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16/5/11

Prof Warwick Anderson
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Australian Health Ethics Committee
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Dear Prof Anderson, Dr Hacker and members of the AHEC,

I understand that your 'DRAFT NHMRC Public Statement on Homeopathy' came unintended by yourselves into my email. I read it with surprise, because it suggests your organisation could be better informed in this matter. I discussed the matter with a member of your staff, who said you had no intention of discussing it with representatives or experts in the homeopathic profession. I wonder if you have given adequate consideration to the reliability of the conclusions of the UK House of Commons Science and Technology Committee's (CSTC) Evidence Check of Homeopathy (1). Your document provides no suggestion that the NHMRC is basing its position on its own investigation, which would be a sad state of affairs for Australia's peak medical research body, and could be construed as harking back to a British colonial approach to business. This letter is intended to provide you with some perspective, coming from a group of doctors who use Homeopathy in practice.

There are a number of reasons why the CSTC conclusion (that Homeopathy's clinical effects are no more than placebo effects) is unjustified:

a) Science is not based on what people believe is possible or not possible, rather it relies on data and its appropriate analysis. Meta-analyses are at the top of the pecking order of clinical evidence. They deserve this status only when certain criteria are fulfilled. Systematic reviews may be done with or without meta-analysis, depending on whether the investigator has adequate information to do a formal analysis. Something is not rigorous evidence just because it is called a meta-analysis or systematic review. The ideal meta-analysis is one that is designed prior to the prospective studies (on which it is based) being performed. When meta-analysis is performed retrospectively, it needs to be based on identical studies, or at the very least on very similarly designed studies with similar end points. This necessity is based in statistical theory. The more disparate the studies are, the more assumptions must be made about how to do the analysis; the more speculative the results of the analysis or review becomes. A poor quality meta-analysis can come to diametrically opposite conclusions with minor changes in assumptions, and therefore provides unreliable evidence. Homeopathy comprises many different practices, and the studies collected in reviews to date comprise many different methods and experimental designs. The best quality evidence available at the moment is in the positive statistical association demonstrated by various double-blind randomized controlled trials or blinded randomized controlled laboratory studies. There is no data which demonstrates that homeopathic medicines in general are inactive, although there are specific studies that failed to show efficacy of certain remedies under certain conditions. The studies which have been clumped together in reviews and meta-analyses retrospectively to date are inferior evidence, and lack the homogeneity

to be used for negation of the evidence of positive RCTs and clinical/laboratory studies. (2)

b) Para 69 describes that the CSTC was most influenced by Shang et al's (3) conclusion. Unfortunately, while these authors purported to be designing a review methodology to eliminate publication bias from skewing analyses of homeopathy RCT's, they introduced their own bias into their analysis. "Professor Eggers stated at the onset that he expected to find that homeopathy had no effect other than that of placebo." (4). The CSTC failed to note the unrefuted criticisms of this trial (5,6), which were presented to them in evidence. Quality was assessed differently from previous analyses, and the only conclusion that can be drawn, relating to their predefined hypotheses, is that for the trials chosen, quality of homeopathic trials is better than for conventional trials. The subgroup of homeopathy trials used for the final analysis was not comparable with the group of conventional trials: cut-off values for larger trials differed between the homeopathy and conventional group andShang's conclusion was based on 8 trials on 8 different indications, which were also not matched with the conventional trials. The result was highly dependant on the cut off point for defining 'larger trials', as well as their subjective decisions about what constituted higher quality, and they did not include a sensitivity analysis to justify the validity of the choices they made in constructing their analysis. Shang also excluded some homeopathy trials because he could not find a matching conventional trial eg Wiesenauer's trial on polyarthritis (7) is a larger trial that could have altered their results. Shang also chose to disregard safety, including trials on some conventional treatments that are no longer available because of serious adverse events. Shang's negative results were largely due to one trial on preventing muscle soreness in 400 long-distance runners, a contraversial prophylactic use of the remedy, not usual in clinical practice. In fact 5 other of the 8 large trials used in the final analysis gave the same homeopathic medicine to every subject, regardless of their individual symptoms. Only in unusual circumstances would homeopaths be likely to use these remedies in these clinical situations, one of which was the use of Thyroidinum (a remedy made from thyroid tissue) to induce weight loss. To make valid conclusions about homeopathic practice, one needs to use research that can validly be generalized to clinical practice. Shang ignored this necessity. Consequently Shang's conclusions were not supported by the data, only by his group's biased interpretation of it. One has to ask how the study ever made it through the Lancet's editorial board, also because some of the crucial information (on which some of the criticisms are based) was not included in the publication, eg which 8 trials were used for the analysis! It took 6 months for Shang et al to release this information, time enough for their intended media damage to be achieved. (6 yrs later those 6mths are still having their repercussions!) Considering also that publication's rejection of Ludtke & Rutten's subsequent critique, which is greater, Shang's sham, or the Lancet's shame?

c) In their rush to reach a conclusion, the CSTC failed to consider at least 11 RCTs (noted in the written submissions), which were published subsequent to all the trials considered by Shang et al. Eg one of which (8) shows highly significant results in favour of giving certain intubated patients in ICU a homeopathic remedy based on Potassium bichromate, resulting in a reduction of length of stay by an average of 3 days. This could translate into saving $1000s/patient, and increasing bed availability.

d) The CSTC claimed to be considering the evidence that homeopathic preparations were not placebos, yet completely ignored written evidence submitted by Dr Peter Fisher (HO21) concerning laboratory experiments demonstrating activity in ultradilutions in contexts where the placebo effect is unlikely to be a confusing factor.

e) It appears that the CSTC had the characteristics of a kangaroo court, dancing to 'Sense about Science's' tune. Supporting this conclusion are the fact that they gave contributors a mere 17 days to prepare and submit their evidence, and 60 written submissions and 2 days of hearings were collected by the end of Nov2009. From then to 8th Feb 2010 the CSTC constructed their report of 275 pages, which includes reference to hundreds of scientific articles. One wonders how a group of politicians could do justice to that volume of unfamiliar material in that time frame. The limited breadth of their enquiry (HO46), a - d above, and the analysis of the committee's membership and voting patterns(9) support this conclusion. The report was 'ratified by 3 MPs: 2 of whom were not present at the committee meetings – and one of the two was not even a member of the committee when the hearings were held' and the third has an open history of his predjudice against homeopathy. 1 member was opposed, and a fifth abstained. The other 9 members of the CSTC were not present and provided no indication of their position.

f) Although the CSTC can be excused for not considering trials published after their data collection period, you can not be so excused. In one journal (Homeopathy) I note 5 original research articles which provide evidence against your proposed conclusion (10-14). That is just the first source I have looked at.

g) A consultation aiming at prescribing homeopathy goes beyond collecting the information required to diagnose the pathology (mental or physical), attempting to understand why the patient has become ill, and what is peculiar to this individual in the disease. This information assists in finding the appropriate remedy, but it also takes the patient on a reflective journey, which may add to the healing potential. It may be difficult to be sure whether the consultation, or the remedy taken, initiates the healing process. Most RCTs have compared the homeopathic remedy with a placebo, and there has been little investigation aimed at comparing the consultation's therapeutic potential with standard medical consultations. Trials that fail to investigate this may fail to detect treatment success. Indeed the CSTC makes the point: 'Homeopathic consultations may therefore have a positive impact on patients' perception of the intervention and result in a more powerful placebo effect.' (15) The report goes on to ignore the utility of this benefit, (and the lack of research into it) as if to say that patients should be denied this healing potential because it is unethical as a placebo effect. Should we not be trying to maximise the healing effect of our interaction with our patients, improving our 'bedside manner'?

NOTE that **the UK Parliament chose NOT to act on the recommendations of the CSTC.** That body felt that it was important to preserve the right of an informed patient to choose their own treatment.

The public statement that you are proposing is ill considered, and is aimed at undermining the practice of Homeopathy. Much evidence was presented to the CSTC concerning the

effectiveness of Homeopathy in clinical practice, and the cost effectiveness compared to standard treatment(16). The CSTC ignored all of this, because they said it was outside the remit of the ethical issue they were focussed upon. You appear to be following their lead. However, government and private health insurers would do well to examine it closely, because the companies behind the skeptics and detractors of Homeopathy are aiming to remove marketplace competition, so they can sell more drugs. One wonders why Homeopathy's detractors are so concerned about the 0.004% of the UK NHS budget that Homeopathy consumes, when there are much larger pickings to be found in other areas of modern medicine, eg minimising iatrogenic disease (the third largest killer in the USA). Perhaps to keep the regulators occupied with the small fry, while business continues as usual. Maybe they're disturbed by an inaccessible growing market of patients who use Homeopathy. Maybe they have a variant of OCD which directs them to attempt to stamp out what they can't understand. Or perhaps it is because they have been spooked by the placebo effect itself, which seems to be growing, making it harder to get drugs to market (17).

Much of general medical therapeutics in use today also lacks an evidence base according to the BMJ (18). 'Of around 2500 treatments covered 13% are rated as beneficial, 23% likely to be beneficial, 8% as trade off between benefits and harms, 6% unlikely to be beneficial, 4% likely to be ineffective or harmful, and 46%, the largest proportion, as unknown effectiveness'. Why single out Homeopathy, when it has a stronger evidence base than 50% of those treatments?

Let us change focus from the rarefied world of statistics and clinical trials, to the space involving the patient and clinician. Using homeopathy, we have all experienced clinical situations where a patient with acute illness has responded well, or their warts have disappeared within a week, or a chronic illness the patient has strugged with for years has settled down. I have occasionally seen homeopathy reverse pathology, that I did not expect to be possible eg osteomyelitic bone loss, or neurodegenerative disease. We know that this isn't necessarily the action of the remedies, it could be spontaneous remission, or it could be the effect of the interpersonal relationship (which presumably is somehow more potent than that of the other doctors previously consulted). We are aware that 10% of the Indian health system functions with homeopathy, including hospital medicine. That's around 100 million people in India alone, who make use of Homeopathy; and it's not just the poor and perhaps less educated, it is used throughout the society. The WHO considers Homeopathy to be the second most internationally used medical discipline. It is a relatively safe and cheap system of therapeutics, which adds to its attractiveness. Adding homeopathy to a medical practice is certainly challenging, but for many reasons is interesting and enjoyable. As GPs, our members can attest eg that our use of homeopathic remedies reduces our reliance on antibiotics (and other drugs), assisting the effort to contain the spread of resistant bacterial strains, and diminishing some govt expense through the MBS. For most of us, it has been our experiences rather than clinical trial results that have led to our use of Homeopathy. We applaud those with the perseverence to conduct clinical trials, but our knowledge of the effectiveness of Homeopathy does not rest there. We understand that it is an individual case phenomenon. One cannot guarantee results. One has to work with the healing potential of the patient, and it is an art as well as a science. This is the background to the frame of mind with which the homeopath generally approaches a consultation. There are a few variables that together create the scenarios relevant to the question - Is it ethical to practice homeopathy in this case?

Following are examples:

a) Patient wants to be managed homeopathically because of good prior experience, or referred by another patient/wants 'natural' treatment/ doesn't care what treatment, but has heard we can help him/wants some treatment that has been proven to work.....
b) After taking the case I assess Homeopathy has a good/moderate/poor chance of helping
c) There are several other therapeutic options which have /have not been already tried, and they have significant/insignificant side effect risk and are financially possible/difficult/impossible.

As clinicians we make decisions with every patient concerning whether or not to use Homeopathy. I hope it has become evident that this does not resolve itself with a universal answer from a distant bureaucrat; it requires individualisation, and our patients appear to understand that, indeed they sometimes express their appreciation of it.

Concerning the placebo response. There are people who are healers, who use their consciousness and 'energy', possibly through their hands, to induce healing. They are sometimes referred to as 'faith' healers. Are the 'faithful' responding via a placebo effect (ie their faith in the treatment) and if so, is this therefore unethical practice? The consultation is an essential part of the process of connecting the remedy to the patient, if it contributes to the healing power of the remedy, what part of this process is unethical? So long as the patient and clinician accept that there is a degree of unknown about this process, and the clinician is not willfully misleading the patient for the clinician's benefit, we are satisfied that we are behaving ethically.

Your proposed response indicates a lack of independent enquiry and thought, accepting other's conclusions with a minimum of critical examination, about a subject of which you appear to have little experience. To come out with a public statement on this basis, degrades the good name of the NHMRC into nothing more than a common news service. I urge you therefore to abandon the proposed Statement. If you decide to develop your understanding in this area, you could start with the Memorandum submitted by the Complementary Medicine Research Group, University of York (19) and the BHA's response to the CSTC (20), both of which provide some balance to the CSTC's conclusion and recommendations. You could also discuss the matter with experts in the field of Homeopathy. Indeed it is worth considering the ethics of releasing a statement of the nature you are considering, without such consultation. As well you could extend to Homeopathy your usual business of assisting further research.

Yours sincerely,

Dr Nick Goodman

1. http://www.publications.parliament.uk/pa/reports_200910.htm

2. My thanks to Dr Michael Kuzeff for the basis to this paragraph (a).

3. A Shang, K Huwiler-Muntener, L Nartey, P Juni, S Dorig, J A Sterne *et al.* "Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy", *Lancet,* vol 366(2005), pp 726–732

4. EHM News Bureau. Condemnation for The Lancet's Stance on Homeopathy. Express Pharma Pulse, October 6, 2005.

5. Ludtke R, Rutten AL. The conclusions on the effectiveness of homeopathy highly depend on the set of analyzed trials. *Journal of Clinical Epidemiology*. 2008, 61(12):1197-204.

6. Rutten AL, Stolper CF. The 2005 meta-analysis of homeopathy: the importance of post-publication data. *Homeopathy*. 2008, 97(4):169-77.

7. Wiesenauer M. Gaus W. Wirksamkeitnachweis eines Homoopathikums bei chronischer Polyarthritis. Eine randomisierte Doppelblindstudie bei niedergelassenen Arzten. *Aktuelle Rheumatologie* 1991;16:1-9 .

8. Michael Frass, Christoph Dielacher, Manfred Linkesch, Christian Endler, Ilse Muchitsch, Ernst Schuster and Alan Kaye. Influence of Potassium Dichromate on Tracheal Secretions in Critically Ill Patients *Chest* 2005;127;936-941 http://chestjournal.chestpubs.org/content/127/3/936.full.html

9. http://vonsyhomeopathy.wordpress.com/2010/02/27/stop-funding-nhs-homeopathy-mps-urgewho-are-these-mps/#more-293

10. I Camerlink et al. Homeopathy as replacement to antibiotics in the case of E coli diarrhoea in neonatal piglets *Homeopathy* (2010)99, 57-62

11. D F Naude et al. Chronic primary insomnia: Efficacy of homeopathic simillimum *Homeopathy* (2010)99, 63-68

12. A Banerjee et al. Chelidonium majus 30C and 200C in induced hepato-toxicity in rats *Homeopathy* (2010)99, 167-176

13. R Hofbauer et al. Heparin-binding epidermal growth factor expression in KATO-111 cells after H. plori stimulation under the influence of strychnos Nux vomica and calendula officinalis *Homeopathy* (2010)99, 177-182

14. R Spin-Neto et al. Homeopathic Symphytum officionalis increases removal torque and radiographic bone density around titanium implants in rats *Homeopathy* (2010)99, 249-254

15. CSTC Page 22 Para 81 c)

16. CSTC evidence HO 04, 09,15, 22, 23, 27, 29, 35, 48

17. http://www.wired.com/medtech/drugs/magazine/17-09/ff_placebo_effect

18. http://clinicalevidence.bmj.com/ceweb/about/knowledge.jsp

19. http://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/memo/homeopathy/ucm2402.htm

20. http://www.homeopathy-soh.org/whats-new/documents/STparts1-6forpdf.pdf