# Response to the Consultation on the Report to Ministers from the DH Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK


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## Executive Summary

Statutory regulation lends prestige, but needs to be balanced by a requirement for practitioners to be competent, as is the case for doctors and nurses. Regulation almost exclusively deals with conduct, but the unique risks posed by alternative medicine are not addressed by this. The harms which will arise from licensing practitioners who are not required to show evidence of competence and efficacy are:

- **Harm 1.** Misdiagnosis of serious conditions. Alternative practitioners offer to diagnose illnesses without proper training. This can lead to avoidable death, such as treating an ectopic pregnancy with ginger.
- **Harm 2.** Withdrawal from treatment. Clients of alternative practitioners risk being encouraged to withdraw from life saving treatments in favours of treatments without evidence, as in the death of baby Gloria Thomas.
- **Harm 3.** Harms arising from the nature of the alternative practice, but not covered by the regulatory framework, such as adulterated herbal remedies.
- **Harm 4.** Lack of informed consent. If alternative practitioners are not required to study or show evidence of efficacy, how can they inform patients of their options?
- **Harm 5.** Equity. Doctors and nurses have to use evidence based methods, but it is proposed that alternative practitioners are not held to this standard. Is this fair? Health Minsters should ask themselves if they advocate withdrawing the requirement for evidence based treatment from doctors and nurses. If not, why not? And if not, why should alternative practitioners be treated differently?
- **Harm 6.** Promotion of irrationality. If no evidence of efficacy is required, where do you draw the line? Witch doctoring is a 'traditional practice' in communities in the UK, and astrology is used by some herbal healers.
- Harm 7. Opportunity Costs. If no evidence of efficacy is required of alternative medicine, significant sums will be wasted by individuals and by the NHS.
- Harm 8. Reputational harms for UK Higher Education. UK Honours Degrees are based on the ability to think critically and to assess evidence. Alternative medicine Degree programmes do not require this. These positions are not compatible.
- Harm 9. Health care futures. We are making slow but steady progress on health indicators through the use of evidence based methods. Why should the requirement for evidence be abandoned now?

**Instead, safe regulation of alternative practitioners should be through:**

- The Medicines and Healthcare Products Regulatory Agency
- The Office of Trading Standards via the Unfair Trading Consumer Protection Regulations,
- A new Health Advertising Standards Authority, modelled on the successful Cancer Act 1939.

## Introduction

The Joint Consultation document focuses on *"identifying the nature and degree of risks to the public associated with the practice of acupuncture, herbal medicine and TCM, and on whether these risks can best be managed by introducing statutory professional regulation for these groups or some other means of regulation".*

However, this promotes the view that the sole significant benefit of professional regulation is the safety of the public. This is a poorly informed view. There is an extensive literature on professionalism which makes it clear that professional regulation increases the status of an activity or practice [1]. As Rueschmeyer [2] states:

*Individually and… collectively, the professions 'strike a bargain with society' in which they exchange competence and integrity against the trust of client and community, relative freedom from lay supervision and interference, protection against unqualified competition as well as substantial remuneration and higher social status.*

Professional recognition confers status and validation for a profession. However, the price of this is the meeting of certain standards of competence. It is for this reason that health professionals are required by the Health Professions Council to *"Practise based on evidence of efficacy"* [3]. Subsequently, and without adequate supporting argument, the HPC has taken a different view with regard to alternative medicine [4]. *"The accepted evidence of efficacy overall for these professions is limited, but regulation should proceed because it is in the public interest".*

The HPC's statement that evidence of efficacy is not required for the promotion of health safety is flawed for a variety of reasons. It assumes, first, that current potential harms will be alleviated by regulation. Then it fails to take it account the further harms may arise. The assumption that current harms will be alleviated by regulation ignores the fact that most professional regulatory matters deal with conduct, while the likeliest cause of harms from the alternative practices under consideration arise from the fact that herbal and traditional remedies are not standardised, quality controlled and lack evidence of safety or efficacy. This will not be addressed by statutory regulation of the profession. A well-behaved herbalist prescribing an ineffective or dangerous herb is not a matter of professional conduct, but professional competence – for which the definition relies on evidence.

Other unconsidered harms which will arise from regulating a health profession without requiring evidence of safety or efficacy are as follows.

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[1] Thistlethwaite JE, Spencer J (2008) *Professionalism in medicine* , Oxford: Radcliffe . Eraut, M. (2003). *Developing Professional Knowledge and Competence*. London. RoutledgeFalmer.

[2] Rueschmeyer D (1983) Professional autonomy and the social control of expertise. In Dingwall R and Lewis P (eds) The Sociology of the Professions: lawyers, doctors and others. London, Macmillan. pp38-58.

[3] http://www.hpc-uk.org/aboutregistration/newprofessions/criteria/

[4] http://www.hpc-uk.org/assets/documents/100023FEcouncil_20080911_enclosure07.pdf

### Harm 1. Diagnosis

A view might be taken that alternative medicine merely operates as a placebo effect and for conditions which are chronic, difficult to diagnose or difficult to treat, and therefore does not pose potential harms. However, to tell which conditions are treatable by rational[5] means requires training in evidence based methods. Rational diagnosis is not taught in alternative medicine degree programmes, and misdiagnosis can be lethal. University of Westminster teaching material describes a set of clinical signs and symptoms consistent with an ectopic pregnancy. This condition can rapidly prove fatal, but the course material recommends treatment with ginger[6]. Retrospectively striking an alternative practitioner off the register for making a fatal misdiagnosis through not using evidence based methods is impossible **if they were never required to use evidence based methods in the first place by their regulatory body.** This is not a matter of **conduct**, but of **competence**.

### Harm 2. Withdrawal from evidence based treatments

Private practitioners have a vested interest in patients using their services. Alternative practitioners frequently attack rational evidence based medicine in a variety of ways, often tacitly in promoting their own view, but sometimes explicitly[7]. The natural outcome is for clients under their care to *abandon* evidence based methods for methods which by HPC definition do not require evidence. The consequences for this can also be lethal: in one recent case[8], a 9 month old baby died from an eminently treatable condition (eczema) because her parents withdrew her from rational treatment.

### Harm 3. Risks from the nature of the practice, not covered by regulation

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[5] In this document I will describe health decisions based on evidence (as required of doctors, nurses and other current health professionals) as *rational* rather than using the value laden term of *conventional*. Health systems which do not require evidence of efficacy (as proposed by the HPC) I will describe as *alternative*.

[6] The following is taught at the University of Westminster. http://www.dcscience.net/?p=2007

*"Woman presenting with painful periods, focused contracting pain in central lower abdomen, dark blood with black clots, bleed not very heavy, better with warmth, pulse tight, tongue dark area at root. Since removal of gall bladder by key hole surgery.*

*Diagnosis: blood stasis in the uterus. Aetiology & Pathological process: invasion of cold during operation consumes yang qi and contracts blood vessels*

*Treatment strategy and principle: warm channels to expel cold and move blood*

*Treatment: follicular phase – St 28, 29 with moxa on ginger; Sp8, During pain – shiqizhui with moxa on ginger, Luteal phase – moxa stick on Ren4, St 36. Treatment plan: treat through three cycles; moxa at home luteal phases; once per week follicular phase, daily during pain".*

However, this could easily represent a diagnosis of an ectopic pregnancy. A patient with these signs and symptoms must be referred immediately for emergency care by a qualified doctor.

[7] http://www.medicinescomplete.com/journals/fact/current/fact1002a05t02.htm; See also the current University of Westminster course on TCM, which attacks immunisation.

[8] http://www.smh.com.au/national/parents-guilty-of-manslaughter-over-daughters-eczema-death-20090605-bxvx.html

Chinese medicines show high incidences of adulteration[9]. In this study, Bandolier concluded *"We simply do not know what the rate of adulteration is. One UK study of 11 herbal creams showed that eight contained dexamethasone at concentrations up to 1.5 mg/gram of cream. In the absence of better information, we should assume that Chinese medicines are adulterated".* One death and 6 potentially fatal circumstances are reported in this survey. Ironically, these adulterated TCM remedies are likely to 'work' in that they will have a biological effect. However, the doses of pharmaceutically active doses delivered are uncontrolled and delivered without the knowledge of the patient or their health care team. The MHRA issued a warning about 'herbal viagra' in April 2009[10], where the doses of pharmaceuticals were up to 4 times the recommended dose. Where such products are purchased as in this case, from a supplier, the individual alternative practitioner may not even be aware of the adulteration. **This is not a matter of conduct, and without a requirement for evidence of efficacy and safety will not be addressed by regulation**. All regulation will do is add spurious authority to the alternative practitioner.

### Harm 4. Lack of informed consent

If evidence of efficacy is not a requirement of professional health care provision, then informed consent cannot be obtained. If the practitioner as an individual has not been trained in evidence based medicine, they cannot present to their client an appropriate basis on which to make choices about their health care actions. Eraut [11] points out with regard to professional regulation: *"The protection against unqualified competition is to prevent clients from being deceived when they lack the knowledge to discriminate".*

But how can an alternative practitioner help a patient to discriminate between treatments, if the practitioner themselves is not required to even consider the evidence of efficacy? The concept of informed consent is one of the key ethical advances in medical treatment of the last decades. Doctors can be found negligent for failing to obtain informed content for a treatment. GMC Guidance[12] requires that *"The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment"* and makes it clear that *"serious or persistent failure to follow this guidance will put your registration at risk".* But under the proposed regulatory framework, an alternative practitioner is under no obligation to operate by evidence, and therefore cannot explain the benefits of 'each option', including rational treatments, to patients.

### Harm 5. Lack of equity between alternative and rational health care providers

A mistaken view seems to prevail with regard to regulation, perhaps due to faulty guidance. The Health Minister's Office wrote:[13] "*Professional regulation, whether statutory or in this case, voluntary, is about*

[9] http://www.medicine.ox.ac.uk/bandolier/band104/b104-8.html

[10] http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON043905

[11] Eraut, op cit.

[12] http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance/contents.asp

[13] Letter to the author

*protecting the public, not about the efficacy of the therapies involved*". **This is quite incorrect.** The GMC states[14] *"In providing care you must provide effective treatments based on the best available evidence".* The Code of the Nursing and Midwifery Council[15] states *"You must deliver care based on the best available evidence or best practice".*

If rational health care providers such as doctors and nurses are held to the standard of efficacy in their practice, and alternative practitioners are not, this creates a dangerous imbalance. If the imprimatur of regulation is applied without the requirement for the study and application of evidence based approaches, the rational professions are being held to a much more demanding standard. The Health Minsters should ask themselves these questions. Would they advocate withdrawing the requirement for evidence based treatment from doctors and nurses? If not, why not? And why should alternative practitioners be treated differently?

### Harm 6. Promotion of irrationality

Evidence based thinking is a valuable skill for the citizenry of any country, and is generally good for the political process and body. It is a benefit for participation in the political process, and acts to counteract prejudice and ignorance. Health care, of course, is an area in which consideration of evidence is both important and beneficial for the citizen. For a Government regulatory body to determine that evidence of efficacy is not required for regulated health practice runs directly contrary to the trend of education in recent decades. Moreover, there is no natural frontier between irrationalities. Many alternative practitioners combine their practice with other non-evidence based treatments. The leader of the BSc Hons in Herbal Medicine at UCLAN, Graeme Tobyn, believes that herbal medicine should be combined with astrology[16]. He says of his teaching *"I was able to prove to the student that it was Mercury square Jupiter, because he [the client] knew the month in which it started, and in that month Jupiter progressed exactly to the square of Mercury. Then there was a Mercury-Jupiter conjunction transiting in the sky that month as well, so that was absolutely conclusive. So then I started to treat him with Jupiter and Mercury herbs".* This would be the level of "Degree Level courses with Honours" proposed in the consultation document.

The DH Steering Group Report also mentions "Other Traditional Medicine Systems Practised in the UK". On what grounds would witch doctors be excluded if evidence of efficacy is not required? Such practices pose significant risks in some UK communities, such as selling expensive potions to 'cure' cancer, and even the use of human body parts [17].

### Harm 7. Opportunity Costs

[14] GMC Good Medical Practice - Delivering Good Clinical Care. Para 3. In GMC documents "must" means that it is obligatory, as opposed to "should". http://www.gmc-uk.org/guidance/good_medical_practice/index.asp

[15] http://www.nmc-uk.org/aArticle.aspx?ArticleID=3056

[16] http://www.skyscript.co.uk/tobyn.html

[17] http://www.thisislondon.co.uk/news/article-10033336-details/Exposed%3A+witch-doctors/article.do. http://www.telegraph.co.uk/news/uknews/1540527/Child-witches-case-dropped.html

In 2007, NIH estimates that Americans spent $33.9 billion on alternative medicine[18]. While there are no directly comparable figures collected by the same methodology for the UK, this indicates that very significant sums indeed are spent on such practices. Since for most of these practices, **evidence for lack of efficacy exists[19],** then this represents a major waste of scarce health resources. Regulation, and the apparent validation this brings, may well lead to increased use of unevidenced treatments by the NHS: this is certainly the hope and intent of practitioners. But without the requirement for evidence, this is a waste of NHS resources. As we try to introduce evidence based practices to the NHS, why should double standards prevail?

### Harm 8. Reputational harms for UK Higher Education

The proposition that evidence of efficacy is not required for Honours degree courses in health education (if and only if they are in alternative medicine) is not compatible with the standards of Honours degrees in UK Universities, which universally *and independently of subject*, currently require the ability to assemble and review evidence, and to apply critical thinking skills. I have given examples in Harm 1 and Harm 5 of University courses or teachers who promote dangerous or absurd ideas respectively. Health Ministers should ask themselves this question. Do they wish health care to be delivered to themselves, their families and the public by 'regulated' individuals who have been through training at this standard?

### Harm 9. Health care futures

The UK has a good record of improvement in health indices, but it is not excellent compared to other advanced societies, and much still needs to be done. But this can only be done through evidence based approaches. If 'alternative' practices prove to be effective by evidence based means, then they become medicine. If not, they should not become part of regulated health care provision. Regulated nonsense is still nonsense. Regulated health care nonsense is dangerous nonsense.

## Conclusions

There are real risks arising to the public from the practice of alternative medicine. However, these are not risks of *conduct*, but of mistaken diagnoses and abandonment of rational treatment. Such risks will not be addressed by statutory regulation. Risks to the public arising from alternative medicine should be managed by:

1) The Medicines and Healthcare Products Regulatory Agency requiring evidence of efficacy and safety before health claims can be made for individual products and practices, including traditional and alternative products and practices.

2) The Office of Trading Standards rigorously enforcing the Unfair Trading Consumer Protection Regulations, with additional training for Trading Standards Officers with regard to health claims.

[18] http://nccam.nih.gov/news/camstats/costs/nhsrn18.pdf

[19] Singh S, Ernst, E (2009) Trick or Treatment. Alternative medicine on trial.

3) New legislation, modelled on the Cancer Act 1939, forbidding the making of health claims without evidence, and creating a Health Advertising Standards Authority to enforce this. This body could usefully be modelled on the non-statutory Advertising Standards Agency, which currently does an excellent job of identifying false claims, but has no statutory powers to enforce its determinations.

**Note on the author**

The author is Professor of Medical Education and Associate Dean of Medicine at the University of Durham. He advises the General Medical Council and the Medical Schools Council on a number of issues, including assessment, selection and revalidation. He has a particular interest in the assessment of professionalism in health care settings, and has published recent articles in international peer reviewed journals on this subject. He was formerly Editor-in-Chief of the journal *Medical Education.* He does not earn money from alternative medicine, pharmaceutical industries, or health care providers, and has no competing interests of any kind to declare.