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The practice and regulatory requirements of naturopathy and western herbal medicine in Australia

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Abstract: Australian health workforce regulation is premised on the need to protect public health and safety. Specific criteria are set out by governments to ascertain the degree of risk and the need for government intervention. A study was undertaken to understand the current state of usage and the practice of naturopathy and western herbal medicine, and to ascertain whether statutory regulation was warranted. We found increased use of these complementary therapies in the community, with risks arising from both the specific practices as well as consumers negotiating a parallel primary health care system. We also found highly variable standards of training, a myriad of professional associations, and a general failure of current systems of self-regulation to protect public health and safety. Statutory regulation was the preferred policy response for consumers, insurers, general practitioners, and most of the complementary therapists. While we found a case for statutory registration, we also argue that a minimalist regulatory response needs to be accompanied by other measures to educate the public, to improve the standards of practice, and to enhance our understanding of the interaction between complementary and mainstream health care.

Keywords: health workforce regulation, complementary health care, protection of public health and safety, health care policy

Introduction

Community demand for complementary and alternative medicine (CAM) has increased significantly over the past 20 years in western developed countries.^{1–7} Australian survey data show that use is widespread in both sexes and across all ages and conditions.^{4,5,8,9} Use is sufficiently prevalent and well established to warrant scrutiny in public policy.

Internationally, increased attention is being given to the question of whether CAM should be regulated. The UK, the USA, Canada, and New Zealand have all been reviewing policy and legislation in relation to the regulation of CAM practitioners.^{10–12} Statutory self-regulation with title protection is under discussion in the UK, Ontario (Canada), and New Zealand, and has already occurred in California (USA). The US White House Commission considered that ‘the heterogeneous array of education, training, and qualifications makes it difficult to target recommendations about who to regulate.¹¹ In 2004–2005, an Australian state government body, the Victorian Department of Human Services (DHS), commissioned research on the benefits, risks, and regulatory requirements for the professions of naturopathy and western herbal medicine (WHM).

The aim of the study was to investigate and understand the practice of naturopathy and WHM in Australia, and to make recommendations on the need, if any, for regulatory measures to protect the public. The key recommendation was that statutory regulation is warranted for naturopathy and WHM. This article briefly describes the

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policy criteria and the methodology deployed in the eight components of the study to address these criteria, and reports on the findings most pertinent to the question of regulation. The assessment of the evidence against the criteria for statutory regulation is then provided, along with the study group's recommendations for policy action.

Policy framework for occupational regulation

Under Australian federalism, health workforce regulation is the responsibility of the states. In 1995, the Australian Health Ministers' Advisory Council (AHMAC) adopted a general policy of limited government involvement in professional regulation. The states agreed that the following criteria, known as the 'AHMAC criteria', must be satisfied if a profession is to be regulated:

1. Is it appropriate for health ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another ministry?
2. Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?
3. Do existing regulatory or other mechanisms fail to address health and safety issues?
4. Is regulation possible to implement for the occupation in question?
5. Is regulation practical to implement for the occupation in question?
6. Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?

These national policy frameworks informed the focus and the design of the study, in addressing the key question of whether occupational regulation should be pursued by governments.

Methodology

The eight components of the study and an overview of the approaches adopted for each component of the study are also listed in Table 1.

Several of the various components overlapped in terms of issues addressed, but they were covered from different perspectives. As such, the different components served as means of triangulation. The findings from each of the components were considered against the AHMAC criteria through workshop processes within the study group, and also with a reference group of industry stakeholders (such as professional associations). The recommendations and conclusions thus reflected synthesis of the findings and consensus of the study group.

Key definition of practice and scope of study

Numerous therapeutic practices can be grouped under the umbrella term 'complementary and alternative medicine' (CAM). This term is often used interchangeably with such terms as 'natural therapies', 'complementary health care', 'holistic medicine', and other variations. This study is concerned only with naturopathy and western herbal medicine and does not consider a range of other unregulated practices (such as kinesiology, reflexology, iridology, Reiki, Bach flower therapy, aromatherapy, Ayurvedic medicine, and so on).

For this study, a naturopath was taken to be a practitioner whose practice and modalities have been defined by the National Health Training Package introduced in 2002 – that is, a practitioner having core training in naturopathic principles and philosophy and in at least three of four practice modalities: i) herbal medicine; ii) nutritional medicine, and iii) either or both massage and homeopathy. A WHM practitioner was defined as a health practitioner who engages in extemporaneous compounding of herbs for therapeutic purposes for individuals under his or her care, and who has satisfied the core training requirements in herbal medicine principles, philosophy, and practice, as defined by the National Health Training Package¹⁸ for WHM.

The modalities encompassed by naturopathy may be practiced individually. However, this study was not concerned with practitioners whose training and practice is in only one of the specific single modalities of massage, nutritional medicine (sometimes called clinical nutrition), or homeopathy.

Key findings

Risks of naturopathy and WHM

Governments in Australia are interested in regulation if there are risks to public health and safety, as stated in the second of the AHMAC criteria. The evidence from this study found that there are risks related to the practice of naturopathy and WHM, and these risks arise from both the 'tools of trade' and the primary-care practice context. Table 2 sets out the categories of risk identified during research for this study.

The risks from acts of commission by practitioners of naturopathy and WHM relate to direct and inappropriate actions during treatment, while the risks from acts of omission arise when practitioners have inadequate skills or are unaware of the limits of their practice. Acts of commission and omission can lead to various types of adverse events (see Table 2).

Table I The eight components of the study and an overview of the approaches

Component	Methodology
1. Risks	Literature review (computerized literature searches and bibliography searches); media reports; litigation search, coroners' data and court records; complaints data from the Health Services Commissioner; data from professional associations; reporting in workforce surveys; data from Adverse Drug Reactions Advisory Committee and Drug information services
2. Benefits	General citation review (10 most widely used herbs and 10 most popular supplements); evaluation of the extent of pharmacological research in herbal medicine; literature review of herbal medicine and nutritional supplements research; review of 72 systematic reviews published between 2001–2003; literature review of homeopathic research
3. Workforce (a) Naturopathy and WHM (b) Western medicine	(a) National survey of naturopathy and WHM practitioners (1778 practitioners located via a major health insurance provider's national database) (b) National survey of GPs (representative sample of 2000 GPs drawn from Health Insurance Commission database)
4. Education and training	National survey of naturopathy and WHM educational institutions (43 providers located)
5. Professional associations and institutional recognition	National survey of 17 professional associations; enquiries of 36 health insurance funds and two industry bodies, workers compensation authorities in six states and two territories, the Australian Taxation Office, and six professional indemnity organizations; survey of hospital practices in Victoria; survey of policies on registration board websites (medical, nursing and pharmacy); review of statutory education authorities that accredit naturopathy and WHM courses; allocation of relevant research grants from national funding bodies
6. Consumers (a) Opinions (b) Patient profiles	(a) Literature review; four focus group discussions in Victoria of CAM users with chronic conditions (b) National survey of patients in practices – patient profile mailed to practitioners with workforce survey (see 3a)
7. Regulatory arrangements	(a) Search for Australian and international acts and regulations relevant to CAM followed by mapping and comparative analysis of their key features (b) Internet search for reports by health and consumer authorities on health practitioner regulation models to assess options and their advantages and disadvantages
8. Assessment of regulatory requirements	Assessment of data from Components 1–7 against AHMAC criteria for registration of health professions

Abbreviations: AHMAC, Australian Health Ministers' Advisory Council; CAM, complementary and alternative medicine; GPs, general practitioners; WHM, western herbal medicine.

Herbal and nutritional medicines produce both predictable and unpredictable effects. The official reporting of adverse events is likely to be an underestimation of the real number of adverse events – given that (i) the Therapeutic Goods Administration (TGA) Adverse Drug Reactions Advisory Committee (ADRAC) database cannot be analyzed in terms of component ingredients,¹⁹ and (ii) consumers often do not advise their medical/CAM practitioners about all medications they are taking.

The survey of patients completed for this study showed that 34% of patients who consumed herbal medicine were concurrently taking pharmaceutical medications, a cause for concern given that the literature reviewed for this study identified a wide range of adverse reactions associated with herbs and nutrients, and interactions between herbal medicines and western pharmaceuticals is an area of increased reporting in the literature.

A survey of the naturopath and WHM workforce¹⁷ suggested that, on average, practitioners experienced one

Table 2 Categories of risk identified in the practice of naturopathy and western herbal medicine

Category of risk	Major risks	Principal types
Clinical judgment of the practitioner	Acts of commission Acts of omission	Removal of therapy Incorrect prescribing Misdiagnosis Failure to refer Failure to explain precautions
Consumption of herbal and nutritional medicines	Predictable toxicity (type A reactions) Unpredictable reactions (type B reactions) Failure of good handling and manufacture	Direct over dosage Interaction between herbal medicines Interaction with pharmaceuticals Allergy/anaphylaxis Idiosyncratic reactions Misidentification Lack of standardization Contamination Substitution

adverse event every 11 months of full-time practice, and 2.3 adverse events every 1000 consultations (excluding mild gastrointestinal events). The most common adverse events reported in relation to both herbal medicines and nutritional medicines were more severe gastrointestinal symptoms, headaches, menstrual irregularities, and skin reactions. However, the research was unable to determine whether these adverse events are a result of poor practice (including inappropriate prescribing) or a result of the medicines themselves. Nevertheless, the research suggests that the practices do have potential for toxic effects.

The survey of general practitioners (GPs) undertaken for this study indicates that GPs perceive a large number of adverse events to be associated with CAM therapies. According to the survey estimates, GPs see approximately one adverse event arising from CAM therapies every 125 GP consultations. The therapies indicated as responsible for the greatest number of adverse events were, in order, chiropractic, herbal medicine, naturopathy and vitamin/mineral therapy, and Chinese herbal medicine. GPs attributed adverse events to several causes – including ineffective treatment, wrong diagnosis, allergic reaction, drug interaction, and profit-motive overriding clinical judgment.

A majority of GPs perceived Chinese herbal medicine and WHM to be occasionally harmful or frequently harmful (67% and 62%, respectively). GPs attributed adverse events to several causes including ineffective treatment, wrong diagnosis, allergic reaction, drug interaction, and profit-motive overriding clinical judgment.

As complementary health care is used by a significant proportion of the population,^{5,7} and many of them also use conventional medical services, the survey and focus group data undertaken in this study suggest that people have to navigate two systems. This produces difficulties and potential dangers if consumers do not discuss with all practitioners their use of particular services, or if they choose not to inform all practitioners. Our study found that poor communication

between GPs and naturopaths and WHM practitioners is of particular concern given that a majority of CAM patients seek care for chronic conditions (and are therefore likely to be frequent and routine users).

Our review of coroners' records, reports from professional associations, data from the health services commissioner, and media reports showed that there have been some deaths related to inappropriate clinical advice; and there are community concerns about interactions between pharmaceuticals and herbal medicines. Complaints brought by patients to professional associations are more likely to be triggered by communication problems and poor professional conduct than by concerns with treatment interventions.

Workforce: Characteristics of practitioners

Bensoussan and colleagues¹⁷ estimated that there are approximately 3117 practitioners of naturopathy and WHM in Australia, with the majority of practitioners being located in NSW, Victoria, and Queensland. The number of practitioners can be expected to increase, given the number of training institutions that were established from 1990 to 2004 and a general trend towards annual increases in graduates. It was difficult to quantify particular segments of the workforce because most practitioners used several titles to describe their practice, and most practised a range of overlapping modalities (although 'naturopath' and 'herbalist' were the most common titles and practice modalities). A significant proportion (11%) had a prior qualification in another clinical health profession.

Our survey showed there was wide variation in the clinical experience, client loads, and incomes of naturopaths and WHM practitioners. They each spent, on average 24 hours per week in clinical practice, representing 22 consultations per week. Extrapolated across the whole workforce in Australia, this represented 1.9 million consultations per annum. Total turnover in consultation fees in Australia was estimated to be more than \$85 million in 2003.

Most practitioners in our survey had at least three years education in herbal or naturopathic practice, although the length of training was variable and practitioners feel under-prepared in some areas. The average clinical experience held by practitioners was nine years, and 75% received patients through word of mouth. Only 7% worked in multidisciplinary environments that include medical practitioners. Approximately two-fifths of naturopaths and WHM practitioners used medical tests at least 50% of the time to guide clinical practice, and some reported that they guide their interventions by using diagnostic approaches specific to naturopathic and herbal practice.

In the national sample of GPs surveyed in this study, GPs perceived that demand for complementary therapies was increasing, and they expressed interest in incorporating CAM in their practices. The demographics of GPs who practice complementary medicine reflect the overall demographic profile of GPs.¹⁶ The use of, and referral for, some complementary therapies (such as acupuncture and massage) by GPs can be considered a mainstream practice. The majority (84%) agreed that acupuncture and massage were moderately or highly effective, and a large percentage was likely to refer patients to massage and acupuncture (87% and 83%, respectively). In contrast, under 5% of GPs reported they had or had considered practicing herbal medicine or naturopathic treatment, while actual referrals or suggestions to use herbal medicine or naturopathy were 12% and 10%, respectively. Both herbal medicine and naturopathy were perceived to be moderately effective by GPs (62% and 40%, respectively) but cross-referrals between GPs and naturopaths and WHM practitioners remain limited – in part because GPs are uncertain about how to identify qualified CAM practitioners.

The findings of the present study point to a high level of acceptance and use of CAM by the medical profession, but despite some convergence, there remain distinctive differences between orthodox medicine and CAM in philosophical outlook and in practice. In particular, the link between prescribing and dispensing is seen within naturopathy and WHM as central to the individuation of therapeutic intervention, whereas that link was severed during the twentieth century for medical practitioners.

Education and training of naturopaths and WHM practitioners

The number of institutions that provide education and training in naturopathy and WHM has increased significantly in Australia since the beginning of such education in the 1940s.²⁰ In 2003, our research identified 43 naturopathy and

WHM education providers in Australia, offering a total of 104 undergraduate and postgraduate courses. Of all courses identified, 49% had emerged since 2000 and continued growth is likely, as 19 campuses were planning new undergraduate and/or postgraduate courses in the next five years. The estimated number of undergraduate enrolments in the present study was 3500, with about 500 graduates (350 naturopathy and 150 WHM practitioners) each year. It would appear that the workforce is likely to expand considerably.

Developments in CAM education within the vocational education and training (VET) sector in general, particularly the 2002 national health training package for naturopathy and WHM, were important steps towards the establishment of uniform educational standards, but there remain significant variations among courses in content and approach. In this study, courses in naturopathy and WHM were found to range from 2 to 4.5 years. Mean course contact hours also varied (see Table 3). The number of clinical contact hours is especially low compared with institutions in the USA and Canada offering 1200–1500 hours.

There has been a trend in Australia towards a higher level of qualification since the first bachelor's degree in naturopathy commenced in 1995, but there is no significant movement towards alignment of curricula. At the time of the study, ten universities offered degree programs, but university courses are subject to less external scrutiny than courses in the VET sector. Current competitive pressures in higher education have the potential to encourage some institutions to exploit their self-governing status for commercial gain – especially with regard to conversion (ie, degree upgrade) courses, some of which had no subjects specific to naturopathy or WHM.

The proliferation of education providers has had several consequences that are problematic for raising the standard of the profession. These include: a lack of appropriate academic teaching staff; fragmentation and lack of a critical mass of academics; a limited research environment (and few people with research qualifications); and variable arrangements for clinical training. Our survey revealed that teaching is primarily undertaken by sessional staff who make up 89% of the reported academic workforce. Of a total of 821 reported academic staff, only eight (all from universities) had published papers in peer-reviewed journals during the period 1999–2003.

Bensoussan and colleagues¹⁷ estimated that the length of undergraduate or first qualification for naturopaths and WHM practitioners ranges from six months to six years, with an average of 3.1 years. In their workforce survey, 22% of practitioners reported that they felt under-prepared in clinical

Table 3 Range of teaching hours by course type, number of courses, and content area for undergraduate courses

Course type	Naturopathy/WHM Theory		Clinical education		Biomedical and social sciences	
	Number	Teaching hours	Number	Teaching hours	Number	Teaching hours
Advanced diploma naturopathy	13	706–1850	14	198–800	12	300–840
Advanced diploma WHM	10	462–2376	12	100–272	11	507–923
Bachelor's degree naturopathy	10	533–2550	10	280–765	11	416–930
Bachelor's degree WHM	1	635	1	100	1	815

Abbreviations: WHM, western herbal medicine.

training and nearly half felt that they were inadequately prepared for inter-professional communication.

Participation in continuing education was high in the profession, with 89% of survey respondents attending seminars and higher-degree programs.¹⁷ Our study found only five of 14 associations provided seminars in 2002, so it is highly likely that product manufacturers are the major providers of continuing education for CAM practitioners as well as for GPs.

GPs surveyed in our study reported on the extent of their CAM education (any level of training). Proportions of GPs with CAM education were: 14% for herbal medicine, 23% for vitamin and mineral therapy, and 5% for naturopathy compared with meditation 25% and acupuncture 23%. The training tended to be relatively limited (self-taught or through introductory workshops). Our GP respondents believed that inclusion of complementary therapies in medical undergraduate curricula is important, and were interested to receive training in acupuncture, herbal medicine, vitamin and mineral therapy, hypnosis, massage, meditation, and yoga.

Organization of the profession: The professional associations

At the time of the study there were five major professional associations – Australian Naturopathic Practitioners Association (ANPA), Australian Natural Therapists Association (ANTA), Australian Traditional Medicine Society (ATMS), Federation of Natural and Traditional Therapists (FNTT), and National Herbalists Association of Australia (NHAA) – and a large number of smaller groups. The oldest professional association was formed in 1920 (NHAA), but there was a proliferation of groups in the 1990s, with half of the fourteen organizations surveyed in this study having been formed between 1990 and 2003. There has also been a tendency for groups to form and then to split from federated arrangements.²¹ As a result, the numbers of organizations within the two major federations – Federation of Natural

and Traditional Therapists (FNTT) and Complementary Medicines Practitioner Association Council (CMPAC) – have been reduced considerably compared with their original numbers. This has weakened their ability to represent a unified profession with respect to the regulatory requirements of government. About half of the practitioners report membership of two or more associations.¹⁷

Our survey found that the various associations have different entry criteria and different definitions of membership categories, as well as different approaches to the maintenance of ethical standards and investigation of complaints. Their main activities are of a representational nature, such as providing a vehicle for accreditation of practitioners for private health funds, policy lobbying, and offering membership services (such as eligibility for professional-indemnity insurance). They receive few complaints, and do not appear to liaise regarding the question of practitioners who have been removed from one association subsequently applying to join another. Most associations are not active in professional-development activities, such as continuing education and the development of practice guidelines.

Associations have separate arrangements for the recognition of qualifications. These include: accreditation of courses; acceptance of any government accredited qualification; individual assessment of applicants; and combinations of the above. The associations also have diverse views about the educational standards that are required now, and in the future. Varying requirements for accreditation of practitioners weaken attempts at self-regulation.

Each association has its own mechanism for handling complaints, although not all promote their availability to consumers. There appear to be no mechanisms for associations to cross-report to one another. The study group was unable to detect circumstances in which associations routinely reported complaints to relevant authorities, although some complaints submitted to ATMS were being handled by the police. In the constitutions of some associations, there was

a lack of clear process regarding how complaints were to be handled. The study group was unable to identify whether the people involved in complaint resolution were appropriately trained or qualified for this task.

In effect, there is no real self-regulation of naturopathy and WHM. The numerous associations constitute an *ad hoc* and inconsistent system. Attempts to develop a coherent approach across the professions have been frustrated by variation among associations with respect to educational standards and attitudes to regulation.

Institutional recognition of naturopathy and WHM

There has been growing institutional recognition of growing consumer usage of CAM, including naturopathy and WHM. Institutions surveyed for this study included workers compensation organizations; private health insurance funds; professional indemnity insurers; the Australian Taxation Office; selected statutory registration boards, hospitals and non-CAM professional associations; higher education authorities, and major medical research funding bodies.

The increased use of CAM modalities is recognized by private health funds, the majority of which offer rebates for consultations with approved practitioners. Given the growth in payments for CAM treatments, private funds were preparing guidelines for accrediting practitioners. Guidelines provided to the study group included assessment on the basis of qualifications and experience.

Professional-indemnity insurance is readily available to practitioners. Most insurers accept membership of a professional association as a criterion for eligibility.

For the purposes of exemption from the requirements of the goods and services tax (GST), the Australian Taxation Office recognizes a practitioner who is a member of a 'recognized professional association' (of which there are more than 20) regardless of how the standards for entry and membership of the particular association are set.

The services of naturopaths are allowable under some workers' compensation schemes. In most states and territories, recommendation or referral by a medical practitioner is required for workers' compensation cover.

Health care practitioner registration boards are beginning to recognize the growing adoption by their registrants of CAM modalities, and the dual use of conventional and CAM services by consumers. Guidelines have been produced for medical practitioners, nurses, and pharmacists, and both the Australian Medical Association and the Royal Australian College of General Practitioners have developed policies

supporting integrative medicine, provided that the approach is evidence-based and that doctors are appropriately qualified in the practices they offer.

In addition to its use in home and community settings, CAM is also used by consumers in institutional settings such as hospitals and residential aged care. However, apart from a few specific instances, such institutions have been slow to adopt policies that recognize changing consumer practices. This raises concerns about patient safety in acute and chronic care settings.

Consumers of naturopathy and WHM

The consumers of naturopathy and WHM represent the broad spectrum of society, and research shows consumers opt for CAM practitioners for reasons beyond use of specific products or seeking effective treatment for health problems. Studies suggest that reasons for use may include maintenance of health and wellness approaches and support for the philosophy of naturopathy and WHM.^{13,14}

According to the patient survey in the present study, 46% of patients were tertiary-educated (including technical and private colleges), whereas 44% had high-school education or less. In terms of occupational distribution, 48% of the patients surveyed in this study worked in managerial or professional sectors, and 35% were employed in trade, service, or clerical work. These results are somewhat different from those of earlier studies of CAM usage, which showed most use by educated middle-class women and little use by low-income groups, although tertiary-educated women remain disproportionately represented in this study. The results here suggest the usage of CAM has become more widespread across the Australian community.

The majority of patients surveyed in the present study were self-referred (72.5%), but 5% were referred by medical practitioners. Reasons for seeking care were diverse, but psychological, gynecological, and endocrine disorders were the most common reasons for seeking treatment (see Table 4), and 78% reported that they were receiving treatment for a chronic or recurrent complaint. More than 60% had previously consulted another health practitioner (with nearly 50% of those being medical practitioners) and 34% continued to see other practitioners. However, communication between practitioners had occurred for only 27% of the patients. Thus, consumers negotiating and managing parallel primary health care systems is an important concern from a policy perspective.

Victorian consumers involved in this study as focus group participants sought the advice of naturopaths and WHM

Table 4 Principal diagnostic categories for patients seeking care

Diagnostic category	Number (%)
Lower respiratory	11 (2.2%)
Upper respiratory	14 (2.8%)
Gastrointestinal	28 (5.6%)
Neurological	10 (2.0%)
Rheumatological	31 (6.2%)
Dermatological	26 (5.2%)
Ophthalmological	3 (0.6%)
Endocrine	41 (8.2%)
Immunological	17 (3.4%)
Hematological	2 (0.4%)
Cardiovascular	18 (3.6%)
Psychological	58 (11.6%)
Gynecological	60 (12.0%)
Renal	4 (0.8%)
Gerontological	2 (0.4%)
Missing	170 (34.1%)
Cancer	1 (0.2%)
Pre-menstrual tension	2 (0.4%)
Total	498 (100%)

practitioners for a similar range of reasons to those reported in the literature,^{8,22,23} including: holistic care (attention to the whole person); treatment and support for chronic conditions; mitigation of the effects of pharmaceuticals; and maintenance of well-being. Several study participants were using conventional and complementary practitioners concurrently and problems were raised regarding communication with all parties regarding risks for therapies, communication between different professionals, particularly with respect to treatment interactions and the accurate recording of medications.

Overall, the majority of focus-group participants were very satisfied, although this appeared to be dependent on their finding the 'right' practitioner. Some people reported 'shopping around' and 'trying out' various practitioners until they found a suitable practitioner. One person felt experimented upon, and others were concerned about the knowledge and experience of practitioners. Satisfaction was linked to: quality of the relationship; time for discussion, and being listened to; knowledge and skills of the practitioner; and opportunity to participate in their health care.

The importance of a good relationship with a practitioner was emphasized. However, this is an aspiration of all consumers of health care, and is frequently mentioned in any evaluation research.²⁴ Naturopaths and WHM practitioners were seen to be able to offer a sought-after approach to health

care, and they generally provided sufficient consultation time to establish a good relationship.

Our focus groups demonstrated that some users of complementary health care, although not all, participated actively in their health care and appeared to be avid seekers of information – using the Internet, books, and magazines as important sources of information.

Current regulatory arrangements and views about regulation

Given the trends in use by consumers and conventional health care practitioners, there is increased regulatory interest in CAM around the world. This is reflected in the development of policies and regulatory strategies internationally as noted in the introduction. In Australia, the most significant policy review to date is the Expert Committee on Complementary Medicines in the Health System, which reported in 2003 and recommended a number of measures to tighten the regulatory net and to improve the surveillance system and the evidence base.¹⁹

Current arrangements

Although they are unregulated in Australia, naturopathy and WHM practitioners are subject to a diverse range of state and federal government legislation and regulation, including:

- Therapeutic drugs legislation (related to registration, advertising, and labeling of products);
- Drugs and poisons legislation (and schedules) in relation to prescribing rights, which prevents access by naturopaths and WHM practitioners to some 'tools of the trade';
- Quarantine legislation (in relation to importation and use of certain products);
- GST legislation (in relation to GST exemption for their services);
- Commonwealth and state health acts (in relation to rebates from private health funds and infectious diseases regulations); and
- Health complaints commissioners, for example the Health Services Commissioner in Victoria.

The training and education of practitioners are subject to state and federal legislation governing education and training, but accreditation of courses remains voluntary.

Current arrangements for the accreditation of courses and the setting of professional standards are *ad hoc* and inconsistent. The legislative infrastructure does not support consistent standards of education and consistent professional standards for herbal medicine practitioners and naturopaths.

The legislative framework, including the *A New Tax System (Goods and Services) Act 1999*, encourages this situation. The Expert Committee (2003, p. 134)¹⁹ has recommended that the Australian government should ‘give consideration to revising the definition of organizations whose members satisfy requirements for “recognized professionals” for the provision of GST-free services’.

Professional and institutional views about regulation

This study found that the professional associations are divided with respect to the desirability of statutory regulation of naturopathy and WHM. Most associations believe that self-regulation is not working, and some actively support statutory regulation, but others believe that ‘government-monitored self-regulation’ is to be preferred to statutory regulation, which is perceived as ‘government interference’. There is some concern about the cost and administrative burdens associated with statutory regulation.

In their workforce survey, Bensoussan and colleagues¹⁷ reported that a majority of practitioners perceived regulation to be positive for professional status, standards of practice, standards of (and access to) education and research, access to scheduled herbs and products, quality of herbs and products, and definition of occupational boundaries. However, these practitioners had concerns about potential negative effects of regulation on litigation, freedom of practice, and medical influence on practice.

A significant majority (77%) of GPs surveyed in the present study believed that CAM practitioners should be regulated. In relation to specific therapies, GPs strongly supported regulation for acupuncture (87% of respondents), Chinese herbal medicine (80%), herbal medicine (77%), naturopathy (73%), homeopathy (66%), and vitamin and mineral therapy (66%).

Private health funds responding to this study also expressed significant support for statutory registration. They reported concerns about education, professional standards, dubious claims and costs, and having to deal with multiple professional associations.

Consumers' expectations about regulation

Victorian consumers involved in this study had mixed views about regulation, although the majority of participants thought that there should be some form of regulation. A number of focus group participants felt that consumers

put a lot of trust in practitioners, and are often vulnerable, and that practitioners should therefore have an appropriate qualification and should be regulated. The consumers who thought that there should be regulation said it was needed to: raise the standard of practitioners; ensure consistency of care; and stop unethical practice.

There was some confusion about the benefits that regulation would confer on consumers, but the focus-group discussions indicated that quality of care and continuing education were the main issues. Quality of care encompassed the relationship with the provider, the importance of communication, and the knowledge and technical competence of the provider.

Some participants felt that regulation would ensure a greater degree of protection for consumers, but others were concerned about the potential for increased medical influence or control. However, it was felt that this should be balanced against the need for the two systems (conventional medicine and complementary health care) to work together. Comments made in the focus groups suggest that regulation of naturopaths and WHM practitioners would enable consumers to navigate the systems more easily, and that it would enable better communication between practitioners.

The potential for ‘false’ consultations is an issue of concern regarding consumers who believe that assistants in health-food shops are qualified naturopaths. This is a safety issue, given that many of the people who participated in the present survey were active in self-prescribing.

Assessment of regulatory requirements and policy recommendations

There are four general models of occupational regulation of the health workforce in Australia:²⁵ 1) self-regulation, which would require the formation of a peak professional association and uniform national standards, 2) negative licensing, a practitioner may practice in a self-regulated profession unless listed on a register of persons who are ineligible to practice because of a finding of poor practice, 3) co-regulation, members of a professional association are regulated by that association together with government, and 4) reservation of title only, a statutory registration board registers members of a profession and reserves the use of specific titles for those who are registered. Protection of practice and/or title is the current model applied to registered professions in Australia, with protection of title being more common.

In considering the application of these models for health workforce regulation to the current state of naturopathy and WHM use and practice within Victoria and Australia, this

study came to the following conclusions in relation to the AHMAC criteria, as set out in Table 5.

Statutory registration would provide the same protection to consumers of naturopathy and WHM as is currently available to consumers of conventional medical services, including establishing independent and transparent complaint mechanisms, particularly in relation to matters of professional conduct. The practice of naturopathy and WHM would be improved through the requirement for developing uniform minimum educational standards and establishing quality

standards and safety protocols for the use of naturopathic and Western herbal medicines. Additionally, in the view of the study group, statutory regulation would confer additional benefits, including: facilitating the development of communication and referral mechanisms between conventional medical providers and CAM providers; providing incentives for health services to collect accurate records of patients' medications; providing system incentives to develop appropriate policies for the reporting of adverse drug reactions by CAM practitioners, with the aim to increase practitioner

Table 5 Assessment against AHMAC criteria

Criteria	Findings
1. Health portfolio?	It is clearly appropriate for health ministers to exercise responsibility for regulating naturopathy and WHM, given patients are seeking relief for health-related concerns.
2. Risk to public health and safety?	There is a level of risk comparable to other regulated professions; there is a particular risk related to interaction of herbal medicines and pharmaceutical drugs, and the need for appropriate clinical guidelines. Thus, the activities, the scope of practice, and the practice context of naturopathy and WHM clearly pose a significant risk of harm to the health and safety of the public. Minimization of the risks should be a priority of both government and the profession.
3. Adequacy of existing regulations?	There is no legally enforceable regulatory framework governing the prescribing of drugs and poisons by naturopaths and WHM practitioners. There are significant variations in standards for professional education and membership among professional associations, and the professional associations have been unable to agree upon a common arrangement. There are significant variations in standards among education and training institutions and a lack of movement towards common standards – including the failure of current regulatory frameworks for education to ensure minimum standards. Existing regulatory frameworks provide insufficient protection for consumers against professional misconduct. Thus, existing regulatory mechanisms – by government and the professions – are inadequate in safeguarding and protecting the public as consumers of naturopathy and WHM. Statutory regulation would provide a higher standard of complaints process with regard to access, transparency, and equity; moreover, disciplinary actions would be given the force of statute, and an appeals process would be provided.
4. Feasibility?	Naturopathy and WHM are defined professions, with defined modalities and established educational provision, for which the implementation of regulation is possible. There are complexities in relation to naturopathy – because of the diversity of practices adopted by the profession and the fact that some practitioners choose to specialize in only some modalities and do not practice others.
5. Practicality?	Occupational regulation is not without some practical difficulties, but there are models in other jurisdictions in Australia and experience in relation to statutory registration of Chinese medicine practitioners in Victoria that can be drawn upon to design and implement a suitable regulatory scheme.
6. Public benefit outweighs cost?	There would inevitably be some costs associated with regulation. These would largely be borne by the professions in the form of registration fees, costs to practitioners of upgrading qualifications, and costs to educational institutions of upgrading courses. Barriers to entry to the professions would be established, and some existing practitioners might face difficulty in gaining registration if their qualifications and experience proved to be insufficient. The benefits of promoting public safety, however, outweigh the potential negative impacts of occupational regulation, given the negative impacts are primarily restrictions and impost on the profession while the benefits accrue to the broader community, including other in the health care and health financing institutions.

Abbreviations: AHMAC, Australian Health Ministers' Advisory Council; WHM, western herbal medicine.

reporting of adverse reactions to herbs and supplements; and supporting improved public education in communicating risks to consumers.

Supplementary measures needed

In reviewing the current situation against the AHMAC and NCP criteria, we also concluded that statutory regulation would be an insufficient response to meeting the health care quality and safety requirements for consumers. A range of other policy measures would be required to complement regulation.

Understanding and reducing risks

There is a need for better understanding of risks as the basis for a multifaceted approach to reducing the risks. In 2007, the National Health and Medical Research Council (NHMRC) announced research funding to be allocated specifically for CAM and the National Institute for Complementary Medicine was established. These developments will support the efforts of educational institutions to ensure that adequate training is available for these practitioners to minimise the specific adverse events identified in this report, to promote the ability of practitioners to deal with these adverse events, and to report adverse events related to practice. Professional associations could develop further guidelines for professional practice, for example, guidelines for referral to other practitioners, the reporting of adverse events, infection control, drug-herb interactions, the safe use of potentially toxic herbs, and adequate standards of record-keeping and advertising. Professional associations can also support hospitals to develop protocols for managing adverse events related to naturopathic and herbal medicines. Continuing professional education should then be made mandatory by regulatory bodies.

Improving the standard of education and training

Improvements in education and training standards are fundamental to improved practice – including quality and safety – at entry into the profession. There is a need for an independent body, informed by the profession, to develop educational standards and curriculum requirements to bachelor's degree level and to accredit these courses. The 2004 WHO guidelines²⁶ for education and quality assurance in traditional medicine would be a suitable basis to assist providers to identify areas in need of improvement such as inter-professional communication and clinical training. Minimum standards should be set for clinical training

to ensure that: (i) graduates attain core competencies; (ii) assessment processes are rigorous; (iii) clinical teachers have a minimum of five years full-time equivalent experience; (iv) all student clinics have a protocol manual; and (v) all students and staff members working in clinics have adequate first-aid qualifications.

Improving mainstream health services

From the viewpoint of health care quality, particularly patient safety, there is a need for hospitals or hospital associations to develop protocols regarding the use and consumption of complementary medicines in hospitals by patients, and the practice of CAM in hospitals by clinical staff. Medical practitioners should also be required by a regulatory authority to meet educational standards before prescribing herbal and nutritional products. Interdisciplinary education between GPs, nurses, allied health and CAM practitioners at undergraduate level and in continuing professional education settings, will also be a basis for enhancing communication and counseling, including collaboration in the care of patients, particularly patients with chronic illnesses.

Improving access to accurate information

Given consumers have chosen to seek CAM practitioners, informed and empowered consumers are crucial partners in the effort to protect public health and safety. There is a need for quality-assured websites (such as the government-run HealthInsite and BetterHealth Channel in Australia) to ensure that up-to-date and evidence-based information is provided on commonly used CAM treatments. The National Prescribing Service is currently reviewing websites which provide CAM information. The National Institute of Complementary Medicine is also working as part of an international consortium to share best practice and optimize resources to improve online CAM information services to health care providers and consumers. Consumer and professional bodies can also contribute through community education campaigns to: (i) inform consumers about the different roles of general practitioners and CAM practitioners; (ii) encourage disclosure of use of complementary medicines; and (iii) ensure that appropriate medical diagnosis for any underlying conditions is obtained.

Conclusion

The Australian government framework for regulating health workforce considers protection of public health and safety the first and foremost policy objective. This study examined the usage and practices of naturopathy and western

herbal medicine in the Australian community against the regulatory criteria.

This study concluded that statutory regulation is warranted because: there is a level of risk comparable to other regulated professions; there is a particular risk related to interaction of herbal medicines and pharmaceutical drugs, and the need for appropriate clinical guidelines; there is no legally enforceable regulatory framework governing the prescribing of drugs and poisons by naturopaths and WHM practitioners; there are significant variations in standards for professional education and membership among professional associations, and the professional associations have been unable to agree upon a common arrangement; there are significant variations in standards among education and training institutions and a lack of movement towards common standards, including the failure of current regulatory frameworks for education to ensure minimum standards; and existing regulatory frameworks provide insufficient protection for consumers against professional misconduct.

This study concluded that the additional benefits that would come from statutory regulation include: facilitating the development of communication and referral mechanisms between conventional medical providers and CAM providers; providing incentives for health services to collect accurate records of patients' medications; providing an incentive for the development of uniform minimum educational standards; providing system incentives to develop appropriate policies for the reporting of adverse drug reactions by CAM practitioners, with the aim to increase practitioner reporting of adverse reactions to herbs and supplements; establishing transparent and independent complaints mechanisms, particularly in relation to matters of professional misconduct; supporting improved public education in communicating risks to consumers; establishing quality standards and safety protocols for the use of naturopathic and western herbal medicines; and providing the same protection to consumers of naturopathy and WHM as is currently available to consumers of conventional medical services.

There will inevitably be some costs associated with regulation. These would largely be borne by the professions in the form of registration fees, costs to practitioners of upgrading qualifications, and costs to educational institutions of upgrading courses. Barriers to entry to the professions would be established, and some existing practitioners might face difficulty in gaining registration if their qualifications and experience proved to be insufficient. However, this study found that there would be a net public benefit in statutory regulation.

Disclosure

The authors report no conflicts of interest in this work.

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