Policy Document

Complementary and Alternative Medicines (2023)

Position Statement

AMSA believes that:

1. Evidence based medicine is the cornerstone of medical practice.
2. Good Medical Practice is rooted in patient autonomy, and doctors must respect patient choices even when they are not based on high-quality evidence.
3. Medical education in Australia should promote an understanding of Complementary and Alternative Medicine (CAM) usage, as well as its associated risks and benefits as per current best evidence.
4. Medical education should emphasise holistic patient care, promoting respectful and sensitive conversations with patients regarding CAM usage.
5. Medical students and doctors should strive to hold informative conversations with patients based on evidence-based best practice, adopting a harm minimisation approach, as well as considering cultural and social sensitivities about the reasons why patients may choose to use CAMs.
6. The Australian Government has a critical role in regulating CAM goods and services, ensuring all regulatory practices are rooted in individual and public safety.

Policy Points

AMSA calls upon:

1. Medical students and doctors to:
    a. Consistently take a comprehensive history which includes Complementary and Alternative Medicine (CAM) use;
    b. Understand the importance of respecting patient choice regarding CAM in the context of the doctor-patient relationship;
    c. Understand the risks and benefits of various CAMs and communicate this to patients;
    d. Understand the wide variation in levels of evidence for CAM — as highlighted by TGA regulatory categories — and communicate this to patients;
    e. Recognise that the decision to use CAMs is multifactorial, with patients considering various factors, including but not limited to cultural, religious, social and economic, prior to initiating CAM therapy;
    f. Understand that certain patient groups, such as those with differing health epistemologies from the biomedical model and/or Culturally and

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Linguistically Diverse (CALD) patients, are more likely to engage with CAM goods and services;

g. Continue professional development on advances in CAM therapies, following new evidence surrounding these therapies;
h. Advocate for, as well as conduct, more research into CAM therapies, including but not limited to their epidemiology, drug interactions and additional adverse effects, recognising the role of modern-day doctors as clinician-scientists.

2. Medical schools to:
    a. Promote evidence-based medical practice as a central pillar of modern medicine;
    b. Provide education, including on but not limited to drug pharmacology, interactions, and the socio-economic impact of CAMs at both the individual and public health level, particularly focusing on CAM goods and services which carry high risks;
    c. Provide education to improve student skills in literature appraisal, in order to facilitate the analysis of the scientific evidence surrounding CAM-centred research;
    d. Provide opportunities at both the pre-clinical and clinical levels for students to develop their communication skills, in order to develop a sensitive approach to conversations with patients regarding complex and contradictory evidence, especially when consulting with minoritised groups;
    e. Underscore the significance of evaluating the interplay between evidence-based medicine, and legal, ethical, and professional practice arguments as a rationale for not endorsing CAMs, while still upholding the trust and integrity of the patient-doctor relationship;
    f. Provide education on the regulation of CAM goods and services in Australia, and the current limitations of such regulations;
    g. Conduct comprehensive research to assess the potential integration of CAM within the medical curriculum, ensuring alignment with evidence-based standards and socio-ethical considerations.
3. Government at all levels and the Therapeutic Good Administration (TGA) to:
    a. Ensure that the regulation of CAM sufficiently protects patients 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.
    c. Reform the regulation of CAM goods falling into the *AUST-L* (*listed*) category; to require their Sponsors and/or manufacturers to submit evidence of safety and efficacy, to the TGA for substantiation;
    d. Establish a national public register of non-registered CAM practitioners (ie. those not covered by an Australian Health Practitioner Regulation Agency (AHPRA) National board to assist the general public in identifying unethical and incompetent practitioners;

e. Legislatively establish a duty of care between non-registered CAM practitioners and their patients;
f. Guarantee a pathway for patients to seek a legal remedy for failed CAM treatments, or those producing adverse outcomes, especially those administered by non-registered practitioners;
g. Amend the Therapeutic Goods Advertising Code to require:
    i. CAM goods advertisements to:
        1. Submit advertisements to the TGA for substantiation of statements;
        2. State products are CAM goods and not rooted in EBM;
        3. State that patients should consult their medical doctor prior to consuming CAM goods;
    ii. CAM services advertisements to:
        1. Submit advertisements to AHPRA for verification of statements;
        2. Disclose the practitioner is not a medical doctor;
        3. State that patients should consult their medical doctor prior to initiating CAM therapies;
h. Produce and disseminate Consumer Medicine information-like packages to the general public, making them aware of new developments brought into light surrounding the efficacy or dangers of CAM treatments as discovered through:
    i. EBM research;
    ii. Significant reports in the TGA's Database of Adverse Event Notifications (DAEN);
i. Review and reconsider the medicare-subsidised funding for CAM therapies which have poor-quality research underlying them, instead favouring therapies, CAM or otherwise, which have a stronger grounding in EBM;
j. Reviewing the regulation of imported CAM products, and establishing the types and patterns of use of commonly imported CAM goods.

4. Research organisations to:
    a. Provide high-quality gold-standard research, with the aim to bridge existing gaps in literature regarding the efficacy, safety, quality and cost of CAMs;
    b. Quantitatively explore patterns of CAM usage, and how this varies across minority populations such as First Nations peoples, CALD groups, low socio-economic status (SES) groups, and groups with poorer health literacy.
5. Allied health practitioners to:
    a. Stay up-to-date on evidence-based research on common CAMs;
    b. Ensure thorough and holistic medication histories are taken, which includes CAM usage, when interacting with patients;
    c. Encourage patients to disclose CAM usage, and ensure that doctors are aware of such usage.

6. Pharmacists to:
    a. Counsel and educate patients on the efficacy and harms of CAMs;
    b. Raise concerns about undisclosed CAM use with doctors to ensure patient safety and minimise risks of unwanted interactions occurring;
    c. Reflect on and consider their position on placing and advertising non-evidence-based CAM products for sale, recognising that pharmacies are where the majority of CAM goods are purchased, and how this may conflict with their professional and moral responsibilities to patients in providing the best, evidence-based care possible.
7. Medical Colleges to:
    a. Provide up-to-date evidence-based professional development on CAMs, including their usage, efficacy and risks.
8. Medical Deans Australia and New Zealand to:
    a. Develop nationwide, standardised guidelines on the teaching of CAM within medical curricula.
9. Insurance companies to:
    a. Reconsider and review funding priorities for CAM treatments in favour of treatments with more grounding in EBM.

Background

Definitions

The current Australian Medical Association (AMA) position statement defines Complementary and Alternative Medicine (CAM) as a wide range of products and treatments with therapeutic claims that are not presently considered to be part of conventional medicine. [1] The term 'complementary medicine' refers to both complementary medicines and physical therapies. The Agency for Clinical Innovation categorises CAM therapies into mind body techniques, body-based practices, therapies using herbs, therapies using diet and other therapies such as Homeopathy. [2]

A diverse array of definitions concerning Complementary and Alternative Medicine (CAM) exist, both within the peer-reviewed literature and health organisations. The definitions put forth by WHO [3] and Cochrane [4] suggest that the approach to classification of a CAM varies based on whether it's intrinsic to a nation's cultural heritage, considered conventional medicine, or integrated into the local healthcare system.

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. [5]

Traditional and integrative medicine are frequently used terms in the conversations 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". [3] 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. [6]

Modern medical practices are heavily dictated by evidence-based medicine. Evidence-based medicine (EBM) is defined as a systematic approach to clinical problem-solving which integrates best available research evidence with clinical expertise and patient values. Evidence based medicine helps to promote methods that work; and to eliminate practices that are ineffective and harmful. [7]

Regulation

Complementary and Alternative medicines are regulated across two broad categories in Australia. These include the regulation of CAM Products, such as herbal medicines and diet-based therapies, or the regulation of CAM Services, such as acupuncture and reflexology.

Regulation of Complementary and Alternative Medicine Products

Generally, the regulation surrounding the supply, import, export, manufacturing, and advertising of CAMs which encompass therapeutic goods are regulated by the Therapeutic Goods Administration (TGA). [8] Through the Australian Register of Therapeutic Goods (ARTG), the TGA stratifies all therapeutic goods into three categories based on their risk profile, efficacy as well as degree of evaluation by the TGA; the categories being AUST-L, AUST-L(A), and AUST-R. [9] It is important to note that while all goods on the ARTG have different levels of regulatory oversight, all therapeutic benefits must be produced in a facility which is certified as complying with Good Manufacturing Processes (GMP) guidelines to assure product quality. [10]

AUST-L refers to *Listed* therapeutics on the ARTG. These must be formulated from a pre-approved list of ingredients deemed to be low risk by the TGA, and only for certain medical conditions which are considered minor and are often self-limiting. [11] This category includes most CAMs, such as dietary supplements, herbal remedies, and traditional medicines. Listed products are not assessed for efficacy, and the TGA does not investigate if they have their claimed effect. Instead, Sponsors — often from the company producing the benefit — self-certify that there is conclusive evidence to support product claims. [11]

AUST-L(A) refers to *Assessed Listed* therapeutics. This category is similar to AUST-L, with the major distinction being that Sponsors submit evidence for the efficacy of these therapeutics, which is subsequently assessed by the TGA prior to approval. [12] CAMs which do not meet TGA approval criteria for the AUST-L(A) class, and contain AUST-L approved ingredients, are placed within the AUST-L class instead. [13]

The last category is AUST-R, or *Registered* therapeutics. These benefits are produced using ingredients considered to be higher-risk and includes all prescription medicines that have been rigorously tested and assessed for safety, quality, and efficacy, with evidence submitted to the TGA from Sponsors for approval. [14]

Within the current regulatory framework for therapeutic goods, it is important to note that most CAM therapies fall into the *Listed* classification, meaning the TGA does not independently verify if these therapeutics have the claimed effect. [15] As the regulator does not require high level and conclusive evidence of therapy claims, the evidence for AUST-L products is largely self-reported with Sponsors able to claim they have evidence for product efficacy. [16] Due to this loophole, patients who chose to use CAMs as a therapy may become vulnerable to misinformation by such companies. [16]

Regulation of Complementary and Alternative Medicine Services

Healthcare Practitioners in Australia are registered and regulated by the Australian Health Practitioner Regulation Agency (AHPRA). [17] AHPRA has fifteen National Boards, each of which concern a particular healthcare profession. Of these boards, three oversee and regulate alternative medicines, and include the Chinese Medicine Board, the Chiropractic Board and the Osteopathy Board. [18] With the exception of these three boards, the majority of other practitioners who provide CAM Services are not regulated under AHPRA; this includes Ayurveda, Reflexology, Hypnotherapy, Aromatherapy, Reiki, and Yoga, among others. [19] A key function of the AHPRA National Boards is to regulate the profession, as well as to provide patients with a clear pathway to complain about mistreatment and adverse reactions from the treatment administration. [20] The lack of regulation and statutory oversight of many CAM services may mean that patients may miss out on legal remedies and compensation. [21] As many patients who use CAM therapies are often less health literate in biomedical conceptions of health and likely to be from CALD backgrounds, the lack of legal solutions to report CAM practitioners further impacts an already underserved population of patients. [22]

The complex interplay between the Office of the Health Ombudsman (the independent agency dealing with healthcare complaints), AHPRA, the national boards and professional bodies in the handling of medical complaints does not extend to CAM practitioners. [23, 24] Further compounded by the state-based differences across Australia, CAM practitioners exist in a grey area with minimal statutory oversight. This opens up the potential for practitioners to provide therapies with no verification of qualifications and for patients to have minimal pathways to raise any issues that may arise over the course of treatment. [25] Therefore, a consistent framework should be produced across the states and territories, which aims to establish national regulation for all non-registered practitioners who engage in the provision of CAM services. This body should also be able to receive, direct, and, in-conjunction with AHPRA and other agencies, investigate complaints which arise against CAM practitioners. This position is in line with the AMA's position statement, which calls for the establishment of a national public register of non-registered health and complementary medicine

practitioners to aid in identifying unethical and incompetent practitioners (*point 7.9*). [1]

Advertising

One of the most complex issues with CAM professions is the regulation of advertising standards. The major guideline outlined by the Therapeutic Goods Advertising Code requires that goods do not mislead or deceive consumers. [26] This includes making unsubstantiated claims regarding therapies being effective or curative. A common method employed to increase CAM sales includes attempting to evoke unsubstantiated worry in patients regarding their health. [1] Beyond being unethical and not evidence-based, this tool often disproportionately affects patients with reduced health literacy in biomedical conceptions of health. The encouragement of self-diagnosis through listing of vague and non-specific symptoms in advertisements also may further discourage patients from seeking professional medical advice, compelling patients to instead invest time and money in CAM therapies which may not be efficacious or evidence-based. [27]

Taken together, the regulation of CAM goods in its current state is lenient, and assumes that Sponsors of CAM therapies will advertise in good faith, putting the best interests of patients first. [11] In order to make the current system more robust and protective of consumer rights, amendments to the Therapeutic Goods Advertising Code could be considered. This should include clearly stating within the advertisement that the product is a CAM therapy — as opposed to an EBM therapy — and professional medical advice should be sought prior to commencing any CAM therapies.

The current regulation of CAM service advertisement is relatively minimal and insufficient with major issues surrounding practitioner qualifications as well as therapy claim verification. The AMA's position statement on CAMs stresses that advertisements may produce the impression that CAM practitioners are medical doctors, and their treatments and therapies constitute medical advice. [1] This may be overcome by making advertising criteria more stringent, having to disclose that the practitioner is not a medical doctor, and clarifying what the practitioner's qualifications are, as well as stressing that individuals should speak to a medical doctor before considering and commencing CAM therapies. Further restrictions could also be considered, such as by requiring approval to be sought from the TGA or AHPRA — for CAM goods and CAM services, respectively — prior to any advertisements going live, to ensure advertisements are not misleading patients.

The goal of regulating is to ensure that patients have access to holistic health care, with respect given for traditional remedies and treatments, while balancing this with educating patients on the risks of CAM therapies and the need for EBM healthcare to treat any underlying diseases. It is important to protect patients from therapies which may have adverse reactions, without being paternalistic in this approach and having a regard for patient autonomy. Ideally, with the introduction of conditions for CAM advertising, the goal is to promote EBM, such that patients have a better

understanding of the treatment options available to them, with particular regard for patient groups who may be more susceptible to misinformation.

Risks and Benefits to CAM usage

Reason for Using CAMs

Proponents of CAMs state that they provide a holistic approach to healthcare allowing patients to explore a wider range of options. [19] Furthermore, patients report utilising CAMs due to unsatisfactory results from conventional therapies, or the belief that adjunctive therapy yields better results. [28] Other reasons include an improved sense of patient autonomy, the perception all CAMs are safe and a greater sense of empowerment particularly when conventional treatment avenues seem exhausted. [29]

Various CAMs have differing levels of evidence, and the data is not homogenous across studies. A recent scientific review of current CAMs guidelines and randomised controlled trials (RCTs) identified a correlation between the surge of COVID-19 related depression and the interest in CAMs. [30] Rates of depression increased from 24.5% to 30.2% between August and December 2020 and the diminished access to psychotherapy and poor symptom management enhanced CAMs usage. [4] It is important to recognise that some studies have flagged possible benefits. For instance, Chan et al. analysed 13 RCTs which indicated acupuncture when synergistically utilised with SSRIs as opposed to SSRIs alone has demonstrated improvement in symptom management and reduction in depression-related insomnia. [31] Similarly, the dietary supplement St. John's wort administered as a monotherapy has also been attributed to improved depression symptoms when compared to placebo. However, these results cannot be extrapolated in Major Depressive Disorder (MDD). [32] In the case of acupuncture, the Cochrane Review has suggested the risk of bias is substantial, indicating a viable conclusion cannot be drawn due to unreliability and possible fabrication of data. [33] Similar findings are also evident with other medical conditions. For example, there is some evidence suggesting that certain CAMs may improve chronic pain, however there is uncertainty whether it is universally applicable and moreover the individualised risk profiles remain unexplored. [34] From this it can be concluded that whilst many CAMs lack sufficient evidence and strong clinical basis, some interventions have a degree of proven efficacy.

Risks

The lack of standardised regulation and rigorous clinical trials pose a challenge in constructing a robust framework concerning the safety and efficacy of CAMs treatments. Furthermore, due to the ambiguity and apprehension surrounding CAMs, doctors are under-equipped and lack the clinical training to appropriately integrate CAMs into conventional practices. [35] Most CAMs fall under the listed medicines category which is evaluated to contain only "low risk" ingredients recommended for indications related to health maintenance and enhancement and restricted to "non-serious and self-limiting" conditions. [11] Instances have arisen where active ingredients were deliberately substituted with cheaper, toxic alternatives, a practice

which is exacerbated by poor regulations. [36] The potential presence of contaminated heavy metals and toxic chemicals presents significant risks including the onset of acute hepatic and renal failure, as well as worsening of medically treatable ailments. [36]

Simultaneously, other complementary interventions such as chiropractic therapies also lack clinical basis but emerging research indicates possible benefits. Studies have demonstrated a statistical link between cervical artery dissections and cervical manipulative therapy (CMT) Although this correlation is not definitive and there may be confounding factors, patients must be well-informed of the possibility such that they can provide informed consent. Furthermore CMT has also shown limited evidence as a solitary intervention for mechanical neck disorders. [37-38] However, a 2019 study conducted on a cohort of individuals applying for sport and military faculties, illustrated improvements in cervical and thoracolumbar spine measurements after three consecutive chiropractic sessions. [39] These findings suggest the need for more robust interventional research and to implement certain CAMs into practice with precaution when risks are present.

Informed decision-making should prioritise evidence-based practices, integrate CAM within a comprehensive healthcare plan, and ensure vigilant monitoring of potential side effects or interactions. Future research endeavours should focus on rigorous investigation of CAM modalities, aiming to delineate their true efficacy, safety profiles, and appropriate integration within conventional medical practices.

Social and Cultural Perspectives on CAM

From a social perspective, there is limited research on the factors that influence the rising demand of CAMs. However, there are studies that explore the various factors that may have contributed to the social phenomenon. [40]

In recent years, values such as individualism and autonomy have become imbued in modern Australian culture. In fact, individualism as a cultural or individual value was a strong predictor of desire for medical information in Australia. [41] Increasingly, individuals are less prepared to accept traditional authority figures such as medical professionals and instead prefer to seek control and empowerment over their medical decisions and health. [40] Epidemiologically, Australia's ageing population may also explain the growing use of CAM for chronic illness and lifestyle-related morbidity in areas where conventional medicine is perceived to be less effective, such as acupuncture for chronic pain. [40,42]

Historically, usage of CAM in society was contained by limited research funding, a lack of teaching on CAM in medical schools and CAM treatments not being covered by public and private insurance. [40] In recent years, patient's autonomy has become more valued. Medicare now covers acupuncture with private insurance covering some CAM. [40] This highlights the growing need for health professionals to be educated in this space.

From a cultural perspective there is a lack of research on the usage of CAM in different cultural groups and the ways in which it can influence health-seeking behaviour. However, there is a greater prevalence of CAM usage in both Aboriginal and Torres Strait Islander people and migrant populations. [43] The practice of traditional Aboriginal medicine varies within Australia. However, literature reviews support that with greater research to understand the role of traditional medicine, integrating the strengths of traditional medicine into the current healthcare model can positively impact the primary healthcare outcomes for Aboriginal and Torres Strait Islander peoples. [44] CAM usage is also prevalent in African migrant women populations in Australia in which 72.7% women use some form of complementary and traditional medicine for maternal health and wellbeing purposes. Access to these medicines involved seeking from relatives and healers from Africa and looking for a similar medicinal plant in Australia to prepare home remedies. [45]

From an ethical perspective, medical practitioners are ethically and legally obliged to provide sufficient and accurate information to patients to empower them to make informed decisions and provide informed consent to treatments. [45] However, the limited research on CAM makes it increasingly difficult for medical practitioners to fulfil this role. In fact, Australian doctors have many concerns over the usage of CAM due to a lack of reliable information and issues regarding regulation and safety. They feel ill-equipped to respond to patient questions about CAM use and effectiveness and are frequently cautious about recommending and discussing CAM which impairs the doctor-patient relationship. [22]

Importance of CAMs in Medical Education

The most recent nationally representative study on CAMs estimated that 70% of Australians had used at least one form of CAM in the last 12 months, and visits to CAM practitioners were almost identical to the number of visits to medical practitioners. [47] Despite these high rates of CAM usage, there remains a lack of clarity and standardisation surrounding the implementation of CAM education within Australian primary medical programmes. A potential cause of this may come from the Australian Medical Council's educational guidelines, which provide generic goals and skills that a medical graduate should possess, directing individual medical schools to specify curricula to meet them. [48] Another potential reason for the high degree of variation between universities may arise from the lack of evidence-based knowledge required to form a unified curriculum for how CAM teaching should be delivered. [49] Despite the promotion of evidence-based medicine in teaching, it is worth noting that many universities have affiliated CAM research centres, such as the University of Western Sydney, known for its National Institute of Complementary Medicine (NICM), one of the largest centres in the country, focussing on understanding traditional Chinese medicines, herbal medicines, and acupuncture.

While several medical schools are associated with CAM research centres, they only provide introductory electives to CAMs or include CAM as merely a subtopic within compulsory courses for medical students. Medical students in a national survey reported that CAMs were rarely assessed in examinations and that pre-clinical content had little relevance to clinical practice. [47] There was a consensus that CAMs should be implemented more into the curriculum and better equipped with some skills to deal with

CAMs upon graduation. [49] A survey conducted at James Cook University observed that 68.4% of health professionals felt they needed more knowledge to answer patient questions on CAMs and reportedly discussed CAM with 40.6% of their patients. [50]

Despite the high usage of CAMs in the community, 72% of patients in another study did not report their use of CAMS to their medical practitioner. [51] This is an alarmingly high percentage of unrecorded usage, as CAMs could have adverse health effects when used in conjunction with prescribed medication. [50] Patients reported that reasons for not disclosing their CAM usage were mainly due to not being asked by their physician or feeling a sense of disapproval. [51] Because patients hesitate to disclose CAM usage, CAM needs to be included in a history-taking assessment to explore if the patient uses any form of CAM and if they see any CAM practitioners. [52]

A study from the United Kingdom identified that many doctors harbour scepticism toward CAMs due to the lack of evidence surrounding their safety or efficacy. [53] Regardless of internal bias, medical students and practitioners should be expected to respond to patients in a non-judgemental and professional manner to allow patients to open up further. More open communication may allow doctors to evaluate their concerns and enhance their knowledge of alternate treatments. [53] Positive communication can foster patients to use CAM as a supplement rather than an alternative to EBM. [53] Patients who have been with the same General Practitioner for over two years are less likely to see a CAM practitioner. [53] Clearly, doctors need to be able to facilitate patient autonomy and guide patients to make informed decisions, by maintaining appropriate knowledge of CAM to monitor patient safety. [54]

Integrating CAM into conventional medical education can potentially enhance the abilities of doctors in providing holistic care. Training in CAM increases doctors' cultural competence and how they rationalise a patient's medical decisions based on cultural and religious beliefs. [55] Increased recognition of the importance of identifying CAMs may influence and push for further biomedical, physiological, and sociomedical research toward understanding the mechanisms and safe delivery of CAM teaching. [9] Being taught skills to deal with CAMs enhances clinical decision-making skills in uncertain situations using critical analysis of evidence. [55] This skill is equally required for assessing the complexities and validity of EBM treatments. [55]

In response to the high usage of CAMs within the community, medical students need to be exposed to CAM and strategies to communicate and engage with patients regarding CAM usage. Fostering open communication will help to strengthen the doctor-patient relationship, regulate the safety of patients, increase the treatment knowledge of medical practitioners, and allow students to critically assess the validity of all types of medications, guiding patients to a decision on the foundations of evidence-based medicine.

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