the Nightingale Collaboration

Response to:

# Regulation of Health Care Professionals

Law Commission
Scottish Law Commission
Northern Ireland Law Commission

Joint Consultation Paper LCCP 202 / SLCDP 153 / NILC 12 (2012)

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# Introduction

*The Nightingale Collaboration*[1] *challenges questionable claims made to the public by healthcare practitioners on their websites, in adverts and in their promotional and sales materials by bringing these to the attention of the appropriate regulatory bodies. The vast majority of these claims are made by practitioners of alternative therapies.*

*We also strive to ensure that organisations representing healthcare practitioners have robust codes of conduct for their members that protect the public and that these are enforced.*

1. We welcome the opportunity to contribute to the consultation on the regulation of healthcare professionals.
2. Our interest lies in the regulation of chiropractors and osteopaths because of the lack of a robust evidence base for chiropractic and osteopathic spinal manipulation.2
3. Statutory regulation rightly confers respectability and trustworthiness in the eyes of the public and these need to be protected to maintain that trust. For chiropractic and osteopathy, we do not believe statutory regulation is deserved or necessary and it gives a false imprimatur that misleads the public.
4. Because of this, our overall view is that statutory regulation of chiropractors and osteopaths is not appropriate and recommend that this statutory regulation be abolished.
5. We believe that adequate protection of the public can be achieved by existing regulations (such as The Consumer Protection from Unfair Trading Regulations 2008) as are applied to any other alternative therapies and businesses.
6. However, we appreciate that this may not fall within the scope of the present consultation and we offer our responses regardless.
7. We are concerned that some of the claims made by these practitioners are not founded in robust evidence and that they can therefore mislead. We are concerned that current statutory regulation is failing by not adequately protecting the public from such claims.
8. We are aware that the situation regarding claims made on practitioners' websites has significantly improved in the past three years, but we believe that much more still needs to be done and that the current regulatory framework is not fit for purpose in this regard.
9. The Law Commissioners' consultation on the reform of the legislation is a welcome opportunity to greatly improve the protection of the public and we hope that the Law Commissioners will note and act on our recommendations.
10. We therefore restrict our views to those proposals and questions that directly affect the regulation of chiropractors and osteopaths and we make recommendations that we believe will enhance public protection. We hold no view on any proposal or question we have not addressed.

[1] 'The Nightingale Collaboration' <http://www.nightingale-collaboration.org/> [accessed 28 May 2012].

[2] For example, E Ernst and P H Canter, 'A Systematic Review of Systematic Reviews of Spinal Manipulation', *Journal of the Royal Society of Medicine*, 99 (2006), 192–196 <doi:10.1258/jrsm.99.4.192>.

# Response to provisional proposals and questions

### *Provisional Proposal 2-1*

> All the existing governing legislation should be repealed and a single Act of Parliament introduced which would provide the legal framework for all the professional regulators.

Unlike the other regulated professions, there are few differences between osteopaths and chiropractors, particularly in terms of their training, practice, scientific evidence, claims made and administration. There is also little difference between the two Acts.[3,4]

The report commissioned by the General Chiropractic Council (GCC) that purported to look at the scientific evidence for manual therapies, Bronfort et al.,[5] was used by the GCC as the basis for its advertising guidance to its registrants.[6] However, the studies considered were predominately non-specific spinal manipulation and mobilisation, with a few identified as osteopathic manipulation. None were identified as chiropractic manipulation.

The General Osteopathy Council (GOsC) also refer their registrants to this same report as a source of the scientific evidence for osteopathy.[7] It is clear they are simply variations in technique of manipulation and mobilisation and that separate regulatory bodies is unnecessary and wasteful.

Except for the PSNI, the GCC and GOsC regulate the smallest number of registrants by far, with less than 7,500 combined. The next smallest regulator (the General Optical Council) is over three times this combined size. The fees charged (30% greater than the next most expensive regulator's fees) reflect this costly duplicate structure.

Given this, it is our view that the continued existence of separate regulators for chiropractors and osteopaths cannot be justified.

We therefore recommend that if statutory regulation of chiropractors and osteopaths is to be continued, then they should be combined into one regulator. This will give economies of scale, resulting in lower overall costs, reduced fees charged to registrants (which are currently the highest of all the regulators), simplified regulation and more consistency in the eyes of the public.

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[3] *Chiropractors Act 1994* <http://www.gcc-uk.org/files/link_file/Chiropractors_Act_(As_at_Feb_09).pdf>.

[4] *Osteopaths Act 1993* <http://www.osteopathy.org.uk/uploads/osteopaths_act_1993_(as%20amended).pdf>.

[5] Gert Bronfort and others, 'Effectiveness of Manual Therapies: The UK Evidence Report', *Chiropractic & Manual Therapies*, 18 (2010), 3 <doi:10.1186/1746-1340-18-3>.

[6] 'Advertising Guidance for Chiropractors' (General Chiropractic Council, 2010) <http://www.gcc-uk.org/files/link_file/Advertising_guidance_note_March_2010.pdf> [accessed 29 May 2012].

[7] 'Research | General Osteopathic Council' <http://www.osteopathy.org.uk/resources/research/> [accessed 29 May 2012].

*Provisional Proposal 2-2*

> The new legal framework should impose consistency across the regulators where it is necessary in order to establish the same core functions, guarantee certain minimum procedural requirements and establish certain core requirements in the public interest. But otherwise the regulators should be given greater autonomy in the exercise of their statutory responsibilities and to adopt their own approach to regulation in the light of their circumstances and resources.

We advise caution in allowing regulators too much autonomy.

Where registrants have significant influence in the running of the regulator, even if there is a majority of lay members on the General Council or statutory committees, there is the possibility of bias.

Whilst this bias may not be actual bias, there is the danger that public confidence in the regulator will be eroded by the perception of possible bias and conflicts of interest. This is particularly an issue where registrant members have voting privileges. This is clearly something that has to be avoided if the necessary status of statutory regulation is not to be diminished or even brought into disrepute.

The proposed paramount duty of a regulator is to protect, promote and maintain the health, safety and well-being of the public: we believe this is best carried out in a totally independent, transparent and accountable manner, with all decisions being made by those who are both independent and seen to be independent of the registrants.

The functions of the regulators are, in the main, administrative and these are generally common to all healthcare regulators including the setting up and maintenance of a register and the dealing with FTP issues expediently and appropriately.

We are not convinced that these duties and responsibilities could not be discharged entirely by lay members with the proviso that experts could be consulted when expertise on the treatments or techniques used by registrants is required.

The functions that require input from those with knowledge of chiropractic and osteopathy include setting educational standards, assessing CPD and setting the Standard of Proficiency.

The Code of Practice and Standard of Proficiency published by the General Chiropractic Council states it is not its purpose 'to define the scope of chiropractic' and there is nothing in the Code of Practice that is dependent on a registrant actually performing any chiropractic function (even if that had been defined). It is all about behaviours and administrative matters.

It follows then that making judgements against the Code does not require any specialised knowledge of the practice of chiropractic (or, similarly, osteopathy) and many FTP cases could therefore be decided without any reference to treatments or techniques.

We do appreciate that there will be occasions where FTP panels do need to consider issues of correct and appropriate use of chiropractic or osteopathic practice. We suggest that any expertise and knowledge can be better obtained through experts — including those who may be registrants — rather than appointing some permanent registrant members of FTP panels.

This will also mean that any expert called by either party can be appropriately cross-examined, thus further ensuring that any advice given has been properly scrutinised.

In this regard, see also our response to question 9-2.

This will achieve an important degree of separation between the functions of the regulator and interests of registrants and we believe that this separation of potential conflicts of interest will enhance the standing of the regulator and the profession in the eyes of the public.

The Education Committee is a special case and there is clearly a need for registrant members to sit on this committee. However, particularly within chiropractic, there are competing 'philosophies' and we appreciate that these conflicts are not easily resolved.

It is not in the interest of being seen to be independent in the eyes of the public to have decisions made that could be influenced by those who may have vested interests. This is particularly the case where the constituency of both professions is so small as with the case of chiropractors and osteopaths.

In the interests of transparency, accountability and public confidence in the regulator, we therefore strongly recommend that there should be no registrant members holding positions on the General Council and statutory committees. Expertise in chiropractic and osteopathy should be provided by experts as and when required.

### *Provisional Proposal 2-3*

> The regulators should be given broad powers to make or amend rules concerning the exercise of their functions and governance without any direct oversight, including Privy Council approval and Government scrutiny (subject to certain safeguards).

For the same reasons as given above, we do not believe it is in the public interest to allow any such wide-ranging powers without careful and direct oversight unless our recommendations in our response to provisional proposal 2-2 are implemented and the regulator becomes largely independent of the registrants.

### *Question 3-1*

> Should the statute specify the paramount duty of the regulators and the Council for Healthcare Regulatory Excellence is to: (1) protect, promote and maintain the health, safety and well-being of the public by ensuring proper standards for safe and effective practice; or (2) protect, promote and maintain the health, safety and well-being of the public and maintain confidence in the profession, by ensuring proper standards for safe and effective practice?

We do not see it as beneficial for a regulator to maintain public confidence in the professions of chiropractors or osteopaths for the reasons we set out in the introduction.

We do, however, see it as a paramount duty of the regulator to maintain public confidence in the regulator itself. We believe that public confidence in the profession is an indirect result of good and impartial regulation.

Indeed, we do not see how public confidence in a regulator could even be accurately or meaningfully measured nor what steps a regulator might be expected to take to fulfil this duty that wouldn't put it in conflict with its other duties.

We therefore believe that any such action would raise serious concerns about conflicts of interest and impartiality and may have the concomitant effect of undermining public confidence in the regulator itself.

If, for whatever reason, the standing of the profession as a whole is diminished by its registrants or otherwise, then it would not be in the public interest for the regulator to intervene in any way and become involved in rehabilitating the profession in the eyes of the public.

The regulator would, of course, be involved in dealing with any complaints that may arise from such a situation, but this must, as always, be done with complete impartially.

We therefore recommend that statement (1) be adopted for the regulators of chiropractors and osteopaths.

### *Provisional Proposal 3-2*

> The statute should not include a statement setting out the general or principal function(s) of the regulators.

We agree with this proposal.

### *Question 4-6*

> Should: (1) the statute specify a ceiling for the size of the Councils of and the proportion of lay/registrant members; or (2) the Government be required to specify in regulations the size of Councils and the proportion of lay/registrant members; or (3) the regulators be given general powers to set the size and composition of their Councils and the Government be given default powers to intervene if this is necessary in the public interest?
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> Provisional Proposal 4-7: The statute should define a lay member of the Council as any person who is not and has not been entered in the register of that particular regulatory body, and a registrant member as any person who is entered in the register of that particular regulatory body.

For the reasons stated above, we do not see the need for the Councils to have any registrant members. Any expertise in chiropractic or osteopathy can be obtained as and when required through the use of expert advisors.

### *Provisional Proposal 5-25*

> The regulators should have broad powers to make rules concerning the content of the registers. The only exception to this approach would be that set out in provisional proposal 5-27.

### *Question 5-26*

> Should the regulators be given broad powers to annotate their registers to indicate additional qualifications or should this power be subject to certain restrictions?

We will address the provisional proposal and question together.

The public registers should contain only such information as would allow the public to identify a registrant (eg name, business address, registration number, phone numbers and website URL and registrant status and FTP sanction details).

The register should not contain, and the regulator should not have the power to add, annotations to the register that indicate additional qualifications or areas of expertise.

Because we believe there is no robust evidence for chiropractic and osteopathy as a whole, we cannot see that allowing the advertising in the register of additional qualifications or expertise will do anything other than further mislead and confuse service users and prospective service users into thinking that chiropractic and osteopathy have sound bases in science and evidence.

Additionally, the problem would arise as to what might constitute a qualification or area of expertise that could be approved by the regulator and determining this could place a considerable burden on the regulator. However, if the regulator took no part in approving such qualifications or expertise, annotating the register with them could lead to the public to believe that the regulator was, indeed, endorsing them. This could have serious consequences for liability.

Also, we do not believe it should be the function of a regulator to advertise any additional qualifications of registrants that are not qualifications in chiropractic or osteopathy.

### *Provisional Proposal 5-27*

> The statute should require all current fitness to practise sanctions to appear in the public register.

FTP panels do not impose sanctions lightly and we believe it is important that all sanctions are made public so that service users and prospective service users are fully informed about the status of a registrant.

We additionally recommend that the statute mandates minimum periods that each type of sanction must appear in the public register.

### *Provisional Proposal 5-28*

> The regulators should have discretion to include details of undertakings, warnings and interim orders in the public register (subject to the main duty of the regulators to protect the public by ensuring proper standards).

For the same reasons of transparency and fully informed decision-making, we believe that details of all undertakings, warnings and interim orders must be included in the public register.

### *Question 5-29*

> Should the regulators be required to publish information about professionals who have been struck off, for at least 5 years after they have been struck off?

Yes.

### *Question 5-30*

> Should the regulators be required to include in their registers details of all previous sanctions?

Yes.

### *Question 5-33*

> How appropriate are the existing protected titles and functions?

The current list of protected titles includes 'or any other kind of chiropractor/osteopath'. We are aware that there are many similar titles used such as 'osteomyologist', 'neurosteomyologist', 'spine/spinal specialist', 'spinologist', 'bonesetter' and similar and we understand that what they practice may be very similar to chiropractic or osteopathy.

We appreciate that the function of chiropractic or osteopathy is not protected (nor do we see how it could be, particularly given that spinal manipulations and mobilisations are also carried out by other regulated professions such as physiotherapists), but we believe the plethora of similar titles could cause confusion in the eyes of the public.

We therefore urge the Law Commissioners to consider the confusion that this might cause in the minds of the public and how the public could be better protected.

We understand that some training establishments award Doctor of Chiropractic degrees and that some chiropractors use the courtesy title 'Dr'. Many osteopaths also call themselves a 'Doctor of Osteopathy', even though none of the training establishments award doctorate degrees.

We are aware that the CoP of the GCC and the GOsC give restrictions on the use of 'Dr' or 'doctor', however, we believe this causes confusion in the minds of the public and that it is important that the public are not misled into believing that chiropractors and osteopaths are qualified medical practitioners.

We therefore recommend that the statute includes a provision to prohibit any chiropractor or osteopath from using the title 'Dr' or the prefix 'Doctor' or otherwise represent themselves as a qualified medical practitioner at any time unless they are also registered with the General Medical Council.

### *Provisional Proposal 6-3*

> The statute should require the regulators to establish and maintain a published list of approved institutions and/or courses and programmes, and publish information on any decisions regarding approvals.

It is in the interest of students and prospective students that full information about training establishments is published so they can make an informed decision about their choice of training provider. This should include full curriculum details, accreditation details, inspection reports, remedial actions required by the regulator, etc.

### *Question 6-8*

> Is too much guidance being issued by the regulators and how useful is the guidance in practice?

### *Provisional Proposal 6-9*

> The statute should require the regulators to issue guidance for professional conduct and practice.

We will address the question and the provisional proposal together.

Too little guidance is issued by the GCC and GOsC. We believe that guidance should be issued on the scope of practice for chiropractors and osteopaths. We further believe that the public cannot be protected unless there is clear guidance on what conditions can and cannot be treated by registrants.

In 2009, we saw claims being made by chiropractors (similar claims are made by some osteopaths) that they could treat conditions such as colic, sleeping and feeding problems, frequent ear infections, asthma and prolonged crying, hay fever, menstrual problems, OCD, Tourette Syndrome, dyslexia, arthritis, vertigo, eczema, emphysema, infection, ADHD, PMS, ADD, bed wetting, tinnitus and hyperactivity. We were not aware of any robust evidence for the treatment of any of these conditions by chiropractic or osteopathy.

Because of this, we believed they were misleading the public and in breach the GCC's CoP and we submitted formal complaints on over 500 chiropractors in June 2009.[8]

Despite the fact that the CoP specified that all advertising had to be "factual and verifiable" and "must not be misleading or inaccurate in any way",[9] the regulator had issued no specific

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[8] 'Omnibus Complaint to the General Chiropractic Council', *Zeno's Blog* <http://www.zenosblog.com/2009/06/omnibus-complaint-to-the-general-chiropractic-council/>.

[9] 'Code of Practice and Standard of Proficiency Effective from 8 December 2005' (General Chiropractic Council), para. C 1.6 <http://www.gcc-uk.org/files/link_file/COPSOP_Dec05_WEB(with_glossary)07Jan09.pdf>.

guidance on what the best available evidence suggested could or could not be treated by their registrants, nor to what standard its registrants would be held if challenged on these claims.

These claims have now largely — but not completely — disappeared from the websites of chiropractors and we consider that the public are now far better protected from misleading claims. It was unfortunate that this had to be done and see it as a complete failure of the regulator to monitor and enforce its registration requirements and a dereliction of its duty to protect the public as well a failure of its registrants to abide by the CoP and evidence-based principles.

It was as a direct result of this success that the Nightingale Collaboration was set up.

Although both the GCC and the GOsC have now issued guidance on advertising, we believe it is not specific enough and leaves too much room for interpretation by individual chiropractors who cannot be entirely dispassionate and who may not have the necessary skills with which to thoroughly evaluate the scientific literature.

We believe that it therefore must fall to the regulator to provide good quality tier one guidance to its registrants so that service users are treated according to the best available evidence.

To not give such guidance leaves service users and prospective service users unable to come to an informed choice about their healthcare treatments.

We therefore recommend that the statute requires the regulators to issue tier one guidance for advertising and practice and that this includes clear and specific guidance on what conditions it is and is not acceptable for registrants to treat or claim to treat. Such guidance must be based on the best available scientific evidence and must be reviewed regularly and independently to take account of new scientific evidence and meta-analyses.

All such guidance must be based on the principles of evidence-based practice as outlined by Sackett et al.[10]

Cognisance should also be taken of the scientific basis for the purported mechanism of action. This would exclude any acknowledgement of the 'chiropractic vertebral subluxation complex' as a basis for chiropractic[11] until such time as robust scientific evidence for its existence and role is available.

We are aware that chiropractors and osteopaths use a variety of treatments and not just chiropractic and osteopathic manipulations. These include dietary, lifestyle and exercise advice as well as advising and frequently supplying food supplements and other treatments. We are also aware that some registrants use diagnostic techniques such as applied kinesiology for which there is no robust evidence of effectiveness of diagnostic capability.

The use of these additional treatments by registrants and particularly whether they fall within the remit of the regulator and are included within the scope of the CoP is not clear. We therefore recommend that the position is clarified and the regulators required to publish guidance.

The paramount function of regulation is to protect the public and that can only happen if they have reliable independent information with which to make an informed choice for their healthcare treatments. Not being informed of the lack of robust evidence for most chiropractic and osteopathic treatments does not serve that paramount function.

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[10] D. L Sackett and others, 'Evidence Based Medicine: What It Is and What It Isn't', *BMJ*, 312 (1996), 71–72 <doi:10.1136/bmj.312.7023.71>.

[11] General Chiropractic Council, 'Guidance on Claims Made for the Chiropractic Vertebral Subluxation Complex', 2010 <http://www.gcc-uk.org/files/link_file/Guidance_on_claims_made_for_the_chiropractic_VSC_18August10.pdf>.

We believe that it is in the interests and safety of service users and prospective service users that any and all diagnostic techniques, treatments and advice given must be based on sound scientific evidence and principles and we recommend that a duty for the regulator to issue such binding guidance be included in the statute.

### *Provisional Proposal 6-12*

> The statute will require the regulators to ensure ongoing standards of conduct and practice through continuing professional development (including the ability to make rules on revalidation).

We agree with this proposal but would recommend that CPD specifically places a duty on the registrant to review and take account of new scientific evidence and meta-analyses and that all practice must be based on the consensus of sound scientific evidence.

### *Question 8-1*

> Should the new legal framework remove the concept of an allegation entirely and instead give the regulators broad powers to deal with all information and complaints in such manner as they consider just (subject to a requirement that cases where there are reasonable prospects of proving impairment must be referred for fitness to practise proceedings)?

Yes.

### *Provisional Proposal 8-2*

> The statute should provide that all the regulators will be able to consider any information which comes to their attention as an allegation and not just formal complaints.

We agree with this proposal.

### *Provisional Proposal 8-5*

> All the regulators should have the power to establish a formal process for the initial consideration of allegations (such as screeners).

We agree with this proposal with the condition that the screening is conducted solely to screen out any allegations that do not fall within the remit of the regulator and that they make no other judgement as to the merits of the allegation or on the evidence for that allegation.

### *Provisional Proposal 8-6*

> The regulators should have the power to prohibit certain people from undertaking the initial consideration of allegations and specify that only certain people can undertake this task.

We agree with this proposal with the proviso that the person undertaking this initial screening is not a registrant.

### *Provisional Proposal 8-7*

> The regulators should have powers to establish referral criteria for an investigation and specify cases which must be referred directly to a Fitness to Practise Panel.

We disagree with this proposal. We believe that consistency across regulators is essential and that if this consistency is not achieved, the public will see the resulting disparity as some professions being held to lower standards than others — we do not believe this can be good for public confidence in that regulation.

### *Question 8-8*

> Should the statute impose more consistency in relation to the criteria used by regulators to refer cases for an investigation or the cases that must be referred directly to a Fitness to Practise Panel?

Yes.

### *Provisional Proposal 8-15*

> The statute should provide that the test for all referrals to a Fitness to Practise Panel across the regulators is the real prospect test.

We do not agree with this proposal. We believe that there is a danger that allegations could be dismissed before sufficient investigation has carried out.

We believe this could also be seen as a lack of transparency and accountability because of possible bias and conflicts of interest.

We recommend that any allegation that falls within the remit of the regulator should be fully investigated and put before a FTP panel.

### *Question 9-2*

> Should the new legal framework ensure the separation of investigation and adjudication, and if so how?

Yes. We strongly believe this will give an essential degree of separation between the functions of investigation and adjudication that will further enhance the credibility and independence of the regulators in the eyes of the public. Such independence can only be good for justice. We also believe this will bring consistency across regulators and economies of scale.

This separation of function goes a long way in allaying our concerns about the perception of bias within regulators we expressed earlier. However, for similar reasons, we would also recommend that investigations are carried out by an independent body.

### *Provisional Proposal 9-6*

> The statute should require each regulator to establish Fitness to Practise Panels of at least three members for the purpose of adjudication.

We agree with this proposal.

### *Provisional Proposal 9-7*

> The statute should: (1) require the regulators to establish a body which is responsible for all aspects of the Fitness to Practise Panel appointment process and which is separate from the Council; and (2) prohibit Council members and investigators from membership of Fitness to Practise Panels; and (3) require that each Fitness to Practise Panel must have a lay member.

(1) We agree with this proposal.
(2) We agree with this proposal.
(3) We agree with this proposal, but further recommend that no registrants are members of FTP panels. Any specialist knowledge required can best be obtained from appointed expert advisors or expert witnesses called and open to cross-examination.

### *Further recommendations*

1. We recommend that the regulators be required to publish details of the risks associated with the treatments offered by registrants.
2. We recommend that the regulators be required to set up and maintain an adverse event reporting system that can be used by both registrants and service users; that registrants are required to report all adverse events and that they inform service users of this system. We further recommend that the regulators be required to review the data so gathered regularly, to publish anonymised but detailed summaries and to act on any specific incidents and trends as appropriate.