MAPPING THE ALTERNATIVE

Regulation of complementary practitioners such as acupuncturists, herbalists, and therapists to weed out the charlatans and protect the public sounds uncontroversial. But, as **Michael Day** reports, proposals for regulation seem to have brought more questions than answers

For a long time complementary medicine was seen, by the public at least, as the gentle alternative to conventional treatment. It might not work, but at least it didn't carry the risks associated with synthetic drugs. That romantic notion was challenged more than a decade ago when nine women in previously good health developed end stage kidney disease months after receiving Chinese herbal treatment at a Belgium slimming clinic.¹

But toxic herbs are not the only concern. A swift trawl through Google seems to back suggestions by the UK Health Professions Council, the regulatory body for 13 health-care professions (box), that there are now over 100 000 counsellors and therapists practising in the United Kingdom. In February, the council's chief executive, Marc Seale, summed up the current situation: "At present you could come out of Wormwood Scrubs and set yourself up as a counsellor."

One obvious solution is to regulate these professions. And nobody has been clamouring more loudly for statutory registers than some of the complementary practitioners themselves. "There are a lot of people who don't have the necessary training and knowledge to protect the public, that's why we need statutory registration," says Amrit Ahluwalia, project director of the European Herbal Practitioners Association (box). "And we're not just talking about knowing how to avoid interactions with other drugs. It's about knowing when to refer patients to other professionals. If you're going to be a professional dealing with the public then you need to know the limits of your competence."

The House of Lords Science and Technology Committee put all these arguments in its report on complementary and alternative

medicine in November 2000. The committee called for emerging health professions to come under statutory regulation.² A series of working groups, consultation documents, and responses followed. But the shockwaves caused by Shipman have seen moves to regulate other health professions take a back seat, and it took until February this year for a white paper finally to emerge that looked to regulate acupuncture and Chinese and herbal medicines.³

The Health Professions Council seems likely to assume the responsibilities. It already regulates radiography, physiotherapy, occupational therapy, and biomedical scientists among others. It is preparing to take on the statutory registration of clinical psychologists within the next 12 months.

Further down the line, but ahead of herbal medicine and acupuncture, the statutory regulation of counsellors and therapists is now on the council's growing "to do" list. Mike Pittilo, the vice chancellor of Robert Gordon University in Aberdeen, is chairing the Department of Health working group looking at how acupuncturists, herbalists, and Chinese medicine practitioners will be regulated. He is in no doubt about the need for statutory regulation

Health Professions Council's current responsibilities

Arts therapists
Biomedical scientists
Chiropodists and podiatrists
Clinical scientists
Dietitians
Occupational therapists
Operating department practitioners
Orthoptists
Paramedics
Physiotherapists
Prosthetists and orthotists
Radiographers
Speech and language therapists

of these professions: "Given that around 42% of the British public access these treatments we should be regulating them and at the same time putting them under pressure to develop and show their evidence base," he says. "If you look at other therapies, such as arts therapy or even physiotherapy or traditional medicine, the evidence base is sometimes pretty thin."

"But the difference is that I see a lot of alternative practitioners being completely indifferent to the need to get better evidence-

European Herbal Practitioners Association

The association was set up in 1994 as an umbrella body for professional associations across Europe wanting to benefit from joint working and to strengthen the role of the herbal profession.

It represents practitioners from ayurveda, Chinese herbal medicine, Tibetan herbal medicine, traditional

Chinese medicine, and Western herbal medicine. It aims to promote the availability of professional herbal treatment and to raise standards of training and practice within the profession. It also campaigns for the legalisation of professional herbal practice throughout the European Union as a

specialty in its own right. A central aim is to encourage the creation of "appropriate European legislation that ensures the continuing right of professional herbal practitioners to access traditional herbal medicines." It notes that this is likely to require statutory self regulation.

How can you regulate acupuncture and herbal medicine if we're not sure if they're effective?

based practice. At least with arts therapy or medicine there's a sense that practitioners are trying to build the evidence."

Section 7.12 of the white paper says that practitioners would have to be assessed for competence before being admitted to a statutory register. But how will regulators assess competency in disciplines where the efficacy is not well established? Professor Pittilo says that the primary role of statutory regulation is one of protecting the public. "Statutory bodies are more about safety than efficacy. Under regulation they will have to understand the significance of how their treatments could interact with other things and of the potential harm they could cause."

Professor Pittilo notes, however: "There's not just the danger of adverse reactions to chemicals in herbs or the risks of infection from needles, there's also the danger that patients might fail to seek appropriate established treatments that could save their life. There are still some terribly false claims being made by practitioners of Chinese or herbal medicines. It's still going on with claims of cures and this kind of thing."

Regulating the unknown

A leading critic of alternative medicine takes a tougher line on the need for measuring efficacy, however. Edzard Ernst, who is professor of alternative medicine at Exeter University, says herbal medicine and acupuncture should not be regulated until there is clearer evidence that they work.

One of his concerns is that statutory registration might be erroneously paraded as evidence of efficacy. "The evidence for the efficacy of chiropractic, for example, is very slim indeed. And since it has been regulated, research for establishing that it works has diminished. People are saying: 'We are fully regulated so don't ask us questions about whether this works or not'; and that is very worrying.

"And how can you regulate acupuncture and herbal medicine if we're not sure if it's effective? In the absence of an evidence base it seems ridiculous."

He concedes there is evidence that acupuncture is effective for back pain and knee osteoarthritis. "However, for most uses the Cochrane Database shows that it is no

IMAGE SOURCE: EX

Chinese medicine practitioner

I visit the Green Healer, a traditional Chinese medicine centre in south London, and ask about treatment for acid indigestion. The practitioner inquires about my diet and sleeping habits in a 15 minute consultation, during which she studies my tongue and feels my pulse in both wrists.

She diagnoses a stomach Ying deficiency, made worse by eating too late at night. "In Western medicine you give out a prescription, and the person takes the drugs and that's it. In Chinese medicine we believe that it's important to make lifestyle changes too," she says.

She then makes up three bags each containing a mixture of around 15 herbs and tree bark taken from hundreds of boxes labelled in Chinese. I am told to boil them up and drink the solution three times a day. I'm assured the mixture is quite safe, if unpleasant to drink. I ask her if she thinks it's a good idea for practitioners like her to come under statutory regulation. She's unconvinced: "I already am a member of the register of Chinese Herbal Medicine."

Acupuncturist

Anton Michael Rocke is an acupuncturist who consults at the Diagnostic Clinic in New

Cavendish Street, London, and treats people in nearby Harley Street. He works with "Western practitioners" so patients "get the best of both worlds."

He says that acupuncture can help relieve my symptoms of acid indigestion. He stresses that Eastern medicine uses products and treatments that are "more natural" and "less likely to cause addiction. This has been around for 3000 years, so it's got to be doing something right." He concedes that sticking lots of needles into someone's body "isn't exactly natural, but there's evidence it works and the evidence shows that it's one of the safest of all interventions." And a *BMJ* editorial by medical safety expert Charles Vincent has confirmed this, he says.⁴

He too seems unconvinced about the need for statutory regulation of acupuncturists and herbalists. "I already am registered with British Acupuncture Council, so I'm not sure whether that's necessary or not."

better than placebo. So we're effectively regulating placebo therapies."

His most serious criticisms surround herbal and Chinese medicines, however, which he says "can kill." He makes a distinction between the over the counter "phyto-medicines," such as St John's Wort, with reasonably well defined pharmaceutical properties, and the more arcane herbal mixtures prescribed on an individual basis.

Professor Ernst says that only three credible clinical trials of individualised herbal medicine have been done: in the UK, Australia, and Asia. "And the results suggest there are no benefits beyond that of placebo.

"The point is the prescriptions contain mixtures of five to 20 herbs, increasing the risk of interaction and toxicity, so we have nothing of benefit but the possibility of adverse reactions. We should not be regulating herbal medicines until there is evidence of a good benefit to risk ratio."

Currently, the Medicines and Healthcare Products Regulatory Agency requires herbal medicines placed on the UK market to have either a traditional herbal registration or a marketing authorisation, if the product contains defined pharmaceutical ingredients. These codes at least ensure the products have been screened for dangerous contaminants.

However, the agency notes that in the large unlicensed sector things “vary considerably” with “evidence of poor or patchy standards.”

Michael McIntyre, a herbalist near Oxford and chairman of the European Herbal Practitioners Association, takes a different view: “There is a huge amount of evidence that herbal medicine works,” he says. “The reason that I’m busy here in this village in the middle of nowhere is that doctors know that I can help with irritable bowel syndrome and migraine—things that they’re not particularly good at treating. There are not going to be big, expensive clinical trials funded by drugs companies that show these things work, because the companies would not be able to patent herbs and therefore would not be able to get their money back. And Edzard Ernst is wrong when he says these professions should not be regulated until there’s an evidence base. Lots of good people would be deterred from entering the professions if they knew there was no immediate prospect of being able to join a proper register.”

Practical problems

But even the supporters of statutory registration can see some daunting logistical hurdles. And these practical problems have been

brought more sharply into focus by a pressing deadline for the regulation of herbal medicine. Changes to section 12 of the Medicines Act that seek to protect people having one-to-one consultations with herbal medicine practitioners will mean that by 2011 practitioners must be part of a statutory register.

If a statutory register is not in place by then, “it will mean that no-one will be able to practise herbal medicine in the UK and the whole practice will be driven underground,” says Professor Pittilo. The omens for this deadline being met are not good.

Victoria Nash, a spokeswoman for the Health Professions Council, admits that her organisation is not even sure how it will measure the competence in professions such as counselling or therapy, which are ahead of acupuncture and herbal medicine in the queue for registration.

“If you’re treating something like a broken leg, it’s fairly easy to see if there’s an improvement. But it’s hard to measure improvement with things like counselling,” she says.

She says the council has not even begun to work out how continuing education and re-accreditation—two key aspects of a statutory register—will be organised. And then there’s the sheer scale of the operation. She says that there are currently around 175 000

practitioners of various sorts registered with the council. “It could rise to 350 000 when we take on counsellors and therapists, and I just don’t know how that will work.”

Intriguing, to say the least, is her suggestion that the size of the workload might require revalidation to be done on a sample basis. So will it be possible to do all this and set up a register for acupuncturists and herbal medicine practitioners by 2011? “In my experience it takes a long, long time to do these things, so they’re probably being rather optimistic.” So if anything can be described as a consensus it might be that there’s an awful lot that needs to be done, and not much time in which to do it.

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