Complementary and Alternative Medicine

Background

The Australian Medical Students’ Association (AMSA) is the peak representative body of Australia’s medical students. AMSA believes that evidence-based medicine is the cornerstone of medical practice and that medical students and doctors should endeavour to counsel and treat patients on the basis of this principle. As such, medical education should encompass skills to evaluate the literature and analyse the risks and benefits of complementary and alternative medicines (CAM). Medical education should also promote respectful conversations with patients regarding CAM as part of their holistic care, whilst not at the expense of evidence-based best practice.

Definitions

The most current Australian Medical Association (AMA) position statement defines CAM as a wide range of products and treatments with therapeutic claims that are not presently considered to be part of conventional medicine. Complementary medicines include herbal medicines, some vitamin and mineral supplements, other nutritional supplements, homeopathic formulations, and traditional medicines such as ayurvedic medicines and traditional Chinese medicines. Complementary therapies include acupuncture, chiropractic, osteopathy, naturopathy and meditation.(1) This list is non-exhaustive.

Literature and organisations provide a wide range of definitions for CAM. WHO and Cochrane definitions also propose that the status of a CAM differs according to whether it is part of a country’s own tradition, conventional medicine or integrated into the health care system of the region.(2,3)

The context of the use of a treatment may also determine whether a particular therapy is considered a CAM. Cochrane provides the example of chelation therapy, which is conventional in the treatment of heavy metal poisoning but ‘alternative’ in the treatment of atherosclerosis.

Traditional and integrative medicine are frequently used terms in the conversation surrounding CAM. The WHO defines traditional medicine as “the knowledge, skills and practices based on theories and beliefs Indigenous to different cultures and used in diagnosis, prevention, treatment and maintaining health”.(2) Integrative medicine is a growing practice defined by the RACGP as a combination of evidence-based CAM and conventional medicine, alongside orthodox methods of diagnosis and treatment.(4)

Evidence based practice is a foundational pillar of contemporary medicine. Evidence-based medicine is defined as the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. In practice, evidence-based medicine involves integrating individual clinical expertise with the best available external clinical evidence from systematic research.

Patterns of CAM usage

A 2007 Australian population-based survey indicated that, in the previous 12 months, 68.9% of the population had used a CAM and 44.1% had visited a CAM practitioner. In the same period, the estimated number of visits to CAM practitioners (69.2 million) almost equalled the estimated number of visits to medical practitioners (69.3 million).(6) A high proportion of CAM use has also been reported in rural Australia, particularly the use of manual therapies such as chiropractic services.(7,8)
In Australia, females reported higher rates of CAM use than males, of which users were more likely to be middle-aged with a higher income and level of education. Almost half of pregnant women consulted with a CAM practitioner during pregnancy. Previous studies have also shown that people with chronic health conditions, such as diabetes, cardiovascular disease and mental health conditions are more likely to use CAM.

**Reasons for using CAM**

Various push and pull factors lead to CAM use by the general public. Patients report resorting to CAMs when conventional therapies are yielding unsatisfactory results, or in an attempt to reduce and manage the side effects of conventional therapies. Other reasons include; the perception that all CAMs are safe; the belief CAMs can be used as preventative or adjunctive therapy; the impression that CAM practitioners are more helpful than conventional practitioners; and the sense of control a patient receives over their treatment.

**Dangers of CAM**

There are various dangers with complementary medicine use and these include unknown interactions with conventional medicines and their poorly regulated regulation (see Regulation of CAM). For instance, the quality of herbal preparations are not as tightly controlled, not all ingredients may be listed, and there have been cases of deliberate replacement of listed ingredients with cheaper and toxic substances. The potential presence of heavy metals and toxic chemicals may result in acute hepatic and renal failure, and the exacerbation of pre-existing conditions. The complementary medicine industry in Australia is worth an estimated $4.7 billion. Thus, there is a considerable financial burden placed upon consumers given the lack of evidence to support the benefits of CAM use.

Similarly, complementary therapies, such as chiropractic, also pose a risk, exacerbated by a lack of regulations (see Regulation of CAM) surrounding their practice. In a statement by the American Heart Association and American Stroke Association, the organisations strongly urged medical practitioners to inform patients of the statistical association between cervical artery dissections and cervical manipulative therapy. This warning is particularly warranted as a Cochrane Review demonstrated that cervical manipulative therapy alone was not beneficial for mechanical neck disorders.

**Regulation of CAM**

In Australia, complementary medicine products and practitioners are regulated separately. The Therapeutic Goods Administration (TGA) is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods, a term which encompasses the majority of complementary and alternative products available for lawful supply and sale in Australia.

**Regulation of Medicines**

All medicines sold in Australia must be listed on the ARTG (Australian Register of Therapeutic Goods). These are then stratified by risk and regulated as three separate groups in ascending order of ingredient risk:

- **AUST-L.** Low risk ingredients are ‘listed.’ Products regulated in this category include most complementary medicines i.e. dietary supplements, herbal remedies and traditional medicines. Sponsors (or companies) self-certify that there is conclusive evidence to support product claims. There is currently no pre-market evaluation of claims on labels and regulatory non-compliance is high. Such claims are limited and must relate only to health enhancement, health maintenance and relief from conditions which are self-limiting and non-serious. To assure product quality, these products must be manufactured by a facility which retains a Good Manufacturing Practice (GMP) license.

- **AUST-L(A):** Low-risk ingredients which are thoroughly assessed to ensure scientific evidence supports their claims. Safety and quality is regulated in the same way as AUST-L products.

- **AUST-R:** These higher risk medicines are ‘registered’ and include over the counter medicines and prescription medicines. High levels of scientific evidence must be provided by sponsors, or companies, proving the effectiveness of their treatment. They are thoroughly assessed for safety, quality and efficacy.
Medical students should be made aware that most complementary medicines fall under the AUST-L category and may not have high level and conclusive evidence of their claims, as this is not required by the regulator. Furthermore, the self-certification process without adequate post-marketing surveillance provides a regulatory loophole through which consumers are vulnerable to exploitation. There has been concern with the quality of regulation in regard to AUST-L medicines, given that there is a high rate of regulatory non-compliance.\(^{19,20}\)

In addition, the regulation of complementary medicines is complicated by a crossover between food and medicine regulation. Foods are not regulated by the TGA, but some complementary medicines may be classified as such. This can create confusion and regulatory inconsistency by creating a regulatory grey-zone in the food-medicine interface.\(^{19-23}\)

**Regulation of practitioner advertising**

The Australian Health Practitioner Regulation Agency (AHPRA) has published guidelines for the advertising of regulated health services, which incorporate the Health Practitioner Regulation National Law, and explain the obligations surrounding the advertising of services offered by registered health practitioners and public endorsement of CAMs.\(^{24,25}\) These guidelines apply to a broad scope of practitioners and non-practitioners, including medical practitioners. They extend to the way in which CAMs may be incorporated into clinical practice, advertised or endorsed to consumers by a medical practitioner, with punitive clauses if AHPRA finds a breach has been made. Examples of clauses include not advertising products in a misleading or deceptive manner, and other clauses taken from s133 of the National Law.\(^{25}\) While not specifically and only regarding CAMs in medical practice, the scope of this legislation does extend to CAM advertising by medical practitioners. Thus, medical students should be made aware of the AHPRA guidelines for advertising of regulated health services.

**What should good regulatory practice look like?**

The WHO suggests that in order to reduce harm there be regulation of medical products to ensure safety, quality and efficacy, and encourages pharmacovigilance in relation to the safety of traditional medical products.\(^{26}\) Under Australian Consumer Law, consumers are offered certain rights and protection from forms of exploitation that may result from the sale of products with little to no evidence basis.\(^{27}\) Following these sources, good regulation of CAMs should provide consumers with transparency and access to information about products available for sale in Australia. However, it is important to acknowledge there has been much debate about the current Australian CAM regulatory system, with concerns that regulatory body crossovers and regulatory loopholes (as per above) may leave consumers vulnerable to exploitation.\(^{16,21-23}\)

**Research into CAMs**

While mainstream medicines have established side effect profiles that can be updated after market release has occurred, the same consumer safety data is yet to be produced for many CAMs.\(^{28,29}\) The FDA notes that the self-report system for CAM adverse events used in the United States, the same model being used by the Australian TGA, may promote under-reporting of adverse events and provide an incomplete picture of the safety profiles of CAMs.\(^{30,31}\) Thus, continued research and evidence-based medicine is central to closing knowledge gaps in CAM risk profiles and providing better protection against unforeseen adverse effects on patients.

Cochrane Complementary Medicine affirms that it is essential to build an evidence base of rigorous trials and studies before evidence-based CAM use will become a reality in clinical practice.\(^{32}\) Continued facilitation of high quality trials and systematic reviews is important to not only extend the evidence base of both emerging and highly-used CAMs but also to determine risk profiles for these therapies.\(^{7}\)

**Importance of CAMs in Medical Education**

As per above, Australia has a high rate of CAM usage. Despite this, many patients do not actively discuss their CAM therapies with their doctors, the primary reasons being that; “the doctor never asked”, “the doctor would not understand” and “the doctor would disapprove”.\(^{33}\) The fact that less than 50% of CAM users report their therapy to their doctors is an alarming statistic considering that there exists major drug interactions and potential complications when these alternative therapies are used in conjunction with medical interventions.\(^{34,35}\)
A paper published in 2006 explored the reasons for patients disclosing their CAM usage to their doctors, finding that a doctor's open-mindedness was a key factor in this decision. Integration of CAM education into medical programs has been correlated with a more accepting attitude regarding the potential role of CAM in holistic patient care, as such an increase in CAM education could be a key factor in bridging this divide in doctor/patient communication and thus ensuring the safe usage of CAMs by patients. As such it is vital to the doctor-patient relationship that medical students feel equipped with the correct medical knowledge to educate and advise patients on their CAMs usage as the current lack of CAM education is only contributing to the gap in doctor-patient rapport.

There is limited information as to what extent CAM education is integrated within current Australian medical curriculums, however evidence suggests that students feel both the quality and quantity of CAM education, particularly in pre-clinical years, is lacking and sporadic at best. Literature suggest that approximately 65% of students report feeling like they do not receive a sufficient education on CAMs from university, with 50.2% of students believing that CAM education ought to be implemented and enhanced within medical curriculums as they believed it to be important for their medical careers. Similarly, General Practitioners have been shown to feel ill equipped to answer patient's questions on their CAMs use and their effectiveness; and consequently, have felt cautious about recommending or discussing any form of CAMs.

In a study it was shown that the implementation of CAMs education in medical school is beneficial for students as it sharpens their clinical reasoning, increases their cultural sensitivity and encourages them to engage with the complexity and uncertainty of clinical medicine. The study also highlights the importance of patient-centred care and the role of clinicians to be informed about CAMs so they are capable of communicating openly with patients, and be able to provide evidence-based guidance.

The study also outlines four key reasons for the education of medical professionals in CAMs: being that medical schools are defining the push towards a more progressive and integrative medicine movement, that the skills required to assess all therapies whether conventional or CAM is valuable in dealing with the uncertainty of clinical decision making, that CAM training increases cultural competence which is in-line with social interest in cultural sensitivity, and finally, that the exploration of therapies which are currently categorised as CAMs will help inspire productive biomedical, psychological and sociomedical research.

As such, it is important that all Australian medical students have sufficient knowledge on CAMs as it is not only beneficial for patients and the doctor-patient relationship but also medical students' capabilities to assess practises based on their validity and reputability and provide evidence-based counsel to patients.

**Position Statement**

AMSA believes that:

1. Evidence based medicine is the cornerstone of medical practice.
2. Medical education in Australia should promote an understanding of CAM use in Australia, and its associated risks and benefits as per current best evidence.
3. Medical education should promote respectful conversations with patients regarding CAM as part of their holistic care.
4. Medical students and doctors should strive to hold informative conversations with patients based on evidence-based best practice.

**Policy**

AMSA calls upon:

1. Medical students and doctors to:
   a. Consistently take a comprehensive history which includes CAM use
   b. Understand the wide variation in levels of evidence for CAM and communicate this to patients
   c. Understand the risks and benefits of various CAMs and communicate this to patients.
d. Understand the importance of respecting patient choice regarding CAM in the context of the doctor-patient relationship

e. Recognise that there are various cultural factors which may contribute to patient choice to use CAMs.

2. Medical schools to:
   a. Promote evidence-based medical practice
   b. Provide basic education on common and high-risk CAMs
   c. Provide education to increase skills in evidence and literature appraisal in order to analyse the evidence for CAMs and evaluate their scientific merits
   d. Provide opportunities for students to learn how to sensitively approach conversations regarding complex and contradictory evidence.
   e. Provide education on the basic regulation of CAM practitioners and products, and the limitations of such regulations
   f. Provide context for the limitations of medical practitioners endorsing CAMs with respect to the boundaries of evidence

3. Government at all levels and the Therapeutic Good Administration (TGA) to:
   a. Ensure that the regulation of CAM sufficiently protects consumers from harm and exploitation
   b. Ensure that the regulation of CAM provides consumers with sufficient information to make an informed decision regarding their medical treatment.

4. Research organisations:
   a. To provide thorough research that aims to bridge the existing gaps in literature regarding CAMs

References


Policy Details

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