
A 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

Department of Health Consultation

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Executive Summary

Issues

1. Current models of statutory regulation of alternative therapy practitioners have little interest in the efficacy of the treatments they are charged with regulating.
2. Current models of statutory regulation of alternative therapy practitioners are failing to protect the public.
3. Statutory regulation of alternative therapies has led to many practitioners heralding that regulation as a flag of undeserved and unfounded legitimacy, which misleads and endangers the public.
4. To set up further statutory alternative therapy regulation along the same lines will be costly and will not lead to the public being protected.
5. On the contrary, it will lead more — and frequently vulnerable— members of the public being misled into believing that homeopathy, herbalism, TCM and acupuncture are effective and safe, when there is no robust evidence that this is the case.
6. With increased legitimacy given to alternative therapies by Government regulation, the public will have an even lower regard for evidence-based medicine. It is easy to see, given attitudes to the MMR vaccine and the increase in measles cases, that the public understanding of what is scientific could be disastrous for the health of the nation.

Recommendations

1. That the misconceived and dangerous Pittilo proposals are abandoned in their entirety.
2. That a new statutory body is set up or the role of Trading Standards and/or the MHRA enhanced to:
 - a) set clear guidance on what can and what cannot be claimed for alternative therapies;
 - b) ensure this guidance is based on best available scientific evidence;
 - c) enforce this guidance, such enforcement to be pro-active and not run on a complaints-only basis;
 - d) ensure such regulation does not give undeserved and unfounded legitimacy to alternative therapies.

Introduction

I will use the term *alternative therapy* as shorthand when referring to the subjects of the consultation. However, I do not regard these therapies to be alternatives to 'conventional' medicine. Both these terms (alternative and conventional) are not ideal, but are in common usage.

It must be clear to all — including their proponents — that these alternative therapies do not meet the standards of evidence for efficacy and safety required of conventional medicine. Many have been shown to be ineffective; homeopathy, for example, has been shown in the better quality trials to have an efficacy no better than placebo. Many are unproven or disproven or unsafe (particularly herbalism).

Another feature of homeopathy and acupuncture is that their suggested modes of action are highly improbable in light of current scientific and medical knowledge. This is why homeopathy falls decisively into the alternative category and not the conventional category. The same can be said for acupuncture, herbalism and TCM, although the level of evidence for them is different.

It is understandable that the Department of Health — who rightly has concerns about public health and wellbeing — should be interested in ways to best protect the public. Proponents of alternative therapies are making claims about being able to prevent/help/treat/cure a wide variety of ailments and medical conditions — some serious — and providing a statutory regulatory framework could be seen as a way of controlling those practitioners to ensure public safety.

However, even though such regulation as proposed may ensure practitioners abide by a code of conduct and, if enforced pro-actively and effectively, may protect the public from the *misconduct* of those practitioners, the issue of efficacy and risk/benefit analysis is missing completely. This is very worrying and has severe implications for public safety.

Failures in statutory regulation of chiropractic

I recently submitted complaints to the General Chiropractic Council (GCC) against 524 of their statutorily registered chiropractors. Although it is not appropriate to discuss the details of these ongoing cases here, it is abundantly clear that the statutory regulation of chiropractors has not been fit for purpose.

Whilst it is true that ensuring that registered chiropractors have appropriate public liability insurance; have had some kind of training; that there is a Code of Practice in place (against which their behaviour can be judged and, if necessary, sanctions applied), is important, it is clear that this statutory regulation has spectacularly failed in the most fundamental of areas: that of protecting the public from bogus claims.

The GCC state their statutory aims as¹:

- To protect the public by establishing and operating a scheme of statutory regulation for chiropractors, similar to the arrangements that cover other health professionals
- To set the standards of chiropractic education, conduct and practice
- To ensure the development of the profession of chiropractic, using a model of continuous improvement in practice

It remains to be seen what the outcome of my complaints will be, but some of the claims made by registered chiropractors include being able to treat the following (the percentages, which are taken from the list of claims made by the chiropractic clinics I complained about, show the proportion of chiropractors making claims for those conditions²):

Colic	29%	PMS	7%
Whiplash	25%	Sleeping problems	6%
Bed wetting	23%	Menstrual problems	3%
Infection	19%	ADHD	3%
Asthma	18%	Vertigo	2%
Arthritis	18%	Tinnitus	1%
Feeding problems	15%	Dyslexia	1%
RSI	11%	Eczema	1%
Hyperactivity	8%		

While there may only be a few claiming to treat some of these conditions, these figures show that claims for many conditions are widespread.

This would not be a problem at all if there *was* good evidence that chiropractic was an effective treatment for these conditions. The reality is, however, that there is no good evidence for any of them³. Yet neither this, nor the fact they are statutorily registered, prevents such wild claims being made. Additionally, these claims are still being made despite many adverse ASA adjudications. This is astonishing because it is a mandatory requirement of the GCC's Code of Practice that chiropractors only make claims consistent with the ASA's guidance.

Whilst many chiropractors will claim that they have the evidence to support the use of chiropractic for these conditions, the robustness of that evidence is paltry to say the least and does not measure up to the ASA's standards. It would not be appropriate to examine the evidence here, but suffice to say, that evidence put forward by chiropractors tends to be anecdotal or from discredited and poor quality trials.

¹ http://www.gcc-uk.org/page.cfm?page_id=7 accessed 15 November 2009

² <http://www.zenosblog.com/2009/05/ok-so-how-many-chiroquacktors-claim-to-treat-colic/> accessed 15 November 2009

³ *A systematic review of systematic reviews of spinal manipulation* E Ernst P H Canter J R Soc Med. 2006 Apr;99(4):192-6 available at <http://jrsm.rsmjournals.com/cgi/reprint/99/4/192> accessed 15 November 2009

But the evidence of efficacy (and safety) for the alternative therapies under consideration are no different and it does not seem likely that any similar structure of statutory regulation would protect the public from bogus claims than the abysmal regulation of chiropractors currently does.

Herein lies a fundamental problem: if a regulator *were* to take evidence of efficacy and safety into account, and excluded any treatment or condition for which there was no good evidence, there would be nothing left to regulate. That is why these therapies are *alternative*.

Status and respectability

The GCC claims that it provides regulation 'similar to the arrangements that cover other health professionals'⁴. As a result, many chiropractors see themselves as 'primary health-care' professionals⁵; a view emphasised by some chiropractic trade associations⁶.

This attempt to raise the standing of these alternative therapists simply misleads the public into believing that their therapy is generally accepted as being effective for the conditions claimed. They are not.

Denigration of conventional medicine

The anti-science and anti-conventional medicine attitudes of many alternative therapy practitioners are also very worrying. Allopathy, meaning any medical paradigm that is not alternative, was coined by Samuel Hahnemann, the inventor of homeopathy. It is most commonly used by practitioners of alternative therapy to disparage conventional medicine. Chiropractic clinic websites are riddled with anti-science and anti-medical views⁷ as are the websites of homeopaths and TCM practitioners. It is not uncommon to see support for 18th century vitalism being touted as superior to modern day medical knowledge⁸.

Such views are antithetical to the vast majority of those in the NHS who provide evidence-based treatments and care: the treatment and care that has saved the lives and reduced the suffering of millions.

⁴ http://www.gcc-uk.org/page.cfm?page_id=7 accessed 15 November 2009

⁵ <http://www.westmidlandschiropractic.co.uk/> accessed 15 November 2009

⁶ <http://www.chiropractic-uk.co.uk/default.aspx?m=3&mi=3&title=About+Chiropractic> and http://www.sca-chiropractic.org/index.php?option=com_content&view=article&id=56&Itemid=61 both accessed 15 November 2009

⁷ For example, see <http://www.edinburgh-chiropractor.co.uk/doctor/chiropractor/525S/chiropractic-Edinburgh/chiropractors-are-real-doctors.htm> accessed 30 October 2009,

<http://www.backinmotion.co.uk/sw/chiro/welcome/internet/truth.asp> accessed 30 October 2009 and

http://www.isischiropractic.co.uk/chiropractic_painkillers.html accessed 02 November 2009

⁸ For example, see <http://www.remedycentres.co.uk/printformat.asp?chiropractor=10246S> accessed 16 November 2009

Failure to protect the public

What the above situation describes is a regulatory regime, set up by Parliament, which has totally failed to protect the public.

The public are being misled in several ways by these failures: they are led to believe that chiropractic can treat a wide range of medical conditions; that chiropractors have the same legitimacy as doctors registered with the GMC and that they should be the first to be consulted for any number of medical conditions.

Conclusion

These are systemic problems and can't easily be rectified: giving legitimacy to an alternative therapy modality that has a scant evidence base is what has caused these problems as much as the failure of the GCC to ensure that its members only practice within the evidence base for chiropractic.

This leaves what really amounts to the only question necessary, but one that has not been asked by the consultation, never mind answered: How can you regulate nonsense?

Current statutory and non-statutory regulatory bodies

Advertising Standards Authority

The ASA has an excellent history of requiring advertisers to substantiate any claims made. They do this to protect the public by ensuring adverts are 'Legal, Decent, Honest and Truthful'⁹.

They have high standards of substantiation: for medical claims, they will only accept robust evidence from randomised, controlled, double-blinded trials, ideally peer reviewed. And rightly so. We are talking about potentially vulnerable members of the public and the health of everyone who views those adverts.

However, the ASA is non-statutory and has limited sanctions it can impose on those it finds has broken the rules. This is a major shortcoming, particularly on those making health claims, who are frequently small traders who publish their own advertising material and over whom the ASA therefore has little sanction.

Trading Standards

Trading Standards enforce consumer protection legislation, but it is becoming apparent from the many complaints against chiropractors that they have very inconsistent procedures of investigation and levels of robustness for the substantiation of claims made¹⁰.

⁹ http://www.asa.org.uk/asa/codes/cap_code/CodeIndex.htm?code_id=19#expanded accessed 15 November 2009

TS do have the power to prosecute a trader and this makes them very powerful in their duty to protect the public from those making claims that cannot be substantiated.

However, it is not clear whether they have the systems, expertise and resources to deal with the current level of complaints against alternative therapies, never mind any additional future burden.

Conclusion

While these two organisations have roles to play in protecting the public from misleading claims, neither is inherently suitable for the role of protecting the public from the misleading claims of alternative therapies.

Conclusion

The consultation questions assume statutory regulation of alternative therapies is both necessary and desirable. These are dangerous assumptions.

There is no need to create a two-tier system of medicine: we already have an excellent NHS, which in the main, and with guidance from bodies such as NICE and the MHRA, provides an excellent evidence-based health system that all can benefit from.

There cannot be any room for treatment modalities that fall significantly below this existing standard. To introduce such a system will endanger the lives and health of many, misled into thinking non-evidence-based therapies such as homeopathy, herbalism, TCM and acupuncture can be effective for a wide variety of conditions.

It is with all this in mind that I urge you to wholly reject the recommendations of Pittilo and instead set up a system designed to truly protect the public.

¹⁰ <http://skepticbarista.wordpress.com/2009/10/16/trading-standards-post-code-lottery/> accessed 16 November 2009