitalisation and discuss the issue with them.
- Discuss with the treating Consultant and Treating Team any information available regarding a CAM.
- Ensure the patient/parent/carer is aware of the recommendations of the treating Consultant and Treating Team regarding the use of the CAM during hospitalisation.
- Monitor the use of the CAM during hospitalisation for potential adverse effects and document in IIMs accordingly.
- Where relevant communicate with the patient's outpatient team regarding the use of CAM during hospitalisation, noting any adverse effects observed during the admission, details of the CAM the patient wishes to continue using after discharge and any follow-up required post-discharge.

6.6 Pharmacists

- On admission, the Ward Pharmacist should investigate any CAM-medication a patient has been receiving prior to admission and document these on the inpatient medication chart in the relevant section.
- **The Pharmacist:**
 - Must inform the medical team regarding known effects, side effects and drug interactions of the CAM-medication as required. *Often information is limited or unreliable: that is no randomised controlled trials and no studies looking at drug interactions.*
 - Should provide information to the patient/parent/carer in consultation with the treating Consultant.
- **The Pharmacy Department:**
 - Will not order or dispense CAM-medication, except in the following cases:
 - i. Vitamins, minerals and trace elements prescribed in a dose and for an indication that is supported by the literature and is in line with evidence based medicine. Some examples are multivitamin use in cystic fibrosis, pyridoxine use in pyridoxine dependent seizures, zinc & vitamin B12 use in deficiency etc.
 - ii. Amino acids that may be used in metabolic disorders.
 - Will not dispense vitamins, minerals and trace elements for non-conventional uses. For example high dose vitamin C.
 - Will not dispense homeopathic and naturopathic remedies.

7 CAM Practitioners

7.1 Employed by SCHN

SCHN staff must not practice CAM on patients at SCHN unless authorised to do so. Authorisation includes the identification of the CAM practice written into their position description and demonstration of current credentialing by a relevant governing professional body.

Note: Discretion should be applied in situations where a 'routine' work practice may be considered a CAM-therapy (e.g. art therapy) and is not reflected in the position description.

7.2 Not employed by SCHN

Credentialed CAM practitioners not employed by SCHN are **not permitted** to practice within SCHN without specified authorisation from SCHN. To gain authorisation a letter of application is submitted by the CAM practitioner to the Director of Clinical Governance requesting to practice the CAM at an institution of SCHN on a particular patient. The application should be accompanied with current credentials, other supporting information including a letter of support by the treating Consultant. The applicant should be able to demonstrate paediatric care.

CAM practice is not to commence until authorisation is given.

8 Additional Resources

The following web links may be of assistance to provide information for the support (or not) of a CAM.

- **Cochrane Library:** <http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME>
- **National Centre for Complementary and Alternative Medicine (USA):** www.nccam.nih.gov
- **CIAP:**
 - Natural Medicines: <http://www.naturaldatabase.com/>
 - Allied and Complementary Medicine (AMED): <http://www.ovid.com/site/products/ovidguide/ameddb.htm> which covers complementary or alternative medicine as well as physiotherapy, acupuncture, and occupational therapy.
- **Memorial Sloan-Kettering Cancer Centre, NY:** <http://www.mskcc.org/mskcc/html/11570.cfm>
- **Complementary and Alternative Therapies Evidence-based Summaries, NZ:** <http://www.moh.govt.nz/moh.nsf/indexmh/cam-evidence-based-summaries-2003-2006>
- **UK MHRA (regulatory authority) Herbal Safety News:** <https://www.gov.uk/drug-safety-update/herbal-products-safety-update>

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Appendix 1: Other brief information about CAM

Hypnosis and Hypnotherapy

Hypnosis is a non-invasive technique which can bring about positive change and can be used to treat a variety of conditions including pain syndromes, insomnia, nausea and vomiting, anxieties and stress. It can also help to break undesirable habits like nail biting and smoking.

Clinical hypnosis involves the induction of a dreamlike state (trance) by the therapist then the reinforcement of positive suggestions to the client.

People can only be hypnotised and accept suggestions if they are a willing participant in the process and will only accept suggestions which are acceptable to them on a subconscious level.

A person cannot be hypnotised against their will.

Massage

Massage Therapy is the manipulation and soothing of the soft tissue of the whole body to bring about relaxation and general improvement in health. It can be used to treat pain conditions, muscular pain, insomnia, stress and anxiety, constipation, high blood pressure and lymphedema.

Deep massage can bring about feelings of calm and general wellbeing as the use of massage prompts the release of natural endorphins. Stress can be reduced as levels of stress hormones are reduced.

Types of massage include baby massage aromatherapy deep tissue therapeutic Swedish and remedial massage.

Complementary Medicines (oral, topical, inhaled, rectal)

A drug information specialist pharmacist should be consulted and also the Poisons / Medicines Information Centre for expert assistance.

Staff should be aware that different parts of a plant and the different stages of maturity of the fruit may have very different effect and toxicity.

The presence of an Aust L number means the safety and quality has been checked by the TGA (Therapeutic Goods Administration) but the efficacy has not. Also, often the dose in paediatrics is likely to have NOT been established and therefore safety in this group is unknown.