Consultation response

The King's Fund response to a joint 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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Introduction

The King's Fund is a charity that seeks to understand how the health system in England can be improved. Using that insight, we help to shape policy, transform services and bring about behaviour change. Our work includes research, analysis, leadership development and service improvement. We also offer a wide range of resources to help everyone working in health to share knowledge, learning and ideas.

This paper is a formal response to the Department of Health's 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.

Background

This latest consultation follows a series of reports and consultations that have sought to address the question of whether to regulate the practitioners of acupuncture and herbal medicine and, if so, how to regulate them. Both the Department of Health and the professions themselves have invested significant time and resources in the development of regulation of these practitioners particularly since 2000.

The House of Lords Select Committee for Science and Technology Report on Complementary and Alternative Medicine (2000) made a number of recommendations in relation to regulation. It recommended that each complementary and alternative medicine (CAM) therapy should establish a single, unified regulatory or professional body, but that acupuncture and herbal medicine should seek statutory regulation (at the time under the Health Act 1999, which made it easier for professions to join the newly created Health Professions Council or to establish a new Council). It also recommended that existing health care regulators develop guidelines on competency and training for their members and that conventional health care practitioners should be trained to standards comparable to those set out for non-medical CAM therapists. The government responded quickly to the Report and accepted the vast majority of the Lords' recommendations (Department of Health 2001).

Since then, a series of Department of Health working parties and steering groups have prepared the ground for statutory regulation, establishing agreed standards and making recommendations about how to establish a system of statutory regulation (HMRWG 2003; ARWG 2003; Department of Health 2008).

The Department of Health previously put forward proposals for statutory regulation of herbal medicine and acupuncture in 2004 (Department of Health 2004) together with *Proposals for*

the reform of the regulation of unlicensed herbal remedies in the UK made up to meet the needs of individual patients (Medicines and Healthcare products Regulatory Agency 2004). These proposals closely followed those of the HMRWG and, unlike the House of Lords, recommended that as well as acupuncturists and herbalists, practitioners of traditional Chinese medicine and other traditional medicine systems practised in the UK should also be included. There was overwhelming agreement to statutory regulation in response to this first consultation and the government committed to consult on a draft order under Section 60 of the Health Act 1999 in Autumn/Winter 2005 (Department of Health 2005). The draft order was never published.

Separate reviews into the future of professional regulation (Chief Medical Officer of England 2006; Department of Health 2006) which were then followed by the publication of the White Paper *Trust, Assurance and Safety – The regulation of health professionals in the 21st century* (HM Government 2007) further delayed any decision or action to regulate these practitioners.

It is disappointing to note that despite a huge effort and investment of time and resources, both by the government and professional representatives, to develop policies and consult on them, and to establish a consensus on standards, that these practitioners remain unregulated.

As we set out in this response, we support the regulation of acupuncturists, herbalists and traditional Chinese medicine (TCM) practitioners and would urge the government not to prevaricate any longer on this matter. However, we believe it is right to ensure that the appropriate model of regulation is applied to these practitioners and therefore discuss some of the pros and cons of the different approaches. We do not think that this should open the door to statutory regulation of other CAM practitioners but do urge the government seriously to consider strengthening other forms of regulation and possibly to introduce a 'lighter touch' form of licensing for other CAM practitioners in order to protect the public from harm.

Key points

- Acupuncture, herbal medicine and TCM have substantial and direct risks to patients. It is these risks which single them out for regulation. However, together with other CAM therapies they also pose indirect risks arising from missed or incorrect diagnosis, inappropriate treatment and lack of appropriate referral. It is important that there are clear rules for ensuring communication with a patient's GP and other health care professionals, for ensuring that patients have a medical diagnosis, and for referring patients appropriately for conventional medical care.

- If statutory regulation of herbal practitioners and TCM practitioners does not take place by 2011 it will mean that many pre-prepared herbal remedies currently made up by third parties and prescribed by herbal practitioners will be prohibited and thus the scope and range of currently available herbal remedies accessed by the public will be significantly reduced. There is a danger that these products would be traded illegally and a black market in herbal medicines would develop. This would pose a significant risk to consumers.

- Statutory regulation with protection of title is the preferred model of regulation for these practitioners and follows existing models of professional regulation. While there are opportunities to strengthen other forms of regulation with benefits to consumers and without undue regulatory costs falling either to the state or to practitioners (and indirectly consumers), we do not think these other regulatory approaches are sufficient to protect the public from the substantial direct risks of acupuncture, TCM and herbal medicine.

- We think other approaches that could be adopted for CAM therapies from which the risk is indirect rather than direct. For example, the government could introduce a system of licensing (to be managed by one of the existing regulators such as the Health Professions Council (HPC)) which would offer a first level of protection. This could build on international models of regulation found in Norway and Germany.

- We do not think there are any grounds for regulating these practitioners differently because of the (lack of) evidence of effectiveness. Regulation is about protection from harm rather than endorsing the effectiveness of particular treatments. We do acknowledge, however, that there is a danger that statutory regulation might confer a patina of respectability, which patients may equate with effectiveness. It is important that these practitioners establish a consensus on standards of practice in the absence of evidence and invest in developing a culture of research and enquiry to allow the evidence on which these standards rests either to be strengthened or, if interventions are shown not to be effective , to be abandoned.

- The HPC appears to offer a good model for the regulation of these practitioners. It already covers a wide range of practitioners and has an established model of governance for managing this diversity. It also has the advantage of common functions and approaches, which keeps the costs of regulation low for the practitioners and will ensure that cost is not a barrier to registration.

- We support the use of protected titles rather than protected functions. Protected titles need to be simple while at the same time ensuring that practitioners who are unwilling or unable to register cannot continue to practise under another similar title. The key here is the extent to which practitioners try to pass themselves off as registered practitioners. In order for other statutorily regulated professionals to use protected titles we think that they should demonstrate achievement of defined standards and competencies and that this should be noted through an annotation on the register.

- It is important that statutory regulation of professionals is consistent across the four countries of the United Kingdom. We hope that any regulations of acupuncturists, herbal medicine practitioners and TCM practitioners that are introduced are consistently applied in the UK.

Responses to specific questions

Questions 1-4

Question 1: What evidence is there of harm to the public currently as a result of the activities of acupuncturists, herbalists and traditional Chinese medical practitioners? What is its likelihood and severity?

Question 2: Would this harm be lessened by statutory regulation? If so, how?

Question 3: What do you envisage would be the benefits to the public, to practitioners, and to businesses, associated with introducing statutory regulation?

Question 4: What do you envisage would be the regulatory burden and financial costs, to the public, to practitioners and to businesses, associated with introducing statutory regulation? Are these costs justified by the benefits and are they proportionate to the risks? If so, in what way?

Acupuncture, herbal medicine and TCM have substantial and direct risks to patients. It is these risks which single them out for regulation among other CAM therapies and in our view make regulation more important than that in place for some other therapies such as art and music therapy, which are already statutorily regulated by the HPC.

The Lords' recommendation that acupuncture and herbal medicine should be brought under statutory self-regulation were based on three criteria: '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' (House of Lords Select Committee on Science and Technology, 2000a, para V). The House of Lords' Select Committee added a caveat to these criteria suggesting that lack of professional development should not stop statutory regulation proceeding if there is a demonstrable risk.

One of the factors that precipitated demands for regulation of both herbal medicines and herbal practitioners was a series of serious adverse incidents as a result of the ingestion of powerful herbs or herbs contaminated with toxic substances that were widely publicised both in the UK and internationally in the 1990s. The MHRA continues to document such adverse events.

During evidence to the House of Lords' Science and Technology Committee, a number of different types of direct and indirect risk associated with CAM therapies were identified.

The main types of direct risk mentioned were concerned with (i) toxicity or contamination – the adulteration of therapeutic products with poisonous or otherwise harmful or toxic substances (eg, steroids in topical herbal ointments); (ii) potency – the concentration and strength of effect of therapeutic products, which may in some patients produce adverse outcomes (eg, liver disease caused by ingestion of herb); (iii) invasiveness – the extent to which the treatment or substance enters the body either through skin penetration or oral ingestion (eg, lung collapse due to incorrect insertion of needles); (iv) infection – the transfer or introduction of infectious agents into the body (eg, hepatitis or HIV transmission from unclean acupuncture needles); (v) manipulation – direct injury as a consequence of the application of manipulative techniques (eg, from spinal manipulation); and (vi) psychological damage – emotional harm arising from abusive or distressing psychotherapeutic relationships (eg, sexual assault by hypnotherapists) (Dixon 2007b).

Osteopaths and chiropractors who practise the main forms of manipulation are already statutorily regulated, and the government is currently introducing statutory regulation of psychotherapists and counsellors to address the risk of psychological damage. The regulation of herbal medical practitioners and TCM practitioners together with regulations concerning the production of herbal medicines would reduce the risks of toxicity and

potency. Regulation of acupuncture would minimise risks due to the invasiveness of the techniques and the potential risk of infection.

It is in order to minimise these risks of harm that we would support the statutory regulation of acupuncturists, herbal medical practitioners and TCM practitioners.

The House of Lords' report also identified indirect or extrinsic risk and defined this as 'the risk of omission of conventional medical treatment' (House of Lords Select Committee on Science and Technology, 2000a, para 5.54). The following factors were identified as being associated with indirect risks: (i) CAM therapies that had an alternative clinical system – fears of misdiagnosis, inappropriate treatment and lack of appropriate referral; (ii) lack of skills of a CAM practitioner – words such as 'incompetent', 'unqualified' or 'untrained' were used to describe these dangerous practitioners; and (iii) unethical conduct – including abuse, overcharging, false or fraudulent claims (Dixon 2007b).

It may be appropriate to consider ways of reducing these other forms of indirect harm. For example, it is vital that these practitioners, whether statutorily or voluntarily regulated, are plugged into mainstream medical care. It is important that there are clear rules for ensuring communication with a patient's GP and other health care professionals, for ensuring that patients have a medical diagnosis, and for referring patients appropriately for conventional medical care. Recent regulations in Norway, which require a person to have a diagnosis from a conventional medical practitioner and open disclosure of information, could be looked at as an example (Dixon 2007a).

It will also be important that these practitioners are required to meet standards of practice through adequate training and ongoing revalidation. While the limited evidence base may not allow for there to be standards of practice based on effectiveness of treatments, there should be standards that ensure that harm is prevented, including aspects of professional conduct.

Questions 5-7

Question 5: If herbal and TCM practitioners are subject to statutory regulation, should the right to prepare and commission unlicensed herbal medicines be restricted to statutorily regulated practitioners?

Question 6: If herbal and TCM practitioners are not statutorily regulated, how (if at all) should unlicensed herbal medicines prepared or commissioned by these practitioners be regulated?

Question 7: What would be the effect on the public, practitioners and businesses if, in order to comply with the requirements of European medicines legislation, practitioners were unable to supply manufactured unlicensed herbal medicines commissioned from a third party, after 2011?

Restricting the right to prepare and commission unlicensed herbal medicines to statutorily regulated practitioners appears to be one of the main ways of reducing risk from unlicensed herbal medicines and would be the main advantage of regulating herbal and TCM practitioners. Other statutorily regulated practitioners may need to demonstrate competencies in these areas and meet standards comparable to those set out for herbalists and TCM practitioners.

It would seem unlikely that there is any other way of making these preparations available safely. It is expected that the availability of herbal medicines would be severely curtailed if statutory regulation was not introduced given the current provisions in the EU Directive 2004/24/EC.

Proposed changes to section 12(2) of the Medicines Act 1968 depend on herbal practitioners being statutorily regulated and thus able to utilise the derogation permitted under Article 5

of the main EU medicines Directive (2001/83/EC) governing the use of medicinal products, which states:

> *A Member State may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility. (Article 5.1 of the Directive 2001/83/EC)*

If statutory regulation of this sector does not take place by 2011 it will mean that many pre-prepared herbal remedies currently made up by third parties and prescribed by herbal practitioners will be prohibited and thus the scope and range of currently available herbal remedies accessed by the public will be significantly reduced. There is a danger that these products would be traded illegally and a black market in herbal medicines would develop. This would pose a significant risk to consumers.

Questions 8-10

Question 8: How might the risk of harm to the public be reduced other than by statutory professional self-regulation? For example, by voluntary self-regulation underpinned by consumer protection legislation and by greater public awareness, by accreditation of voluntary registration bodies, or by a statutory or voluntary licensing regime?

Question 9: What would you estimate would be the regulatory burden and financial costs, to the public, to practitioners, and to businesses, for the alternatives to statutory regulation suggested at Question 8?

Question 10: What would you envisage would be the benefits to the public, to practitioners, and to businesses, for the alternatives to statutory regulation outlined at Question 8?
The pros and cons of different approaches to regulation of CAM practitioners are set out elsewhere (Dixon 2009 in review).

Statutory regulation offers protection of title thereby ensuring that practitioners using the title meet professional standards and have completed necessary training requirements. Protection of title is easier to enforce than protection of function; however, it is important to ensure that non-registered practitioners do not continue to practise under different titles.

Other regulations could also be strengthened or enforced better such as trading standards, advertising legislation, and mandating improved consumer information. While there are opportunities to strengthen other forms of regulation with benefits to consumers and without undue regulatory costs falling either to the state or to practitioners (and indirectly consumers), we do not think these other regulatory approaches are sufficient to protect the public from the substantial direct risks of acupuncture, TCM and herbal medicine.

It is important that a cost-benefit approach is taken to regulation. Most of the costs of regulation fall to practitioners but are in turn passed on to patients or payers. The costs to practitioners should be minimised in order to limit barriers to registration. The larger the number of registrants the lower the costs of registration will be.

Question 11: If you feel that not all three practitioner groups justify statutory regulation, which group(s) does/do not and please give your reasons why/why not?

We believe that the regulation of these three professions is justified due to the direct risks set out above. However, it should not open the door to statutory regulation of other CAM practitioners. We think other approaches could be adopted for other CAM practitioners where there is no direct risk from the therapy itself but where there are indirect risks.

For example, the government could introduce a system of licensing (to be managed by one of the existing regulators such as HPC), which would offer a first level of protection against abusive practitioners. A licensed CAM practitioner would have to demonstrate basic checks such as that they have no criminal record, they hold liability insurance, etc. These requirements have been set out for individual registrants in Norway (Dixon 2007a). A second level of protection would require practitioners to demonstrate that they are aware of the limits to their practice, legal requirements and trading standards, perhaps by taking an exam similar to the requirements that *Heilpraktiker* in Germany have to meet. This would not provide any assurance that the individual was trained or met standards as defined by a particular therapy. Training and assessment of competence in specific modalities would remain entirely voluntary.

We would urge the government to seriously consider strengthening other forms of regulation and possibly to introduce a 'lighter touch' form of licensing for other CAM practitioners in order to protect the public from harm.

Question 12: Would it be helpful to the public for these practitioners to be regulated in a way which differentiates them from the regulatory regime for mainstream professions publicly perceived as having an evidence base of clinical effectiveness? If so, why? If not, why not?

We do not think there are any grounds for regulating these practitioners differently because of the (lack of) evidence of effectiveness. Regulation is about protection from harm rather than endorsing the effectiveness of particular treatments. There are other therapies that are regulated where there is no clear evidence base, eg, music therapy and art therapy. Indeed when doctors were first regulated under the Medical Act 1858 there was very little evidence of the positive benefits of medical practice. It was the creation of regulation which helped to foster professional standards and led to the development of a body of knowledge. We do acknowledge, however, that there is a danger that statutory regulation might confer a patina of respectability, which patients may equate with effectiveness. It is important that these practitioners establish a consensus on standards of practice in the absence of evidence and invest in developing a culture of research and enquiry to strengthen the evidence on which these standards rests.

Question 13: Given the Government's commitment to reducing the overall burden of unnecessary statutory regulation, can you suggest which areas of healthcare practice present sufficiently low risk so that they could be regulated in a different, less burdensome way or de-regulated, if a decision is made to statutorily regulate acupuncturists, herbalists and traditional Chinese medicine practitioners ?

No comment

Questions 14-16

Question 14: If there were to be statutory regulation, should the Health Professions Council (HPC) regulate all three professions? If not, which one(s) should the HPC not regulate?

Question 15: If there were to be statutory regulation, should the Health Professions Council or the General Pharmaceutical Council/ Pharmaceutical Society of Northern Ireland regulate herbal medicine and traditional Chinese medicine practitioners?

Question 16: If neither, who should and why?

The HPC appears to offer a good model for the regulation of these practitioners. It already covers a wide range of practitioners and has an established model of governance for managing this diversity. It also has the advantage of common functions and approaches, which keeps the costs of regulation low for the practitioners and will ensure that cost is not a barrier to registration.

Questions 17-19

Question 17:

a) Should acupuncture be subject to a different form of regulation from that for herbalism and traditional Chinese medicine? If so, what?

We think these practitioners should be subject to similar forms of regulation and see no strong grounds for different approaches.

b) Can acupuncture be adequately regulated through local means, for example through Health and Safety legislation, Trading Standards legislation and Local Authority licensing?

While the risk of infection could be minimised through local means such as those proposed in the consultation, some of which already exist, this does not deal with the other risks posed by the practice of acupuncture. Statutory regulation offers a level of public protection against poorly trained practitioners, important given the invasive nature of acupuncture.

Question 18:

a) Should the titles "acupuncturist", "herbalist" and "[traditional] chinese medicine practitioner" be protected?

b) If your answer is “No”, which ones do you consider should not be legally protected?

Question 19: Should a new model of regulation be tested where it is the functions of acupuncture, herbal medicine and TCM that are protected, rather than the titles of acupuncturist, herbalist or Chinese medicine practitioner?

The protected titles need to be simple while at the same time ensuring that it is not possible for practitioners who are unwilling or unable to register to continue to practise under another similar title. The key here is the extent to which practitioners try to pass themselves off as a registered practitioner.

Generally it is more difficult to implement protection of function and this is not the common approach used in the UK.

Question 20: If statutory professional self-regulation is progressed, with a model of protection of title, do you agree with the proposals for "grandparenting" set out in the Pittilo report?

Given the robust systems of voluntary regulation that a number of professional associations have in place for acupuncturists and herbal medicine practitioners it would seem appropriate to adopt a system of ‘grandparenting’ in order to minimise the costs of transferring these practitioners on to the new register. It will be important to learn from the experiences of other councils who set up new registers (eg, GCC and GOsC) and the HPC’s own experience of including other professional groups on its register.

Questions 21-23

Question 21: In the event of a decision that statutory or voluntary regulation is needed, do you agree that all practitioners should be able to achieve an English language IELTS score of 6.5 or above in order to register in the UK?

Question 22: Could practitioners demonstrate compliance with regulatory requirements and communicate effectively with regulators, the public and other healthcare professionals if they do not achieve the standard of English language competence normally required for UK registration? What additional costs would occur for both practitioners and regulatory authorities in this case?

Question 23: What would the impact be on the public, practitioners and businesses (financial and regulatory burden) if practitioners unable to achieve an English language IELTS score of 6.5 or above are unable to register in the UK?

As communication is at the heart of being a health professional, it is important that English language requirements are such as to ensure that practitioners can understand and be understood by their patients. They should be consistent with the requirements for other statutory registers.

Question 24: Are there any other matters you wish to draw to our attention?

It is important that statutory regulation of professionals is consistent across the four countries of the United Kingdom. Other countries with federal systems of health care are trying to harmonise professional regulation nationally in order to allow free movement of professionals across the country. We hope that any regulations of acupuncturists, herbal medicine practitioners and TCM practitioners that are introduced are consistently applied in the UK.

We would agree with the recommendations of the House of Lords that existing health care regulators need to develop guidelines on competency and training for their members and that conventional health care practitioners should be trained to standards comparable to those set out for non-medical CAM therapists. We would hope that the regulator would set out standards not only for the acupuncturists and herbalists they register but also for the practice of these therapies by other statutorily regulated professionals. We think that other statutorily regulated professionals using protected titles should demonstrate achievement of defined standards and competencies and that this should be noted through an annotation on the register. This would allow a patient to be confident when consulting a medical acupuncturist or receiving acupuncture from a physiotherapist.

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