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REGULATING COMPLEMENTARY MEDICAL PRACTITIONERS

An international review

Executive summary

Many people worldwide use traditional or complementary medicine and consult traditional/complementary medical practitioners. Estimates of the use of traditional/complementary medicine vary between countries, with about 10 per cent of the UK population reporting use in the previous year, up to 20 per cent in Canada, 60 per cent in Hong Kong and 76 per cent in Singapore. In countries such as Vietnam and China where traditional/complementary medicine is an integral part of the health system, as many as one-third of patients receive traditional medicine. In Ghana a majority of people rely on traditional medicine systems, while in India 70 per cent of the population relies on traditional medicine for primary care. However, there are few estimates of the number of traditional medicine practitioners worldwide. In some countries practitioners of traditional/complementary medicine far outnumber conventional medical practitioners (South Africa, Ghana), whereas in others their numbers are comparable (India, China, Vietnam) and in some traditional medicine practitioners are a distinct minority (Europe, Australia and North America).

Many practitioners of traditional/complementary medicine practise without qualification or without adequate training. In response to the situation, the World Health Organization (WHO) has recommended that governments develop national policies that include legislation and regulation of practice, and of education, training and licensing. In recent years, several countries have introduced legislation to formalise the position of traditional/complementary practitioners within their health care systems or strengthened policies on traditional/complementary medicine practice and training.

In this report the experience of 16 countries in regards to this issue are reviewed: Australia, Canada, China, Germany, Ghana, Hong Kong SAR, India, Japan, the Netherlands, Norway, the Republic of Korea, Singapore, Socialist Republic of Vietnam, South Africa, United Kingdom of Great Britain and Northern Ireland (UK), United States of America (USA). Throughout, three domains of regulation are analysed: practice; education and training; licensing and registration of practitioners of traditional/complementary medicine.

Practice

The need to ensure patient safety and prevent patients from receiving care from unqualified (or poorly qualified) practitioners has resulted in legislation being passed to professionalise traditional/complementary practitioners in many countries. In some countries, for example, the Netherlands, this has meant decriminalising the practice of traditional/complementary medicine.

Many practitioners of traditional/complementary medicine are multi-therapeutic practitioners. Regulations apply either to the practice of a single therapy or recognise a diverse range of therapies. In the UK, legislation in the 1990s recognised osteopaths and chiropractors as separate professions. Whereas proposals (not yet implemented) to establish a Complementary and Alternative Medicine Council in the UK to regulate acupuncture, herbal medicine and traditional Chinese medicine recognise that these are often practiced in combination. In Ghana and South Africa, there is a single act to license all traditional practitioners.

In most countries there are national rules governing the practice of practitioners of traditional/complementary medicine. However, rules can vary by province, territory and state within a country, as is the case in Australia, Canada and the USA. Standards of practice and conduct are usually set out in a code of practice or ethics. Responsibility for standard setting is often delegated to professional associations. The problem may be that standards are set too low in order to increase membership. However, the process needs to be flexible and responsive to changes in technology and practice, so this may be preferable to setting standards in legislation.

In several countries the title used by the practitioner is protected. It is more difficult to restrict the activities that practitioners perform and therefore this seldom occurs. Protection of title does not prevent an unqualified person carrying out therapeutic procedures, some of which carry risks. Protection of practice, on the other hand, is difficult to define and enforce; it is usually only in very limited areas where there are specific risks associated with the practice (such as the use of needles) that protection of practice is used.

Training

In order to ensure that practitioners of traditional/complementary medicine have the necessary skills and competencies to treat patients safely, training may be regulated. The length of training and the qualifications obtained by practitioners of traditional/complementary medicine varies widely. Some practitioners continue to learn as apprentices, or via short courses or correspondence courses. No evidence was found of countries

developing strategies to improve the standards of apprentice training and education such as on-the-job training in the basics of hygiene and anatomy. Other practitioners of traditional/complementary medicine obtain higher degrees, undertake training similar to that offered through the medical curriculum and may be required to complete clinical training.

Medical practitioners who practice traditional/complementary medicine may be required to have completed specialist training following completion of orthodox/Western medical training. In other countries traditional/complementary medicine is a component of the medical curricula, and in others it is fully integrated into medical training. In general, standards of education and training are frequently set either specifying length of training or the content of a core curriculum. Standards that specify only the length of training have limited the ability to ensure the quality of the training. Courses may be accredited by professional associations or by independent bodies. The accreditation systems that are independent are likely to have greater external validity.

Registration and licensing

Some countries require practitioners to register or hold a license as a condition of practice. In Norway, for example, the government accredits professional associations, whose members are then eligible to apply for a license. In most countries reviewed here, individuals have to apply for registration or licensing.

Eligibility is usually determined by the ability to show evidence of qualifications and/or safe clinical practice. In some countries there is automatic registration for practitioners with accredited qualifications: in others practitioners must pass a special licensing exam. Automatic registration of individuals depends on a robust and independent accreditation mechanism. Where there is a large number of existing practitioners who would wish to apply for entry on a new register, licensing exams provide a consistent method of entry.

Increasingly countries require re-licensing to be granted on completion of continuing professional development. Procedures for and the frequency of re-licensing vary and there is as yet no consensus on the appropriate balance between monitoring and compliance burdens on practitioners and requirements for ensuring patient and public safety. In some countries and for some traditional/complementary therapies the risks posed by unlicensed practice are not deemed sufficient to justify statutory regulation. In these cases voluntary regulation is preferred. In other countries statutory regulation is introduced only if traditional/complementary practitioner organisations can demonstrate that they have put in place the necessary structures and procedures.

Major findings

Many of these options are poorly evaluated and there has been little research into the relative merits of different approaches to the regulation of practitioners of traditional/complementary medicine, particularly against specified objectives. Health system objectives as well as the objectives for regulation of such practitioners differ widely between countries. These issues need further attention from researchers and policy-makers.

It appears that in countries where the health status is high among the general population and there is good access to Western medicine, the focus of government attention is on protecting patients against harm and ensuring high-quality health care provision. Regulation is aimed at promoting safety and public protection. The approach is different in resource-poor countries where life expectancy is short and preventable diseases prevalent. The focus of government attention in these countries is on health improvement and prevention; regulation is aimed at enhancing the contribution of practitioners of traditional/complementary medicine to health promotion and securing public access to medical services.

Introduction

Background to the report

The World Health Organization (WHO) published its *Strategy for Traditional Medicine* in 2002. It set out a number of objectives:

Integrate TM/CAM with national health care systems, as appropriate, by developing and implementing national TM/CAM policies and programmes.

Promote the safety, efficacy and quality of TM/CAM by expanding the knowledge base on TM/CAM, and by providing guidance on regulatory and quality assurance standards.

Increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations.

Promote therapeutically sound use of appropriate TM/CAM by providers and consumers.

(World Health Organization 2002 p5)

WHO made a number of recommendations relating to regulation and standards that national governments needed to address, including:

- the legislation and regulation of herbal products and the practice of therapies
- the education, training and licensing of providers.

The 56th World Health Assembly passed a resolution in 2003 that called on the Director General to:

...facilitate the efforts of interested Member States to formulate national policies and regulations on traditional and complementary and alternative medicine, and to promote exchange of information and collaboration on national policy and regulation of traditional medicine among Member States.

(World Health Assembly 2003)

In collaboration with its six regional offices, WHO published a global survey of national policies on traditional medicine and the regulation of herbal medicines (World Health Organization 2005a). Its main focus is on herbal products. The WHO Centre for Health Development in Kobe has also compiled and published a global atlas of traditional and complementary medicine (World Health Organization 2005b). The two-volume atlas contains detailed information on 23 countries worldwide and an overview of each region. It reports data from a questionnaire distributed throughout each of the WHO regions (Bodeker *et al* 2005; Ong *et al* 2005). WHO has also published *Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine* in support of its objectives to promote the rational use of traditional/complementary medicine by consumers (World Health Organization 2004b).

By focusing exclusively on the regulation of practitioners and related legislation, it is hoped this report will complement the work already undertaken by WHO on the issue of regulation of traditional/complementary medicine. Placing its practice on a legal footing and putting in place competence requirements is intended to promote practice that is safe for both patients and consumers. This report examines the approaches to the regulation and registration of practitioners of traditional/complementary medicine in a number of countries in order to identify common issues.

Objectives and purpose of the report

The report aims to provide an up-to-date overview of the regulation of traditional medicine and complementary medicine practice in a selection of countries in order to inform the development of national legislation and policies to regulate their practice globally.

Specifically the objectives of the report are:

- to provide an overview of developments in the regulation of practitioners of traditional/complementary medicine in a selection of countries
- to describe legislation and its implementation to regulate the practice of traditional/complementary therapies
- to provide an overview of systems of education, training and licensing of providers, and to describe how programmes of education and training are accredited
- to evaluate the regulatory models and approaches.

It is hoped that this update on developments in the regulation of traditional medicine and complementary medicine practitioners will demonstrate the progress that has been made by a number of governments worldwide to ensure that patients can benefit from access to safe and high-quality health care. It is also hoped that by highlighting these cases other countries that are contemplating action in this area will be able to consider the different approaches adopted around the world and their relative advantages.

Outline of the report

The remaining part of the introduction elaborates definitions of key concepts to be used in the report and discusses some of the challenges of cross-country analysis in this area. It gives a brief description of the methodology used to collect information for the report and presents the analytical framework. Section 2 gives an overview of the international situation regarding the market for traditional/complementary medicine. Section 3 summarises the developments in the regulation of practitioners of traditional/complementary medicine practitioner in the 16 countries chosen for review. Section 4 discusses the case studies, using the analytical framework to draw out similarities and differences in the approaches. For each regulatory approach identified, the report considers the extent to which it contributes to the goals of regulation. Section 5 concludes by identifying key issues for national and international policy-makers and further research questions that need to be addressed.

Detailed case studies for each of the member countries are available on the King's Fund website (www.kingsfund.org.uk/regulatingcompmed).

Definitions and concepts

There is a wide range of terminology used to describe both orthodox or western medicine and traditional or complementary medicine. Some terms carry additional meaning in that they are used by either the proponents of or critics of complementary medicine. Given that there is little agreement on definitions and classifications, this report will adopt the terms traditional medicine and complementary medicine. However, where appropriate in the report, translations of terms used by regulatory bodies or in legislation are used. Before proceeding with setting out the analytical framework we briefly discuss some of the terms in use.

The terms ‘traditional medicine’ and ‘complementary medicine’ are relatively recent designations for a range of healing practices that have in some cases been practised for hundreds of years. Prior to the mid-twentieth century, such therapies were often referred to as ‘primitive medicine’ in colonial settings and ‘fringe’ or ‘marginal medicine’ in western contexts. In many countries, both developed and developing, there was considerable tension between western scientific medicine and other (indigenous) therapies up until the mid-twentieth century. Historical accounts have documented the extent of competition, coexistence, co-operation, integration and modification of alternative or traditional practices (Porter 1989; Jütte 1996; Lindemann 1999).

The term ‘alternative’ medicine suggests its use substitutes for and excludes use of conventional medicine. The term ‘complementary medicine’, which has been increasingly used since the 1980s, emphasises the use of treatments as an adjunct to, or supplementary to, conventional medicine. The term ‘complementary and alternative medicine’ is widely used in scientific and policy-related discourse and has been defined thus: ‘A broad set of health care practices that are not part of that country’s own tradition and are not integrated into the dominant health care system’ (World Health Organization 2000).

Because complementary medicine is a relative concept, the knowledge and practices that are covered by the term vary between countries and are time-specific. Therefore, at the beginning of each case study the main therapies that are practiced in the country are highlighted. Other terms that are used include ‘unconventional’, ‘holistic’, ‘parallel’, ‘eastern’ and ‘folk’ medicine. These compare with terms such as ‘orthodox’, ‘conventional’, ‘allopathic’, ‘western’ and ‘scientific’ medicine.

Traditional medicine is a distinct concept and is concerned with indigenous medicine. WHO has defined it as:

The sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

(World Health Organization 2000)

In industrialised societies, where western medicine dominates, the term is not widely used. Indigenous traditions, often called folk medicine, are often less widely practiced than

‘imported’ practices. The term ‘traditional medicine’ is more common in countries where indigenous medicine has continued to flourish despite the introduction of western medicine.

A system of health care that embraces conventional and traditional/complementary medicine can be referred to as an ‘integrative system’ (World Health Organization 2002). For example, all health care facilities are able to offer care from practitioners of western and traditional/complementary medicine. The term ‘integrated health’ is also described as ‘the safest and most effective aspects of mainstream medical science and complementary healthcare’ (Foundation for Integrated Health 2007). An individual professional may be trained in both biomedicine and complementary systems of medicine and therefore able to deliver integrated health care. Alternatively, care may be integrated at the level of a clinic, with practitioners of traditional/complementary medicine working side by side with conventional practitioners as part of a team.

The focus of this report is on the regulation and registration of the practitioners of traditional and complementary medicine – that is, those who deliver therapeutic care to patients. Regulation is understood as the application of rules governing the professional behavior of autonomous actors (individuals or organisations) usually by government (or a delegated authority) but also by voluntary agreement (self-regulation). There is a range of regulatory tools available to policy-makers, including legislation, enforced self-regulation, incentives (for example taxes and subsidies), disclosure, rights and liabilities. Regulation usually involves the setting of standards, monitoring adherence with those standards and enforcing compliance with them (Baldwin and Cave 1999). The main focus of this report is on the legislative framework governing the practice of traditional/complementary medicine.

Methodology

We conducted background literature searches in order to identify countries in which recent developments in the regulation of practitioners of traditional/complementary medicine had been reported. Working with experts at WHO, we chose 16 countries to reflect a diversity of cultural traditions, represent different continents, include both high income and less developed countries, and to include some countries where practice is fully integrated. They are all countries that have national legislation in place regulating the practice of traditional/complementary medicine.

The following countries are covered by the report: Australia, Canada, China, Germany, Ghana, Hong Kong SAR, India, Japan, Republic of Korea, Netherlands, Norway, Singapore, Socialist Republic of Vietnam, South Africa, United Kingdom of Great Britain and Northern Ireland (UK) and United States of America (USA).

We devised terms of reference including questions and a template of headings (see Annex 1) for each of the case studies. We also conducted searches of PUBMED to identify relevant published literature on each country as well as internet sites of ministries of health and relevant national bodies for grey literature, such as legislation and policy documents. Gaps and outstanding questions were identified and where necessary we contacted national professional associations and health ministries for additional information. A draft of the report was circulated to the relevant country offices of WHO for comment and correction.

This final report reflects where possible the comments received at the time of publication. Any remaining errors of fact are the responsibility of the authors.

Analytical framework to be used in the report

WHO (2002) set out four types of health care systems based on the relationship between allopathic and traditional/complementary medicine:

- **integrative systems**, in which traditional/complementary medicine is officially recognised and incorporated into all areas of health care provision: it is included in the national drug policy; providers and products are registered and regulated; therapies are available at hospitals and clinics (both public and private); treatment is reimbursed under health insurance; relevant research is undertaken; education in traditional/complementary medicine is available (WHO 2002)
- **inclusive systems**, in which traditional/complementary medicine is recognised but is not yet fully integrated into all aspects of health care; work on policy, regulation, practice, health insurance coverage, research and education will usually be under way
- **tolerant systems**, in which the national health care system is based on allopathic medicine, but some practices are tolerated by law
- **exclusive systems**, in which the national health care system is based on allopathic medicine and the practice of traditional/complementary medicine is illegal.

Bodeker (2000) has suggested that historically the relationship between traditional/complementary medicine and conventional medicine can broadly be classed as *monopolistic* (where modern medical doctors have had the sole right to practice medicine, such as in the Netherlands), *tolerant* (where traditional medical practitioners, while not formally recognised, are legally allowed to practice, as has been the case in many African countries), *parallel* (where both modern and traditional medicine are separate components of the national health system, such as in the Republic of Korea and India) and *integrated* (where modern and traditional medicine are integrated at the level of medical education, research and practice, such as in China, the Republic of Korea and Vietnam).

A variety of different classifications of traditional/complementary medicine were also identified in the literature. A number of classifications are of different therapy types (see, for example, Kelner *et al* 2000; Fulder 1996; Lewith and Aldridge 1991). Given the differences of status and prevalence of different therapies internationally these classifications are of limited use for this report.

Jonas (2002) sets out a framework based on the relationship between traditional/complementary medicine and conventional medicine. It identifies *frontier* therapies (those that challenge conceptual and paradigmatic assumptions about biological and scientific reality), *emerging* therapies (those that involve common areas of interest for complementary medicine and conventional medicine) and *integrating* therapies (those that may be considered conventional but that overlap with complementary medicine practices). In this classification, integration relates to epistemology rather than the extent of integration in the health care delivery system.

Kleinman in (Furnham and Smith 1988) distinguishes three overlapping sectors of health care:

- the *professional* sector, made up of the organised, legally sanctioned health professions
- the *folk* sector, made up of either sacred or secular practices including alternative therapies
- the *popular* sector, which includes lay non-professionals who give advice about health.

In this typology, those practitioners of traditional/complementary medicine who are subject to regulation would fall into the ‘professional’ sector rather than the ‘folk’ sector.

The purpose of this report is not to classify countries according to the extent to which traditional/complementary medicine is integrated with conventional health care. An approach is needed to provide a systematic way of examining different aspects of the regulatory framework as they apply to practitioners of traditional/complementary medicine. Generally, the rules to which health care professionals are subject concern: their education and training; the requirements for licensing and registration; their ongoing practice and conduct. In each of these areas there are different objectives and different ways of implementing the rules.

First, the purpose of setting requirements for education and training is to ensure that those who practice in a specific field of traditional/complementary medicine have the competence to do so safely. Educational and training requirements may be defined relating to the content of the curriculum, the length of educational courses or time spent in training, the level of qualification, and the skills and core competencies that participants must acquire.

Second, systems of registration and licensing aim to help consumers and the public to distinguish between qualified and unqualified practitioners. Licensing usually means that only those who hold a license may practise medicine, whereas registration (or certification) means that anyone can practise but only those who are registered can use restricted titles. The requirements for registration and licensing are usually linked to completion of education and training but may also be conditional on meeting other requirements such as language competence or length of experience of practice. When a new register is established existing practitioners are usually admitted to the register either by examination and/or a minimum period of clinical experience.

Third, rules governing the practice of traditional/complementary medicine are usually designed to ensure ethical conduct and safe practice by licensed or registered practitioners. Cases of unethical conduct may result in the practitioner being subject to some kind of penalty. Breaches of standards might include negligence, poor-quality care, infringements of the legal scope of practice and practice beyond the limits of competence.

It is hoped that a taxonomy of the regulation of practitioners of traditional/complementary medicine can be developed from an analysis of the similarities and differences between countries’ approaches to regulation and registration.

The international context

Status of practice of traditional/complementary medicine

It is a challenge to estimate the number of practitioners providing traditional/complementary medicine services within a country, especially if such practitioners practise without registering. Commonly, conventional health care practitioners who practise traditional/complementary medicine do not need to register formally, so it is difficult to estimate their number. Formal training courses may give an indication of the number of people entering practice. Yet some practitioners have never attended formal training courses but have learned through traditional systems of apprenticeship. Where practitioners are required to register, more robust estimates of the numbers of practitioners are becoming available.

Despite these difficulties, it is clear that in some countries practitioners of traditional medicine far outnumber conventional medical practitioners (South Africa, Ghana), whereas in others their numbers are comparable (India, China, Vietnam), and in some countries traditional medicine practitioners are a distinct minority (European countries, Australia and the USA). It appears that where practitioners of traditional medicine comprise a majority of the health care workforce, policies are more likely to be designed to facilitate their contribution to public health improvement rather than to exclude them. Numbers of practitioners will also impact on the design and implementation of policies. For example, in Vietnam – where every practitioner is obliged to register by law – only 3,000 or so out of an estimated 50,000 have done so to date.

Regulation of traditional/complementary products and medicines

Global estimates of the value of the trade in herbal medicine and other traditional/complementary medicine products are rare. Market assessments often estimate the value of the market in industrially produced herbal medicines and other products such as aromatherapy oils and homeopathic remedies. Herbal preparations are also made up from raw ingredients by practitioners and particularly in low-income countries may use locally available plants. Ingredients for herbal preparations are also traded globally but are more difficult to track than commercially manufactured products. The trend appears to be one of rapid growth, with annual growth rates in the UK market in traditional/complementary remedies running at over 14 per cent at the end of the 1990s. Explicit policies to increase the size of the export market by countries such as China suggest this trend will continue. In the Socialist Republic of Vietnam, where there are active policies to promote use of traditional medicine, 31 per cent of registered drugs in 1995 were herbal medicines (Hien and Truong 2005). In Germany, eight of the top hundred most commonly prescribed pharmaceuticals in 1989 were herbal remedies; this declined to just three in 2001 (Dixon *et al* 2003). Due to de-listing of over-the-counter products by the sickness funds, there is almost no reimbursement of herbal remedies.

At the time of the WHO survey, 92 countries (65 per cent of responding countries) reported that they had a law or regulation on herbal medicine in place in 2003 (World Health Organization 2005a). Within the European Union, product regulation is being addressed

through the implementation of the Directive on Traditional Herbal Medicinal Products. The Directive covers only manufactured products and leaves the regulation of dispensing of unlicensed herbal products to national determination (Ernst and Dixon 2004). There have been a number of high-profile cases where products of traditional/complementary medicine have threatened public health. For example, Australian authorities audited the manufacturing quality control standards of Pan Pharmaceuticals following reports of serious adverse reactions to one of its products. As a result, it recalled more than 1,500 products from worldwide distribution (Burton 2003; Loff and McKelvie 2003). Aristolochia, a common ingredient in traditional Chinese herbal medicines, caused 70 cases of kidney failure in Belgium in 1996 and has been banned from use in unlicensed herbal medicines in the UK since July 1999 (www.mhra.gov.uk).

Use of traditional/complementary medicine products and services

Population surveys often vary in their methodology, making it difficult to estimate the comparative prevalence of use of traditional/complementary medicine. The indications are that use is widespread and growing in most countries. Estimates for the proportion of adults who have used traditional/complementary medicine at some point in their lives are 73 per cent in Canada (1999), 60 per cent in Australia (2002) and 34 per cent in Norway (1997). One-year prevalence is lower, with estimates that in Canada between 12 and 20 per cent (2005) and in Germany 56 per cent (2002) of the population had used complementary medicine within the past 12 months, and 60 per cent of the population of Hong Kong SAR (1994), 66–75 per cent of Japanese adults (2002), 76 per cent of Singaporean adults (2005), 42 per cent of US adults (2003) and 10 per cent of UK adults reporting having consulted a practitioner of traditional medicine. In the Netherlands about 6 per cent of the population reported visiting a practitioner of complementary medicine and up to 15 per cent had consulted a practitioner (including general practitioners) for complementary medicine services (1995). However, it is likely these underestimate current patterns of use. In the Socialist Republic of Vietnam, where traditional/complementary medicine is integrated into the health care system, it is estimated that 30 per cent of patients receive traditional medicine. In China, traditional/complementary medicine accounts for one-third of outpatient and a quarter of inpatient treatment in rural areas. No estimates of prevalence are available for the Republic of Korea but figures are likely to be high given the level of integration of traditional medicine into the health care delivery system. In Ghana, 70 per cent of the population relies exclusively on traditional medicine, while in India 70 per cent of the population relies on traditional systems of medicine for primary health care needs.

Reimbursement of traditional/complementary medicine services

Reimbursement policies also vary between countries and are highly dependent on the overall design of the health care system and the national context. Traditional/complementary therapies may be fully covered (as in China, the Republic of Korea and Vietnam), partially covered (as in Germany and the UK) or not covered at all (as is the case in some low-income countries where there is little public funding available for health care).

In countries with publicly financed health care where there is an explicit package of services, such as Australia, Germany, Japan, the Republic of Korea and the Netherlands,

a few traditional/complementary therapies are covered by public health insurance. The therapies that are covered vary according to the cultural traditions of that country. For example, in Japan national health insurance reimburses fully or partly acupuncture, moxibustion, Japanese traditional massage, judo therapy and Kampo and herbal medicines. Most traditional/complementary medicine services are outside public cover and are therefore purchased out of pocket or covered by supplementary private health insurance. In the USA, with the exception of chiropractic, private health insurance tends to limit coverage of traditional/complementary therapies strictly, with high deductibles and co-payments in place.

In tax-funded systems where reimbursement decisions are less explicit, coverage of traditional/complementary medicine depends largely on historical factors and the dominance of conventional medicine. For example, in the UK homeopathy is integrated in the NHS to some extent, while other therapies are available only in some settings (for example, where local purchasers have decided to pay for referrals or where conventional health care practitioners provide complementary therapies alongside conventional medical care). In Hong Kong SAR, where traditional/complementary medicine accounts for a large part of the health care delivery system, the majority of such services are provided in the private sector operating in parallel with the public system and private conventional medical practitioners. In Canada, some provincial plans provide cover usually for regulated practitioners of traditional/complementary medicine. In Norway, the public health system offers only limited cover for chiropractic; proposals for public reimbursement of traditional/complementary medicine services were rejected by a parliamentary committee in 1998. In addition to referrals to regulated practitioners of traditional/complementary medicine, private health insurance may reimburse other such therapies delivered directly by traditional/complementary practitioners, for example, *Heilpraktiker* in Germany.

In low-income countries where public health care resources are scarce such as Ghana and India, the majority of traditional/complementary medicine services are paid out of pocket. In India, traditional/complementary therapies are available in some public facilities; nevertheless, between only 2 and 4 per cent of government expenditure is on these services. Spending is planned to increase to 10 per cent in future. Where traditional/complementary therapies are integrated, as in China and Vietnam, it is usual for them to be covered by social insurance or provided in public health care facilities.

Developments in the regulation of practitioners of traditional/complementary medicine

WHO has provided strategic direction for national governments in developing policies on traditional/complementary medicine (World Health Organization 2002). The WHO Strategy recommended that governments develop national policies that should include legislation and regulation of practice, and education, training and licensing (World Health Organization 2002). Several countries have enacted legislation in recent years to formalise the position of practitioners of traditional/complementary medicine within the health care system or strengthened policies on traditional/complementary medicine practice and training.

A number of WHO publications have described the situation regarding policies in traditional/ complementary medicine worldwide (World Health Organization 2001; Bodeker *et al* 2005; Ong *et al* 2005; World Health Organization 2005b). In addition, there have been a number of studies of the regulation of traditional/complementary medicine commissioned by national governments in the course of developing their own policies and regulations. The Australians conducted a review of occupational regulation of traditional/complementary medicine in a number of other countries (Bensoussan and Myers 1996). In 2002, the Irish government commissioned a report that included an analysis of the regulation of complementary medicine practitioners in a number of countries (O’Sullivan 2002). The European Union funded a study of regulation in member states – the Council of Science and Technology (COST) Action on ‘Unconventional medicine’ (1993–98). It focused on acupuncture, homeopathy, manipulation and herbalism and briefly described legal aspects of regulation (Monckton 1998). Information about how European Union member states currently regulate practitioners of traditional/complementary medicine has been published more recently (Erdsal and Ramstad 2005).

This section attempts to summarise the main developments in the regulation of practitioners of traditional/complementary medicine, drawing on the country cases studies prepared for this report. It focuses on training and education, licensing and registration, and practice standards as they apply to all practitioners of traditional/complementary medicine. This includes practitioners with some formal training, those who have trained as apprentices, and western health professionals who practise traditional/complementary medicine (with or without formal training). Although different licensing requirements may currently apply to different types of practitioners, the ultimate regulatory objective of ensuring safe and qualified practice of traditional/complementary medicine is the same. Policy-makers may therefore wish to consider legislation and regulations as they apply to all practitioners in order to ensure that the objectives are met in a co-ordinated way. Full details of developments in traditional/complementary medicine in each country can be found in the case studies (see www.kingsfund.org.uk/regulatingcompmed).

Education and training

COMPETENCE REQUIREMENTS

The types of qualifications obtained by practitioners of traditional/complementary medicine vary enormously between and within countries. Training will be offered in some therapies

by correspondence courses or short weekend courses or evening classes. These may be appropriate if the purpose of training is familiarisation with the therapy or for personal or family use. Even among more established traditional/complementary therapies, the length of training and the level of qualification attained may vary considerably. For example, in Japan most practitioners must complete at least three years of training though, where more than one therapy is taught, programmes may last up to five years. In India, the Central Councils for Indian Medicine and Homeopathy award a range of degrees at undergraduate and postgraduate level as well as diplomas.

In some cases the length of study, content of the curriculum and clinical training requirements are similar to those for conventional medical training. For example, naturopathic doctors in Canada must complete four to five years of training at an accredited college including a period of clinical practice training following a three-year university degree (or premedical studies). In China, a doctor of traditional/complementary medicine must usually complete five years of study.

In some countries, formal educational courses have only recently been established; for example, Ghana introduced a Bachelor of Science degree in herbal medicine in 2001. It is the first attempt there to integrate traditional herbal knowledge into a university scientific curriculum.

REQUIREMENTS FOR EDUCATION AND TRAINING

Most associations for practitioners of traditional/complementary medicine establish minimum education and training requirements for members. In the Netherlands, practitioners are encouraged to establish systems of self-regulation before applying for statutory regulation. The Dutch Council of Classical Homeopathy has established educational requirements in line with European guidelines for homeopathic education set by the European Council for Classical Homeopathy and has requested consideration for statutory recognition by the Dutch parliament. In the UK, the Prince's Foundation for Integrated Health has been working with groups of practitioners of traditional/complementary medicine to establish common standards of education and training and common accreditation systems.

Standards may involve establishing norms for the number of hours of training or may give details of the content of the curriculum. For example, in order to join the Canadian Massage Therapist Association members must have completed 2,200 hours of educational curriculum, whereas the Central Councils in India set out a curriculum for traditional/complementary medicine training as well as ensuring training institutions meet minimum standards. In some countries the training standards are the same for those wishing to practise traditional/complementary medicine regardless of whether they are already trained as conventional medical practitioners; in Quebec, for example, the Bureau de l'Ordre des Acupuncteurs du Québec has set rules that apply to both physician and non-physician acupuncturists regarding their training, education and annual registration.

A number of countries have worked to establish a core curriculum for practitioners of traditional/complementary medicine. Some training includes biomedicine as a core component, while in other cases alternative explanatory models are taught and there is

little or no overlap with the training of conventional health care practitioners. In some countries training in traditional/complementary medicine is a formal part of the curriculum of medical practitioners. For example, in Germany ordinances passed in 2003 mean that medical faculties are obliged to include naturopathy and physical therapy in the training curriculum. There are various specialist qualifications in complementary therapies that doctors may take, each with mandatory periods of practice and the skills that need to be learned. These standards are set by the regional medical associations based on templates provided by the Federal Medical Association. In Japan, Kampo medicine was formally incorporated into the model core curriculum for medical schools in 2001. In a number of countries the training in western medicine and traditional/complementary medicine are fully integrated, with common training components, for example, in Vietnam and China.

Because of the lack of implementation of legislation in Ghana, official standards for education are absent and most training is still acquired through apprenticeships. The Traditional and Alternative Medicine Directorate within the Ministry of Health has produced training manuals for herbalists.

Several countries that have established systems of licensing have introduced requirements for continuing professional development or continuing medical education or are discussing proposals. In the UK, chiropractors and osteopaths are required to participate in continuing medical education. In India, there are discussions about making ongoing training mandatory. Many professional associations also run voluntary continuing medical education courses for practitioners.

ACCREDITATION OF TRAINING FOR PRACTITIONERS OF TRADITIONAL/COMPLEMENTARY MEDICINE

In some countries training is provided by private colleges and individual 'masters' and therefore the qualification or certificate gained has no external validity. Increasingly colleges and training institutions have sought external validation for their courses through national qualification authorities.

In some cases these are national or regional curriculum authorities. In Australia, courses of study in traditional/complementary medicine may be accredited by the state/territory educational boards. Chiropractic and osteopathy training standards are set by the Registration Boards in each state and accreditation is granted by the Australasian Council on Chiropractic Education and the Council on Chiropractic Education Australasia Inc. The Australian National Training Authority has also funded projects to establish competency-based standards for complementary medicine training courses.

In other cases the registering bodies accredit training institutions based on the standards required for entry on to the register. The Council for Naturopathic Medical Education accredits colleges in both Canada and the USA. Accredited colleges are allowed to administer the North American Board of Naturopathic Examiners (NABNE) examinations to their candidates. These examinations are often required for licensing.

In other cases the government administration accredits training institutions. This may be the ministry of health or the education ministry. For example, in India the government

accredits training institutions but bases its decision on recommendations from the Central Councils; in Japan, all training institutions and colleges must be authorised either by the Ministry of Health, Labour and Welfare or the Ministry of Education, Culture, Sports, Science and Technology.

Licensing and registration

Most legislation establishes mechanisms for individual practitioners to register. However, in Norway, the Act No 64 allows *associations* for practitioners of complementary medicine to apply for registration to the Norwegian Directorate for Health and Social Affairs. If an association is approved, the individual registrants of the association may apply to be accepted onto the public register, and may, when accepted, use the title ‘registered’. The Norwegian Homeopathic Association was accepted onto the register in 2005 and is still the only complementary and alternative medicine organisation to be accepted onto it. It is the association rather than the individuals that are registered in law.

A number of countries automatically admit graduates of accredited colleges to their registers. For example, the Central Council of Indian Medicine and the Central Council of Homeopathy in India both automatically register graduates of accredited colleges. The General Osteopathic Council and the General Chiropractic Council in the United Kingdom automatically admit graduates of accredited colleges as long as they meet the other requirements such as being in good health and having the necessary professional indemnity insurance.

In other cases graduates of accredited colleges must also sit a licensing examination. For example, in Canada, the College of Traditional Chinese Medicine Practitioners and Acupuncturists of British Columbia sets a licensing examination that must be passed after completing certain education and training requirements. In Quebec, non-medical acupuncturists must graduate from an accredited college and pass an examination set by the regulatory college. Naturopathic doctors in Canada and the USA must pass a licensing exam set by the North American Board of the Naturopathic Examiners after completing their formal education. In Japan, practitioners must pass a national examination in order to obtain a licence from the Ministry of Health, Labour and Welfare after graduating from an accredited school or training institution. Practitioners of traditional/complementary medicine in China must pass a licensing exam designed by the Health Department and administered in the provinces in order to register; on successful completion of the exam, the local health department issues a certificate that specifies any limits to their scope of practice and permits them to practise within that area.

In other countries, particularly those where there is a history of unlicensed practice by apprenticeship-trained practitioners of traditional/complementary medicine, the introduction of mandatory registration has meant establishing transitional systems for recognition of prior experience and qualifications (for example, Hong Kong SAR). These might involve presenting evidence of years in practice or qualifications obtained overseas or prior to accreditation and usually involve sitting an examination as well. In the UK, when the new registers for osteopaths and chiropractors were opened, there was a transitional system whereby prior experience was able to be validated in order to be registered by the General Councils (often called ‘grandfathering’).

Some registering bodies require re-licensing by providing proof of participation in continuing medical education. For example, in Alberta, Canada, chiropractors are required to prove continuing education every three years in order to maintain their license to practise. The Department of AYUSH in India has proposed that all practitioners of traditional/complementary medicine receive reorientation and continuing medical education in order to help them integrate into the public health care system, though this is not mandatory.

In rare cases, practitioners of traditional/complementary medicine may be required only to sit a licensing examination with no requirements for training whatsoever; for example, in Germany *Heilpraktiker* are not required to undertake any formal training in traditional/complementary therapies. In order to obtain a licence, applicants must sit an exam at the public health office; this mainly checks that they know the legal limits of practice and have some basic clinical and biomedical knowledge.

In most countries conventional health care practitioners are not required to register with traditional/complementary medicine bodies in order to practice, though in some (for example, Germany) they are required to meet certain standards in order to use the registered title. In Japan, medical doctors who wish to practise and prescribe Kampo medicine are required to join the Society of Japanese Oriental Medicine and renew their membership every five years. The Japan Society for Acupuncture and Moxibustion also has in place a registration system of doctors. In China, conventional health care practitioners may also apply to take the traditional Chinese medicine examination in order to register.

The practice of practitioners of traditional/complementary medicine

In most countries the practice of practitioners of traditional/complementary medicine is governed by general laws that regulate such things as the possession and dispensing of restricted drugs, licensing of business premises, licensing of premises where skin penetration occurs (due to infection control) and consumer legislation regarding the advertising and therapeutic claims that can be made. These laws are not reviewed in detail here, though they may contribute significantly to the safe practice of traditional/complementary therapies. Here the focus is on legislation specifically to regulate the activities of practitioners.

A number of countries within Europe had previously outlawed practice of medicine by anyone other than a registered physician. These measures to exclude complementary medicine practice were not stringently implemented and have gradually been weakened or reformed. In the Netherlands, the Health Care Profession Bill (BIG) 1993, which came into force in 1998, redefined what constitutes the legal practice of medicine. The practice of complementary medicine is no longer illegal but there is no legislation to establish standards of practice or licensing systems for practitioners of traditional/complementary medicine. In this context, the legislation is being enacted in order to decriminalise the practice of traditional/complementary medicine. Portugal (not included in this report) also passed legislation in 2003 to regulate the practice of acupuncture, homeopathy, osteopathy, naturopathy, phytotherapy and chiropractic, which had previously been illegal by non-medical professionals (Erdsal and Ramstrad 2005). In contrast, the majority of the other pieces of legislation discussed below are enacted in order to professionalise the practice of traditional/complementary medicine.

In a number of countries legislation has been introduced to give legal recognition as professionals to individual groups of practitioners of traditional/complementary medicine. This mono-therapeutic approach was followed in the UK in the early 1990s when osteopaths and chiropractors obtained statutory recognition and protection of title under individual Acts of Parliament.

In other cases a single act is introduced to regulate all practitioners of traditional/complementary medicine under an umbrella regulatory body recognising that such practitioners may be engaged in multi-therapeutic practice. For example, Ghana passed the Traditional Medicine Practice Law in 2000, to establish a Traditional and Alternative Medicine Council in order to register and license traditional medicine practitioners. However, the Law has not been implemented and the Council has not yet been established. In South Africa, the Traditional Health Practitioners Act 2004 sets out provisions for a single council to regulate a range of different traditional health practitioners, including traditional birth attendants, traditional surgeons and healers. In the UK, proposals for establishing a joint Complementary and Alternative Medicine Council were consulted on in 2004. It was proposed that the council would initially regulate acupuncturists, herbal medical practitioners and practitioners of traditional/Chinese medicine, recognising that these therapies are often practiced in combination.

In other cases legislation has been introduced that regulates the practice of all medical practitioners, both conventional and traditional/complementary. For example, in China the Practitioner Act of the People's Republic of China implemented in 1999 regulates all medical practitioners and establishes standards for training and for exams and registration, and codes of practices.

In most countries legislation to regulate practitioners of traditional/complementary medicine is made at national level, thus ensuring uniform standards of practice, free movement of professionals and recognition of qualifications. However, in several countries where there is political devolution legislation on regulation of practitioners of traditional/complementary medicine is made at regional or local level. For example, in Australia, Canada and the USA responsibility for legislation is devolved and lies with the states/provinces and territories. Consequently, only osteopaths and chiropractors are regulated in all states and territories in Australia, and only chiropractors are regulated in all provinces and territories in Canada. Practitioners of traditional/complementary medicine have had statutory recognition in the state of Victoria, Australia since 2002. Some provinces in Canada license massage therapists, acupuncturists and naturopathic practitioners.

CODES OF PRACTICE

Commonly legislation is very general and establishes the regulatory body to which it delegates the responsibility for setting standards. The Indian Medical Central Council Act 1970 established the Central Council of Indian Medicine and the Central Council of Homeopathy, with powers to set standards of education, maintain a register and regulate practice. There may also be government or lay involvement in the setting of standards where issues of public accountability are a concern.

In some cases the responsibility for defining codes of practice is delegated to professional bodies. In Victoria, Australia, there is consensus that standards of practice for conventional health care practitioners who incorporate traditional/complementary therapies into their practice should be established through guidelines and codes of practice rather than legislation. In Canada, standards of practice are set by the College of Chiropractors in each province. In Norway, registered associations of practitioners of traditional/complementary medicine are required to have in place statutes that set professional qualifications for members, ethical rules and professional responsibilities.

Codes of practice are often framed as ethical codes or codes of conduct that embody ‘professional practice’. Practitioners of traditional/complementary medicine have produced codes of ethics in a number of countries – for example Ghana, India, the Republic of Korea and Singapore – or are required to in order to gain legal recognition, for example Norway. It is not always clear how compliance with the code is monitored or enforced. Disciplinary procedures for sanctioning practitioners who fail to meet these standards are often in place but they are exercised only in extreme cases of professional misconduct following a formal complaint.

PROTECTION OF TITLE OR PROTECTION OF SCOPE OF PRACTICE

Some regulations specify the scope of practice – that is, they limit the legal right to perform certain tasks or procedures to certain practitioners. For example, in India it is illegal for practitioners of traditional/complementary medicine to prescribe allopathic medicine. In Norway, treatment of communicable diseases that are hazardous to public health and serious diseases and disorders is allowed to be provided only if its purpose is to alleviate or moderate symptoms, the treatment has been authorised by a doctor, and if no other treatment is available; any other disease or disorder may be treated by anyone. In Alberta, Canada, only a patient who has first consulted a conventional medical doctor may be treated by an acupuncturist; acupuncturists must refer a patient to a conventional medical doctor if there are no improvements within six months.

In other countries the legislation does not give legal rights over practice but limits the use of certain titles, for example, that of acupuncturist. In Germany, only doctors who have taken formal qualifications may use the title of acupuncture doctor or homeopathic doctor; however, there are no limits on practice.

Some do limit scope of practice and confer protection of title on practitioners of traditional/complementary medicine. In Ontario, Canada, chiropractors have the right to use the title of doctor and have a protected scope of practice.

Discussion

From the above analysis of the case studies, which accompany this report (see www.kingsfund.org.uk/regulatingcompmed), it is possible to identify a range of regulatory options in the three areas of regulation identified above: education and training, licensing and registration, and practice (see below). The overview identifies the different options available to policy-makers when designing regulations and discusses briefly some of the possible advantages and disadvantages of the different approaches.

TABLE 1: AN OVERVIEW OF THE REGULATORY OPTIONS FOR REGULATING PRACTITIONERS OF TRADITIONAL/COMPLEMENTARY MEDICINE

Area of regulation	Regulatory options
Education and training	Type of qualification: university education, specific training for practitioners of traditional/complementary medicine and for conventional health care practitioners Educational setting: schools, colleges or universities Specify standards in terms of length of training vs content of core curriculum Shared biomedical curriculum vs alternative curriculum Private/professional associations accredit courses vs independent accreditation (by registering body or government) Training component of conventional medical training aimed at familiarisation vs integration
Licensing and registration	Individual registration vs associations of practitioners register (and all members automatically registered) Automatic registration with accredited qualification vs licensing exam vs both Recognition of prior non-accredited training or experience vs licensing exam Lifetime membership vs re-licensing (associated with continuing medical education) Joint or dual licensing of practitioners of traditional/complementary medicine and conventional medical practitioners practicing traditional/complementary medicine vs no additional licensing requirements for conventional medical practitioners
Practice	Generic laws that also cover the practice of traditional/complementary medicine vs specific traditional/complementary medicine legislation Decriminalisation of practice vs professionalisation of practice Mono-therapeutic (that is, individual traditional/complementary medicine practitioner regulators) vs multi-therapeutic (that is, umbrella regulator for all such practitioners) vs integrated (that is, single regulator for traditional/complementary and conventional medicine practitioners) National vs regional/local standards of practice Setting specific standards (for example, hospital vs primary care; public hospital vs private practice) Delegate standard setting to professionals vs specify in legislation Statement of minimum standards vs statement of limits of practice Protection of title vs protection of practice

Understanding approaches to regulation of TM/CM practice

In most countries there is usually some existing legislation that applies to the practice of traditional/complementary medicine. It may be important to consider first whether these laws could simply be strengthened or amended to ensure higher standards of consumer protection for those people who chose to consult a practitioner of traditional/complementary medicine. The principles of high-quality regulation, which are increasingly being applied to health care as well as to other sectors of the economy (Dixon 2006), require governments to reduce the regulatory burden and ensure that the costs and benefits of any new regulation are carefully evaluated. It is likely that requirements such as displaying prices, having liability insurance, and restricting the health claims that practitioners can make are likely to be lower cost and less burdensome than establishing more complex registration and licensing bodies.

Laws that were established in the eighteenth and nineteenth centuries to regulate the practice of medicine resulted in the criminalisation of traditional/complementary medicine practice in a number of countries. Few prosecutions were made under these laws in more recent years and as public demand for these therapies has grown a number of countries have decriminalised the practice of traditional/complementary medicine. However, decriminalisation means the situation in these countries is now similar to the that which existed in (Anglo-Saxon) countries with common law traditions – that is, anyone can set up practice as a practitioner of traditional/complementary medicine with no training or qualifications. Concern to ensure patient safety and prevent patients from receiving care from unqualified (or poorly qualified) practitioners means positive legislation is needed.

There is considerable fragmentation within and between some traditional/complementary therapies. For example, there are often multiple associations representing a therapy, each with their own knowledge base and approach to practice. Encouraging greater co-operation and consensus among practitioners of traditional/complementary medicine has been a priority for policy-makers in a number of countries prior to the introduction of statutory legislation. Furthermore, where the number of practitioners is small the costs of establishing a professional regulatory body with responsibilities for setting standards of education and practice, accrediting courses and performing disciplinary procedures are likely to be high. This may be one justification for establishing an umbrella regulatory body covering most or all practitioners of traditional/complementary medicine as is envisaged in the UK (Foundation for Integrated Health 2008). Other reasons may be recognition that many such practitioners practise several therapies and therefore to have separate licensing and standards for each therapeutic area would be burdensome. Where integration of practice between practitioners of traditional/complementary and of conventional medicine is an objective, then integrated regulation may provide a means of supporting such practice. More research is needed to understand whether integrated practice can also be achieved even where regulation is not integrated.

The advantages of establishing national standards of practice are that they promote free movement of professionals and provide consistency for consumers in different geographical areas. Where certain practitioners of traditional/complementary medicine are regulated only in some parts of the country, it may create geographical inequities in access because

referring practitioners will be limited in what therapies are available to their patients. The extent to which standards apply to all health care settings may vary and may be highly dependent on the context. For example, where traditional medicine is being practised mainly in hospitals (as in Vietnam, China, the Republic of Korea and India), it may be easier to apply standards than it would be where traditional/complementary medicine is practised in rural clinics (as in South Africa). There may also be grounds to differentiate between standards of practice for those operating in the public health system and those in private practice. For example, regulations for the private sector may focus on standards of facilities. These would not necessarily be appropriate for care delivered via public sector facilities.

In many countries the standards of practice and ethical codes are set down by the practitioners of traditional/complementary medicine themselves. Where there is no regulatory body, the self-governing body may be responsible for setting standards. The problem may be that voluntary self-regulating bodies set the standards too low in order to increase membership.

If regulations are too prescriptive they can quickly become out of date. It is often a long and time-consuming process to revise primary legislation, therefore it may be preferable for the primary legislation to set the framework and to leave the detail of the rules and standards of practice to secondary legislative arrangements such as administrative rules or statutory instruments that can be more flexible and responsive to changes in technologies and practice. Alternatively, the rules and standards can be delegated to an independent regulatory body, which may then have to seek ministerial or parliamentary approval for proposed changes. This would prevent professional interests diluting the standards of practice that would be expected by the public.

Protection of title means that the public can be confident that anyone who advertises or presents themselves as an ‘acupuncturist’ or ‘chiropractor’, for example, is qualified and registered. However, it does not prevent an unqualified person or indeed a conventional health care practitioner without training to carry out procedures such as ‘needling’ or spinal manipulation or dispensing of herbal remedies. Unless the public is made aware of the existence of a register and there are prosecutions of those who falsely use the protected title, it is unlikely to offer full protection to patients from unqualified practice. However, the alternative – that is, protection of practice – is very difficult to define in legislation in a way that is enforceable. If the practices that are restricted are legitimately practised by other health care practitioners, then limiting these practices will require specification of the scope of practice of every health care practitioner. Such legislation may inadvertently prevent lay people from things such as preparing a herbal tea for a family member if this might be construed as ‘dispensing a herbal remedy’. It is usually only in very limited areas where there are specific risks associated with the practice (such as the use of needles) that protection of practice is used.

Understanding approaches to training and education

The type of qualification and education setting for the training of practitioners of traditional/complementary medicine is likely to be determined by the status of the therapy within each country and the entry requirements and training standards that are established.

The advantages of integrating traditional/complementary medicine practice into the mainstream educational system are that the courses benefit from being subject to general standards of education that apply to all courses and educational establishments and are likely to attract a more diverse range of applicants. Where there are public subsidies for further and higher education, these are usually available only to students at accredited colleges and universities. Integration of teaching staff exposes trainers of practitioners of traditional/complementary medicine to wider educational training and curriculum development. Private colleges and universities with no public subsidy will mean that such training is available only to those who can afford the fees. Private colleges may be tempted to reduce entry qualifications in order to protect income.

Standards that specify only the length of training are limited in the ability to ensure the quality of the training and that qualified practitioners have the necessary knowledge, skills and competences for safe and high-quality practice. It is more usual, therefore, to specify a core curriculum or educational standards to which a course leading to a qualification in traditional/complementary medicine must adhere. Therapies that include a shared biomedical curriculum with conventional health care practitioners' training are likely to have greater legitimacy and to acquire the confidence of health care practitioners. If patients can be referred between conventional and practitioners of traditional/complementary medicine, then there are advantages in a common curriculum, in promoting communication and record keeping. Common training may also promote integration of practice.

Accreditation systems that are independent are likely to have greater external validity. There are conflicts of interest inherent in professional associations accrediting courses. Independent accreditation bodies may still be professionally led or at least have significant professional expertise available to them in order to judge the content of the courses. In order to ensure independence they may include lay or public members or be subject to approval by government authorities. General curricular authorities or education regulators may be better placed to judge the pedagogic quality of the training.

Given that many patients consult practitioners of traditional/complementary medicine as well as consulting conventional medical practitioners, a familiarisation course as part of undergraduate training as a conventional health care practitioner is likely to contribute to better patient care and clinical–patient communication. However, if referrals to or from practitioners of traditional/complementary medicine take place within the health care system, then more advanced courses in particular therapies may be appropriate.

Finally, if integrated practice is desirable then the integration of practitioner-level training for practitioners of both conventional medicine and traditional/complementary medicine might be considered. Specialisation courses at postgraduate level also allow conventional medical practitioners wishing to practice traditional/complementary medicine to train to practitioner level. Common standards of training for medical and non-medical practitioners, though desirable to ensure consistency for patients, can be difficult to establish in practice.

There appears to be a growing consensus that minimum levels of anatomical, pharmacological and biological knowledge are required in order to be a competent traditional/complementary medicine practitioner. This suggests that basic training should have a biomedical base on

which specialised traditional/complementary medicine competence can be built. In practice, especially in those countries where apprentice-trained practitioners are in the majority, most practitioners of traditional/complementary medicine do not have this biomedical training. The educational content of apprenticeships is difficult to standardise due to the very nature of apprenticeships; consequently in many countries they are losing ground to institutionally based training.

Despite formalisation of training and education in many countries, the majority of practitioners worldwide are still made up of apprentice-trained practitioners. It is not clear from this review whether countries are developing any strategies to improve the standards of training and education of these practitioners, such as on-the-job training in the basics of hygiene and anatomy.

Understanding approaches to licensing and registering practitioners

The approach adopted in Norway of accrediting associations of practitioners of traditional/complementary medicine appears to be unique among the countries examined in this report, though a similar approach is being adopted in Denmark and Ireland. Further analysis of this approach would be useful to see whether this reduces the regulatory burden and costs associated with statutory regulation but still ensures sufficient safeguards for patients. The standards set by the regulator concern the procedures that practitioner associations must have in place rather than the standards that individuals seeking registration must attain. The model delegates more of the responsibilities for regulation to the practitioner associations themselves.

Where individual licensing systems are in place, automatic registration of individuals is likely to ensure the quality of traditional/complementary medicine practice only if there are robust and independent accreditation mechanisms in place. Where this is not the case or there are a large number of existing practitioners who would wish to apply for entry on a new register, licensing exams provide a consistent method of entry. During the transitional period after setting up a new register it may be appropriate to offer both methods of entry.

There is a wider debate in health care regulation in general about the need to ensure that registrants remain up to date and fit to practice. Traditionally, once registrants had satisfied the entry criteria there were no further checks unless a complaint was received and the individual was found to be unfit to practise or had committed an act of professional misconduct. Procedures for and the frequency of re-licensing vary and there is as yet no consensus on the appropriate balance between monitoring and compliance burdens on practitioners and requirements for ensuring patient and public safety. Continuing medical education requirements are now common for traditional/complementary medical practitioners but whether these or other measures should form the basis of re-licensing will vary depending on other procedures for audit.

Where there is protection of title for practitioners of traditional/complementary medicine, conventional medical practitioners who wish to practise traditional/complementary medicine may wish to obtain the right to use the title as well. This can result in some practitioners being dual registered and unless procedures are defined there may be confusion over which

regulator has the primary authority to investigate or take action if there is a complaint. There may also be grounds for dual registration if it is deemed that conventional medical practitioners wishing to practise traditional or complementary medicine should attain standards of training or qualification equivalent to those of practitioners of traditional/complementary medicine. However, for some practitioners these requirements might deter them from integrated practice. If the regulators of conventional health care practitioners are capable of regulating their practice of traditional and complementary therapies (through taking expert counsel, for example), then dual registration may not be deemed necessary.

Large numbers of apprenticeship-trained practitioners pose a challenge to licensing and registration systems. Other than requiring formal or institutionalised training, some countries have put in place ‘grandfathering’ schemes to accredit prior experience. In high-income countries, marketing and advertising by practitioners of traditional/complementary medicine is monitored and prosecutions brought to the courts against continued practice by unregistered practitioners. In low-income countries, despite their practice being illegal, many unregistered practitioners continue to practise unchallenged. In such situations, where there are many apprenticeship-trained practitioners it may be appropriate to provide support and retraining for these practitioners rather than implement a system of registration from which many of them will be excluded. Lack of resources combined with rurality (for example, the majority of the population and practitioners live in rural areas) make the effective implementation of licensing and registration schemes difficult. However, in rural areas where word-of-mouth may play a greater role, there may be less need for a formal registration process to distinguish the qualified from the unqualified.

In some countries and for some traditional/complementary therapies the risks posed by unlicensed practice are not deemed sufficient to justify statutory regulation. In these cases voluntary regulation is preferred. In other countries statutory regulation is introduced only if organisations of practitioners of traditional/complementary medicine can demonstrate that they have put in place the necessary structures and procedures. The problem with voluntary systems of professional regulation is that there are few sanctions available to those practitioners who fail to comply with the standards; they can be removed from the register but as there is no legal sanction they may continue to practise. Alternatively, they may simply register with another professional association to whom they are not previously known. Such problems concern policy-makers in Australia, where there are estimated to be more than a hundred organisations representing practitioners of traditional/complementary medicine. Despite discussions to establish a single Australian Council of Complementary Medicine, this has not so far been implemented.

Many of these options are poorly evaluated and there has been little research into the relative merits of different approaches particularly against specified objectives. Health system objectives as well as the objectives for regulation of practitioners of traditional/complementary medicine differ widely between countries. These issues need further attention from researchers and policy-makers.

Issues raised for national and international policy-makers

The increasing global demand for traditional/complementary medicine together with

migration of health care workers is likely to mean that differences in the regulation of practitioners of traditional/complementary medicine between countries will come under increasing scrutiny. Within the European Union, despite statutory recognition in the United Kingdom, osteopaths are not free to practice in all other European Union member states. The ability of regulators to recognise overseas qualifications of practitioners of traditional/complementary medicine will need to be addressed. There is a role for international policy-makers to ensure that mutual recognition of qualifications and free movement of labour does not undermine national efforts to promote the quality of traditional/complementary medicine practice nationally.

At national level, policy-makers may need to review the design of regulation against not only objectives of public protection and patient safety but also in light of principles of high-quality regulation and health promotion. It may be necessary to review the appropriateness of models of professional regulation that have been developed for larger established health care practitioner groups. If there is neither the technical capacity nor the financial resources to establish further regulatory bodies, it may be necessary to rationalise regulatory functions or consider other regulatory mechanisms for meeting the desired objectives.

From our reading of these case studies, there is an emerging relationship between regulatory approaches in traditional/complementary medicine and wider health system objectives. It appears that in countries where health status is high among the general population and there is good access to western scientific medicine, the focus of government attention is on protecting patients against harm and ensuring high-quality health care provision. The concern is that if traditional/complementary medicine is delivered by practitioners who are not registered or licensed it is not possible for the patient to be assured of the quality of training or level of competence of the practitioner. If safety is to be promoted and the public protected, regulation of the providers of traditional/complementary medicine and their education, training and practice is needed. The default position is one of exclusion unless proven safe.

In contrast, in resource-poor countries where life expectancy is short and preventable diseases prevalent, the focus of government attention is on health improvement and prevention. The provision of western scientific medicine to the entire population is often beyond the human and financial resources available – thus practitioners of traditional/complementary medicine are the main source of health care provision, particularly in rural areas. The concern is that all human resources and natural resources should be harnessed for the improvement of health in the population. If health is to be promoted and the public given access to medical services, regulation of the practice of providers of traditional/complementary medicine is needed to enhance its contribution and impact. The default position is one of inclusion unless proven harmful.

Given the different objectives for the health care system in general it may be appropriate for these countries to develop different regulatory models.

Further research questions

Research examining in more detail the costs and benefits of different regulatory models is

needed to inform how future regulation is designed and implemented. Research into the application of other regulatory tools, and in particular consumer protection laws and trading standards, to traditional/complementary medicine would open up the potential for alternative approaches to the model of statutory professional regulation currently being pursued in most countries.

In the context of this study it was not possible to examine how the socio-political context in particular countries has influenced the development of regulation. Most regulation is generated by primary legislation and will therefore reflect the political concerns prevalent at the time. In countries where nationalism has been reasserted there appears to be a strong interest in promoting indigenous or traditional medicine. Migration patterns have also influenced the extent to which traditional medicine from one culture has been 'exported' to another. Analysis of how traditional medicine spreads beyond the migrant community and becomes more widely embedded would also be another interesting topic for analysis.

There are some countries in which integrated practice is more widespread. Regulation in these countries is also often more integrated. Research to understand whether the design of regulation influences integration of practice or whether this reflects the cultural acceptability of traditional/complementary medicine would be useful.

Conclusions

Within this brief review it is clear that policy-makers in several countries have taken steps to introduce legislation to improve the regulation of practitioners of traditional/complementary medicine. Much of the experience to date has been with establishing systems of statutory professional regulation. However, the approaches vary considerably between countries. This report has identified a number of regulatory options for policy-makers who are designing regulation of practitioners of traditional/complementary medicine. There is insufficient evidence available at this stage to be able to evaluate these options. This needs to be done in the context of specific regulatory objectives and wider health system goals.

References

- Baldwin R, Cave M (1999). *Understanding Regulation: Theory, strategy, and practice*. Oxford: Oxford University Press.
- Bensoussan A, Myers SP (1996). *Towards a Safer Choice: The practice of traditional Chinese medicine in Australia*. Victoria, Australia: Department of Human Services. Available at: www.health.vic.gov.au/archive/archive2006/chinese/report/contents.html (accessed on 30 August 2007).
- Bodeker GC (2000). *Planning for Cost-effective Traditional Health Services – Discussion paper*. Kobe: World Health Organization Centre for Health Development.
- Bodeker GC, Ong C, Grundy C, Burford G, Shein K (2005). *WHO Global Atlas of Traditional, Complementary and Alternative Medicine*. Text volume. Kobe: WHO Centre for Health Development.
- Burton B (2003). ‘Complementary medicines industry in crisis after recall of 1546 products’. *British Medical Journal*, vol 326, p 1001.
- Dixon A (2006). *A High-quality Regulation Perspective for Health Care Delivery*. Presentation to OECD Group on Regulatory Policy, Paris, 8 December 2006.
- Dixon A, Riesberg A, Weinbrenner S, Saka O, Le Grand J, Busse R (2003). *Complementary and Alternative Medicine in the UK and Germany – Research and evidence on supply and demand*. London: Anglo-German Foundation for the Study of Industrial Society. Available at: www.agf.org.uk/pubs/pdfs/1413web.pdf (accessed on 16 August 2007).
- Erdsal G, Ramstad S (on behalf of CAM–CANCER Consortium) (2005). *How are European Patients Safeguarded when Using Complementary and Alternative Medicine (CAM)? Jurisdiction, supervision and reimbursement status in the EEA area (EU and EFTA) and Switzerland* [online]. Available at: www.cam-cancer.org/mod_product/uploads/camcancer_legal_report_%28FINAL%29.pdf (accessed on 30 August 2007).
- Ernst E, Dixon A (2004). ‘Alternative medicines’ in Mossialos E, Mrazek M, Walley T (eds) *Regulating Pharmaceuticals in Europe: Striving for efficiency, equity and quality*, pp 307–22. Maidenhead: Open University Press.
- Foundation for Integrated Health (2008). ‘Integrated health: the best of all healthcare for the whole person’. Prince’s Foundation for Integrated Health website. Available at: www.fih.org.uk (accessed on 30 August 2007).
- Fulder S (1996). *The Handbook of Alternative and Complementary Medicine*. Oxford: Oxford University Press.
- Furnham A, Smith C (1988). ‘Choosing alternative medicine: a comparison of the beliefs of patients visiting a general practitioner and a homoeopath’. *Social Science and Medicine*, vol 26, no 7, pp 685–9.
- Hien TV, Truong CQ (2005). ‘Socialist Republic of Viet Nam’ in Bodeker GC, Ong C, Grundy C, Burford G, Shein K (eds) *WHO global atlas of traditional, complementary and alternative medicine* (text volume) pp 205–10. Kobe: WHO Centre for Health Development.

- Jonas WB (2002). 'Policy, the public, and priorities in alternative medicine research'. *The Annals of the American Academy of Political and Social Science*, vol 583, pp 29–43.
- Jütte R (1996). *Geschichte der Alternativen Medizin: von der Volksmedizin zu den unkonventionellen Therapien von heute*. Munich: Beck.
- Kelner M, Wellman B, Pescosolido B, Saks M (eds) (2000). *Complementary and Alternative Medicine: Challenge and change*. Amsterdam: Harwood Academic Publishers.
- Lewith G, Aldridge D (eds) (1991). *Complementary Medicine and the European Community*. Saffron Walden: CW Daniel.
- Lindemann M (1999). *Medicine and Society in Early Modern Europe*. Cambridge: Cambridge University Press.
- Loff B, McKelvie H (2003). 'Australia shaken by complementary medicines recall'. *Lancet*, vol 361, no 9370, p 1710.
- Monckton J (ed) (1998). *The Final Report of the European Commission Sponsored COST Project on Unconventional Medicine* [online]. Available at: www.rccm.org.uk/static/Report_COST.aspx (accessed on 30 August 2007).
- Ong C, Bodeker GC, Grundy C, Burford G, Shein K (2005). *WHO Global Atlas of Traditional, Complementary and Alternative Medicine*. Map volume. Kobe: WHO Centre for Health Development.
- O'Sullivan T (2002). *Report on the Regulation of Practitioners of Complementary and Alternative Medicine in Ireland*. Dublin: Health Services Development Unit, Institute of Public Administration.
- Porter R (1989). *Health for Sale: Quackery in England, 1660–1850*. Manchester: Manchester University Press.
- World Health Assembly (2003). *Traditional Medicine*. Geneva: World Health Organization.
- World Health Organization (2005a). *National Policy on Traditional Medicine and Regulation of Herbal Medicines: Report of a WHO global survey*. Geneva: World Health Organization.
- World Health Organization (2005b). *WHO Global Atlas of Traditional, Complementary and Alternative Medicine*. Kobe: WHO Centre for Health Development.
- World Health Organization (2004b). *WHO Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine*. Geneva: World Health Organization.
- World Health Organization (2002). *Traditional Medicine Strategy 2002–2005*. Geneva: World Health Organization.
- World Health Organization (2001). *Legal Status of Traditional Medicine and Alternative/Complementary Medicine: A worldwide review*. Geneva: World Health Organization.
- World Health Organization (2000). *General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine*. Geneva: World Health Organization. WHO/EDM/TRM/2000.1. Available at: www.who.int/medicines/areas/traditional/definitions/en/index.html (accessed on 30 August 2007).

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