

UK: the current state of regulation of complementary and alternative medicine

L. A. Walker,¹ S. Budd²

¹Department of Primary Health Care and General Practice, Imperial College School of Medicine, London, UK ²Complementary Health Studies, University of Exeter, Exeter, UK

SUMMARY. There is no legislation that restricts the practice of CAM in the UK apart from the practice of chiropractic and osteopathy and limits on advertising the treatments of certain conditions such as cancer and tuberculosis. The UK government has increasingly recognised the need for comprehensive regulation of CAM, though it abandoned its original plan for a single overarching regulatory body. Initiatives to examine and hasten the process of regulation have included setting up a central, well-recognised charitable body to facilitate progress for individual professions, and an authoritative survey of the existing professional organisations. One pathway open to individual professions is statutory self-regulation, which requires a single governing body, a systematic corpus of knowledge, recognised training courses and demonstrated efficacy. The other pathway is voluntary self-regulation. Chiropractic and osteopathy have adopted statutory self-regulation, though this has proved expensive for individual members of these professions. A recent House of Lords report on CAM has recommended that the herbal medicine and acupuncture professions should also develop a system of statutory regulation. Other professions, such as aromatherapy, are in the process of establishing single professional bodies as a first step towards self-regulation. Among the issues that remain to be resolved is the relationship between the CAM professions and statutory registered practitioners who also practise CAM. © 2002 Elsevier Science Ltd. All rights reserved.

INTRODUCTION

The number of people using complementary and alternative medicine (CAM) in the UK continues to grow. A study of 5010 adults in 1998, found that 14.2% of respondents had used a CAM therapist and 28.4% had used over-the-counter remedies in the last 12 months.¹ While a BBC survey conducted in 1999, found that in the last year, one in five of those polled had consulted a complementary therapist.^{2,3} Unfortunately, a high proportion of CAM practitioners in the UK are unregulated and with increased demand it is essential that there are mechanisms to protect the public against unskilled practitioners.⁴

With the exception of osteopaths and chiropractors, practitioners of CAM in the UK are able to practice even if they have had no training, are not affiliated to a registering body, or have no

indemnity insurance, under common law. Practitioners are restricted mainly by the relevant provisions of the *Medical (1983), Professions Supplementary to Medicine (1960), and Medicines (1968) Acts*. Under the *Cancer Act 1939*, practitioners must not make claims or advertise the treatment of certain diseases, including cancer, tuberculosis, glaucoma, diabetes, venereal disease and epilepsy.⁵

At present, a General Practitioner (GP) can only delegate treatment to complementary therapists, and in doing so, the GP remains responsible for the treatment given and would be liable should the patient come to any harm. Until effective regulation is in place and GPs are able to refer patients rather than delegate, it is unlikely that patients will receive CAM therapy from a therapist via their GPs. Two therapies which have achieved statutory self regulation are osteopathy and chiropractic.

Lesley Walker
Department of Primary Health Care and General Practice, Imperial College School of Medicine, The Reynolds Building, St Dunstan's Road, London W6 8RP
E-mail: l.walker@ic.ac.uk

THE NEED FOR REGULATION

The areas covered by CAM in the UK are extremely diverse, ranging from the use of manipulative techniques such as in osteopathy and chiropractic to the prescribing of remedies by homeopaths and herbalists to the various forms of self-help such as relaxation techniques. Given such diversity it is important that each therapy determines its own aspirations, practice and regulating structures in the public interest.

In any healthcare profession, the quality of care, treatment and patient safety must be given the highest priority. In addition, the successful integration of complementary and alternative medicine into orthodox practice requires one register and code of professional conduct across each individual therapy. The key components are effective and high quality systems of regulation, high standards of training and continuous professional development (CPD). Unfortunately at present some therapists are not trained adequately in healthcare, some have taken short courses, whilst others are trained only as beauty therapists.

HISTORICAL BACKGROUND

Attempts have been made to obtain statutory recognition for CAM professions since the early 20th Century, notably by herbalists, osteopaths and chiropractors. Although unsuccessful at the time, those professions did go on to develop systems of voluntary regulation, which have been maintained throughout the century. However, since the 1970s there has been a rapid growth in CAM in the UK, which has stimulated an increase in registering bodies. Originally most of these were not aimed at regulating the profession, but were member groups formed for mutual support and were predominantly self-appointed and uncharted. In a Report to the Department of Health,⁶ 322 organisations were identified and contacted; of the 143 eligible organisations that responded, only 25 had been established before 1970, two of which represented medically qualified doctors.

By the early 1980s, with the rapid proliferation of CAM in the UK, both major political parties entered the debate on the need for more effective self-regulation and how to ensure public safety. Lord Skelmersdale (under Secretary of State for Health) in 1987 and Baroness Hooper (junior Health Minister) in 1990, both reiterated the fact that the government would not wish to restrict an individual's right to complementary medicine.^{7,8} Baroness Hooper said:

The Government have no wish to place any restrictions on natural therapy practitioners or to curtail in any way the freedom of the individual to seek the benefits of the natural therapy. We do, however, believe that, members of the public

using those therapies have a right to be safeguarded in the same way as those using the NHS professions.⁸

The political view in the early 1980s was that there might be advantages for an over-arching body to regulate all CAM therapies. This led to various multidisciplinary umbrella organisations. However, by 1987 the Government's attitude on umbrella organisations was beginning to alter. Lord Skelmersdale commented that these umbrella organisations were in fact an addition to the numerous individual therapy organisations and were actually causing more confusion for the public.⁷ This was further expressed by Baroness Hooper who stated that the Government had come to acknowledge the diversity of practice across the CAM sector and firmly believed that each individual therapy should establish its own requirements for the future.⁸

Following osteopathy and chiropractic, other professions made attempts to come together, but due to the constant proliferation of new training schools and registering bodies these were unsuccessful. Schools of beauty therapy began offering courses in massage, aromatherapy and reflexology in order to profit from this rapid growth in CAM. These therapists were not trained for the healthcare sector but the beauty industry. Unfortunately, this has added to the confusion that had already been identified by the Government.

Two major developments occurred during the 1990s. Firstly, the Foundation for Integrated Medicine (FIM) was formed as a charity to work with healthcare institutions and professionals in order to pursue the vision of The Prince of Wales of an integrated healthcare system in the 21st Century. The charity was autonomous and well placed as a link between the various government, CAM and orthodox bodies. FIM set up four working groups to look at the position of delivery mechanisms, education, research and development, and regulation of orthodox, complementary and alternative medicine. It also published a Discussion Document on the integration of healthcare that included recommendations on the regulation of the CAM professions.⁹

Secondly, in an attempt to overcome the continued lack of substantial information about the majority of the CAM professional organisations, a national survey of all these bodies was conducted. The Department of Health (DoH) commissioned the Centre for Complementary Health Studies (CCHS) at the University of Exeter for the purpose.

The Exeter report⁶ produced the first comprehensive address list of CAM organisations in the UK. It marked the shift from the initial instinct that complementary medicine should develop as a whole within appropriate umbrella bodies towards one in which the different professions developed at their own pace. It concluded that although there were weaknesses in co-ordination between

organisations representing the same therapy, and that complaints procedures, formal disciplinary codes and sanctions were often not adequately in place, the CAM professions had generally made progress in self-regulation.

THE SITUATION AT PRESENT

Many organisations are unclear on how to achieve the level of regulation that the Government has indicated is needed to safeguard the public. This problem has been recognised by the Government and Health Minister Baroness Hayman stated that the DoH was working with FIM and CCHS to develop guidelines on regulation.¹⁰

In 1999 FIM organised a major conference in order to widen the debate on regulation of CAM, taking into account the findings of the Exeter report⁶ and the recommendations of the FIM Discussion Document.⁹ To coincide with the conference the DoH commissioned CCHS to conduct a second survey of organisations to assess what developments had occurred, to produce a 'Regulatory Information Pack',¹¹ and to conduct a pilot study to explore the processes involved in improving co-ordination within a therapy.

The FIM conference 'Professional Competence–Public Confidence' brought together for the first time more than 150 different professional and regulatory bodies representing the 40,000 complementary practitioners in the United Kingdom. At the conference His Royal Highness, The Prince of Wales, President of FIM called for more effective regulation to boost public confidence in alternative therapies.

The Prince of Wales said:

People do need to feel confident that the treatment they receive from any complementary practitioner will be safe. Like conventional medicine, complementary medicine is only safe if practiced by a skilled qualified practitioner, and can be harmful in unskilled hands.

Also at the conference, Tessa Jowell, the Minister for Public Health spoke of the powers contained in the imminent *Health Act*. She emphasised the amount of preparation that would be required in obtaining statutory regulation, but recognised that not every CAM profession would aspire to the statutory route.

Statutory regulation has potential advantages over voluntary self-regulation as it makes provision for the protection of title. A single definitive register of practitioners and disciplinary procedures and sanctions means that a practitioner whose name is struck off the statutory professional register is prevented from practicing under that professional title. With the new *Health Act 1999*¹² the Government has provided CAM professionals with the opportunity to become regulated without the long and expensive legalisation which is required through an Act of Parliament, as was the

case with the osteopaths and the chiropractors. However, the majority of CAM professions will probably achieve the desired level of regulation by the voluntary route.

Feedback at the conference identified important roles for the Foundation, such as an information source across a range of issues, as a facilitator, particularly in the area of regulation and as a channel of influence with governmental bodies.¹³ FIM has since held meetings with a number of single therapy organisations interested in exploring how regulation would affect them. Many organisations saw regulation as a threat to their freedom to practice under common law. Established and well trained therapists, with a plentiful supply of patients, often recommended by past patients, sometimes saw no need for stricter regulation. However, with the government calling for more protection of the public, others saw the opportunity for the organisations to act themselves, rather than having regulation imposed upon them.

The key focus for FIM was to establish, facilitate and assist the development of emerging regulatory structures within CAM, in the following five stages:

1. To help those bodies who wish to move towards statutory self-regulation where the practice might put patients at risk of harm from inadequately trained practitioners, for example, acupuncture, aromatherapy, herbal medicine and homoeopathy. Such statutory systems should be based upon an established system of voluntary regulation within each profession.
2. To help other therapies to develop single registering bodies – Alexander technique, cranio-sacral therapy, healing, hypnotherapy, massage and bodywork therapies, naturopathy and nutrition, shiatsu, reflexology and yoga.
3. To help new and emerging therapies establish themselves into professional organisations.
4. To disseminate information to the public about different CAM bodies and act as a channel of communication to the different CAM bodies in relation to developing models of good practice.
5. To maintain an up-to-date database of all CAM organisations.

Further funds were vital to support this process and FIM was awarded a millennium grant of £1 million over 5 years from the King's Fund and has begun to award grants to organisations who apply for help in forming single registering bodies or are attempting to follow the statutory route.

In parallel with the activities of the Foundation, the CCHS completed its project on behalf of the DoH with the publication of the Exeter report 2000.¹⁴ It included 35 new organisations, intentions for regulation and disciplinary sanctions imposed between 1997 and 1999. It

identified an increase in communication between some organisations, with more willingness to work together.

The 'Regulatory Information Pack'¹¹ aimed to provide CAM with a guide to the regulatory processes within the healthcare community and covers the following issues: the importance, benefits and types of regulation; and criteria for regulation as stated in government guidelines and in the FIM recommendations. There is a 'flow chart' and check list of the steps through regulation. Supporting information includes relevant aspects of the *Health Act 1999*, types of professional organisation, and models of regulation with examples from both the CAM and orthodox medical communities. The consumers' view, related initiatives and examples of relevant legislation are also covered.

The pilot study undertook to explore the processes involved in improving co-ordination within a therapy. Reflexology was chosen as the most appropriate model; it had a history of initiatives towards a lead body that had not yet been successful, it had a mix of complementary and statutory-registered practitioners and the practice of reflexology was generally consistent across the different groups. Progress to date has been most encouraging, with participants agreeing formally to set up a new association, the Reflexology Forum, with an agreed constitution which includes a set of standards for self-regulation. A full account is documented in the Exeter report 2000.¹⁴

HOUSE OF LORDS SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY SIXTH REPORT: 'COMPLEMENTARY AND ALTERNATIVE MEDICINE'

At the end of 1999 the House of Lords commenced an enquiry, through a Select Subcommittee, on CAM, and published their report in November 2000. Apart from regulation, the report also makes recommendations on: professional training and education; research and development; methods of delivery; patient satisfaction, the role of the therapist and the placebo response; as well as the dissemination of information. The report also categorised each of the CAM therapies into one of three distinct groups (Table 1).¹⁵

The chapter on regulation quoted from the 'Regulatory Information Pack'¹¹ that the purpose of regulation in healthcare is:

To establish a nationwide, professionally determined, and independent standard of training, conduct and competence for each profession for the protection of the public and the guidance of employers. To underpin the personal accountability of practitioners for maintaining safe and effective practice and to include effective measures to deal with individuals whose

Table 1 Categories of complementary and alternative therapies^{4,15}

Group 1: Professionally organised alternative therapies

Acupuncture
Chiropractic
Herbal medicine
Homoeopathy
Osteopathy

Group 2: Complementary therapies

Alexander technique
Aromatherapy
Bach and other flower extracts
Body work therapies, including massage
Counselling stress therapy
Hypnotherapy
Meditation reflexology
Shiatsu
Healing
Maharishi Ayurvedic medicine
Nutritional medicine
Yoga

Group 3: Alternative disciplines

3a: long established and traditional systems of healthcare

Anthroposophical medicine
Ayurvedic medicine
Chinese herbal medicine
Eastern medicine (Tibb)
Naturopathy
Traditional Chinese medicine

3b Other alternative disciplines

Crystal therapy
Dowsing
Iridology
Kinesiology
Radionics

continuing practice presents an unacceptable risk to the public or otherwise renders them unfit to be a registered member of the profession.

The recommendations on regulation includes the following :

The interests of the public in their use of CAM will be best served by improved regulatory structures for many of the professions concerned. Although there is evidence of progress across many fronts, the Committee found considerable diversity of standards, with an unacceptable fragmentation in some therapies, especially in Groups 2 and 3. In the best interests of their patients such therapies must each strive to unite under a single voluntary regulatory body with the features we highlight.

In a few cases regulation by statute may be appropriate. Our main criteria for preferring such a route are first, the possible risk to the public from poor practice; second, a pre-existing robust voluntary regulatory system; and third, the presence of a credible evidence base. We consider that acupuncture and herbal medicine comply with these criteria and we support their moves towards statutory regulation. In time, such regulation may become appropriate for homeopathy.

There are currently no clear guidelines relating to the regulation and training in CAM practice amongst statutory regulated health professionals (such as doctors and nurses) who wish to incorporate a CAM therapy into their personal clinical repertoire. We recommend that the existing regulatory bodies in each of the healthcare professions (GMC and UKCC)

*should develop clear guidelines on competence and training in the CAM disciplines and on the position they take in relation to their members' activities in CAM.*¹⁵

THE REGULATION PROCESS FOR OSTEOPATHS AND CHIROPRACTORS

The osteopathic and chiropractic professions have for many years endeavored to be recognised as part of mainstream medicine. The osteopaths' drive for statutory regulation began back in 1925, and was pursued by the presentation of various Bills to parliament during the 1930s. In 1934 an Osteopaths Bill was referred to a House of Lords Select Committee. The Bill aimed at giving osteopaths similar rights to medical practitioners, such as administering anaesthetics, performing minor surgery and certifying death. The Minister of Health concluded that this was unacceptable and the Bill was rejected. In 1935 the General Council and Register of Osteopaths was formed to voluntarily regulate the osteopathic profession.¹⁶ The chiropractors' decision to pursue statutory regulation was prompted in 1925 by the Osteopaths Bill, and led to the formation of the British Chiropractic Association (BCA). Their efforts over the following decades were similarly unsuccessful.¹⁷

It was not until 1985 that a change in government policy finally enabled both the osteopaths and the chiropractors the opportunity to explore the possibility of obtaining statutory regulation. During a debate in the House of Lords, Lord Glenarthur, Junior Health Minister set out the criteria that a profession would need to meet in order to obtain proper recognition. He states that a profession needs to: (i) be mature; (ii) have an established and recognised single governing body; (iii) have a systematic body of knowledge; (iv) have recognised training courses; and (v) be able to demonstrate efficacy.

In 1987, Lord Skelmersdale, debating the question of state registration of the osteopaths, added a sixth requirement, that any action must be based primarily on principles that would ensure public safety.^{7,18}

A working party on osteopathy was set up by the Kings Fund in 1989 and included representatives from the osteopathic profession, orthodox medical profession and the public. It reported in 1991 and concluded that there was a case for legislation to regulate the profession of osteopathy and the need for protection of title.¹⁸ During this time the chiropractors were occupied in uniting two forms of chiropractic therapy represented by three organisations, in order to fulfill the Glenarthur Criteria. The Kings Fund set up a working party for chiropractic in 1991.¹⁷

In 1992, a Bill was presented to the House of Commons to establish the General Osteopathic Council (GOsC), to regulate the profession of osteopathy and a single register of members.¹⁹ The

Bill obtained Royal Assent on 1st July 1993.^{20,21} The Chiropractors followed with the Bill forming the General Chiropractic Council (GCC) being passed with Royal Assent on the 5th July 1994.^{22,23} A period of transition followed for both professions.

Securing an Act of Parliament was a costly process for both professions. The chiropractors achieved financial security by charging each member a levy of £500; the osteopaths charged £350 for each osteopath applying to join the statutory register with the GOsC. Once accepted each had to pay a further £1000 to cover the costs during the two year transitional period from 1998–2000. In May 2000 the *Osteopaths Act* came into force, making it a criminal offence for those who are not on the GOsC register to call themselves osteopaths. The *Chiropractors Act* came into force in June 2001, with the same effect for those failing to join the GCC statutory register.^{16,17}

THE REGULATION PROCESS FOR HERBALISTS

The use of herbal remedies predates that of orthodox medicine in the UK, but unlike orthodox medicine is not regulated by statutes, despite three attempts by the National Institute of Medical Herbalists in the last 100 years. In anticipation of directives from Europe that might restrict practice, the European Herbal Practitioners Association (EHPA) was formed in 1993.⁸ The Medicines Control Agency (MCA) and Department of Health have, since 1995, been working with the EHPA on legislation aimed at protecting public safety and the rights of herbalists to prescribe herbs.

Perhaps the strongest recommendation in the House of Lords report¹⁵ was for the regulation of herbal medicine (including the accurate and legal labeling of products). Based on the evidence submitted by the EHPA, the House of Lords concluded that the herbalists met the criteria and recommended they move towards statutory regulation.

THE REGULATION PROCESS FOR ACUPUNCTURISTS

The main regulatory body representing non-statutory acupuncturists in the UK is the British Acupuncture Council (BAcC) with 2200 members. It was formed in 1995 by the amalgamation of five registers and fulfills many recommendations for regulation. For educational standards, the British Acupuncture Accreditation Board (BAAB), is also well established. A Regulation Action Group was set up to carry out an extensive consultation exercise, which included regional group meetings, to discuss options for regulation.²⁴

The House of Lords report concluded that the acupuncturists met the criteria laid down

and recommended they move towards statutory regulation.¹⁵ However, they accepted there were issues to resolve between the non-statutory registered acupuncturists and doctors, physiotherapists and others who also used acupuncture.

In October 2001, at the AGM of the BAAC, 90% of those members who voted, were in favor of giving the Executive Committee a mandate to pursue a suitable route to statutory regulation.²⁵

THE REGULATION PROCESS FOR AROMATHERAPISTS

Aromatherapy was only introduced in the UK during the 1960s. It is however, one of the fastest growing complementary therapies, with the number of registered therapists having increased from 2500 to 6000 between 1991 and 2000.

The Aromatherapy Organisations Council (AOC) is an umbrella body represented by members from thirteen established professional associations and claims to be the governing body for the aromatherapy profession in the UK. It was established in 1991 following the Government saying CAM should 'get its act together' and that joining the EU in 1992 could see the end for traditional UK freedom to practice.^{8,26}

The AOC have welcomed and supported the findings of the select committee report even though it did not identify the need for statutory regulation for aromatherapy. However, the AOC are concerned for the potential harm from using essential oils incorrectly. To ensure public safety the AOC will continue with their process under the *Health Act 1999*, towards statutory self-regulation.

CONCLUSION

Regulation of CAM in the UK has reached a critical and volatile phase. Over the last few years more than 150 different bodies representing CAM practitioners have come together to discuss regulation. Various initiatives are underway to improve moves towards their self-regulation, whether voluntary or statutory, and these have increasingly focused on professions within individual therapies becoming more coordinated, rather than working through overarching umbrella forums. The CAM debate is now firmly on the political agenda with the publication of the House of Lords Report. Many issues remain to be resolved, notably the continuing fragmentation of the CAM professions and their relationship with statutory registered practitioners who also practice CAM.

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