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Letter to the editor and the editor's response

Epistemology and the ethics of homœopathy: a response to Freckelton

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The death of two patients in the care of Australian homœopaths is undeniably tragic and reflects poorly on the homœopathic profession at large. While Freckelton admits that it is not fair to judge a profession by its worst practitioners, this is precisely what he has done.^[1] If the same argument were applied to all Australian hospitals, in which there are an estimated 18,000 deaths each year due to adverse events or medical errors,^[2] then the public could be expected to lose confidence in conventional medicine. Generalising risk by citing extreme examples does not facilitate healthy debate or consideration of the deeper epistemological and ethical issues. While addressing Freckelton's valid concerns, we believe that the appropriate practice of homœopathy is epistemologically robust, ethical and empirically sound. Furthermore, while debate continues on definitions of evidence and the appropriate delivery of health care, we argue that the deliberate exclusion of certain forms of evidence, including positive patient outcomes measured according to different quantitative and qualitative criteria, inappropriately constrains individuals' rights to select models and methods of health care according to their values and to the goals that they wish to achieve.

Epistemology, evidence-based medicine and homœopathy

Freckelton acknowledges that the use of homœopathy has grown in recent years, particularly in Western countries. The suggestion, however, that homœopathy has benefited merely from disillusionment with Western medicine misrepresents the fact that homœopathy has been sought and practised around the world for 200 years,^[3] rather than merely supported by aristocrats and the monarchy, as he asserts. Successful outcomes, experienced and reported by thousands of patients,^[4] have in all likelihood driven the demand for, and spread of,

homœopathy.

Of more concern, however, than the challenges to homœopathy, are the attempts to discount and suppress alternative worldviews and forms of evidence that are not easily understood or explained from within the paradigm of orthodox Western medicine.^[5] In India, as Freckelton acknowledges, homœopathy remains a *mainstream* form of health care, used by hundreds of millions of people. Traditional Chinese medicine and Ayurvedic medicine have been regarded with similar epistemic scepticism, despite substantial clinical evidence. Rather than engaging with these non-orthodox epistemologies, Freckelton pillories the homœopathic profession, its origins, tenets and principles, suggesting that homœopathy at large is a danger to the public.

In focusing on the *Sam* and *Dingle* cases in Australia, Freckelton adopts an approach more consistent with casuistry and rhetoric than with science and medicine – arguing, if you want, beyond the data or, to some extent, in spite of it. His argument^[6] that homœopathy deserves virulent criticism, because its tenets and methodologies do not conform to the scientific principles of evidence-based health care, privileges mainstream medical interventions, among which even the British Medical Journal acknowledges only 11% are conclusively efficacious.^[7] We fail, perhaps fear, to recognise that the best of evidence-based medicine may only confirm the efficacy of a limited range of interventions. Despite this admission, we have become saturated with the epistemic authority of evidence-based medicine through its medical, social and political entrenchment. The commitment to evidence-based medicine has become a commitment to a particular sort of intellectual hegemony.^[8]

We do not dispute that homœopathy should conform to the highest standards of safety, excellence in care and rigorous testing demanded of conventional medicine. We will contend that the testing to which homœopathy has been subjected within the biomedical evidence-based medicine hierarchy provides some evidence that this approach is more effective than placebo. Freckelton cites the United Kingdom House of Commons Select Committee Report, which states that there is no evidence for homœopathy but he does not reference the 2011 Swiss Government report,^[9] which found compelling evidence for homœopathy and recommended its integration within the Swiss health care system. The limited number of randomised controlled trials in homœopathy means that reviews can be used to demonstrate that homœopathy has an effect, or no effect, beyond placebo.

The central issue here is the definition of evidence. Evidence-based medicine has been criticised for excluding non-epidemiological forms of evidence including qualitative research, clinical expertise and patient experiences.^[10] Different study designs provide support for homœopathy. As Sackett^[11] has argued in relation to conventional medicine, diverse forms of evidence from different types of studies are necessary to answer different questions, such as

non-experimental cohort studies, outcomes or effectiveness research, as well as expert clinical judgment.

If we were to accept an evidence-based medicine paradigm to examine the hierarchy of evidence for homœopathy, there are meta-analyses and statistical reviews,^[12] randomised controlled trials,^[13] large outcome studies,^[14] and laboratory studies,^[15] many of which demonstrate that homœopathic medicines have an effect beyond placebo. There have been six comprehensive systematic reviews regarding homœopathy since 1991.^[16] The conclusion for all but the Shang study was that homœopathy has a specific and positive effect greater than placebo. Shang's meta-analysis^[17] highlights how failure to assess for false-negative bias can result in misrepresentation of evidence.^[18] Re-analysis of Shang's post-publication data did not support the conclusion that homœopathy is a placebo effect.^[19] That some meta-analyses have shown positive evidence for homœopathy is interesting, given that studies in homœopathy tend to be extremely heterogeneous, which makes meta-analysis problematic as a higher-level method of evidence gathering. Although the meta-analysis by Linde^[20] did not find homœopathy clearly efficacious for any *single* clinical condition, Freckelton omits Linde's conclusion that the results were *not* compatible with the hypothesis that the clinical effects of homœopathy are completely due to placebo. Linde recommended further rigorous large-scale studies.

While randomised controlled trials are undoubtedly the gold standard for single pharmacological interventions, for complex interventions like homœopathy, in which treatment is individualised, there are a variety of non-local variables^[21] to be taken into account; thus the validity of randomised controlled trials for homœopathy becomes less clear.^[22] Randomised controlled trials measure for efficacy against placebo (relative effects) in an artificial experimental setting. They do not measure the absolute statistical differences in treatment effects or experiences in a clinical setting, which are ultimately what matter to the patient, as well as side effects, costs and the longevity of therapeutic effects.^[23] The results of meta-analyses and systematic reviews of homœopathy are inconsistent due to the heterogeneity of studies. There are systematic reviews for single conditions such as rheumatic diseases and hay fever that are positive for homœopathy.^[24] There are also systematic reviews which demonstrate little or no efficacy in homœopathy, e.g. in the treatment of cancer.^[25] Clearly, homœopathy is not equally efficacious for all conditions.

Randomised controlled trials are important, but the preference for this type of evidence to the exclusion of other forms of knowledge is problematic. Many randomised controlled trials lack external validity,^[26] meaning while they have appropriate internal validity, reducing the possibility of bias, they are often not testing what happens in practice, where prescribing is based on the individualising characteristics of the patient.^[27] Very little innovation in health care

has come about through randomised controlled trials; rather, evidence-based medicine brings about marginally effective treatments based on population averages. Berwick's call for expanding epistemology is based on the experience through which the acquisition of knowledge occurs. He asks, Did you learn Spanish by conducting experiments? Did you master your bicycle or your skis using randomised trials? Are you a better parent because you did a laboratory study of parenting? ^[28] Clearly, a significant range of human skills do not demand randomised controlled trials in order to validate their acquisition or applicability. ^[29] The same logic can be applied to the epistemology and development of clinical expertise. Practice knowledge and skills development require practical experience. The different approaches in homœopathic practice can add complexity to the selection of suitable research methodologies.

Some Cochrane reviews have recommended that, as well as randomised trials, there is a need for observational data to document the different methods of homœopathic prescribing and how patients respond. ^[30] Tonelli ^[31] asserts that evidence-based medicine should include empirical and experiential evidence, as well as patient goals and values in conjunction with the best current evidence from randomised studies. Homœopaths are trained to recognise, locate and incorporate each of these levels of evidence, within the context of whole patient-centred care. In claiming the legitimacy of empirical and experiential forms of evidence, some mainstream health professions such as psychotherapy ^[32] face a similar predicament.

Professional homœopaths value a combination of the best available research along with subjective patient narratives, these being the vehicle within which a patient's health and disease are experienced. Although not privileged in the accepted evidence-based medicine hierarchy of evidence, homœopaths place great emphasis on patient experience. This includes patient self-reports of improvement. Homœopaths acknowledge that health can be measured in many ways, that health goals can be very broad, and that different outcomes and processes in health may be valued very differently. Large-scale outcome studies from homœopathic hospitals show that 70% of patients report improvement in symptoms and wellbeing. ^[33] The majority of these patients try homœopathy as a last resort, and yet have not had such a response from conventional treatment, where hope and expectation might be higher. This clearly challenges what we know about placebo response. We believe it is remarkable that patient experiences do not constitute evidence in the accepted epistemology of evidence-based medicine. Considering the doubt cast over evidence-based medicine's claim to epistemic and moral authority, Kerridge ^[34] argues that the ethics of evidence-based medicine itself ought to be subject to a critique of its social, cultural and political implications: evidence-based medicine is clearly not infallible.

Ethics and the claim that homœopathy is not an ethical system of health care

While the claims that homœopathy is epistemically baseless and inefficacious have been critiqued, the proposition that homœopathy is unethical and poses great risk demands our careful attention. Homœopathy, like other health care modalities, including conventional medicine, is a dynamic and constantly changing system. Its theories, strategies and practices undergo processes of revision and internal critique in an effort to improve them. The claim that homœopathy is unethical is unreasonable: from any vantage-point, e.g. rights-based, consequentialist, virtue-based, feminist. Homœopathy, as a field of practice, rather than as the actions of a single practitioner, is ethical because the action is aimed at restoring health, it is practised in good faith, with the consent of the patient and may achieve valuable outcomes. Homœopathy also privileges the patient's values and narrative and gives great attention to mutual processes and communication. Patients' experiences of feeling better and homœopaths' observations thereof may be evidence that patients are, in fact, getting better. If these premises can be accepted, and if no harm is done to anyone – or at least does enough good to justify the harm – then homœopathy is no less ethical than conventional medicine, which also has its own (specific and flawed) ways of deciding that people are better, and although it causes some harm, does not cause enough harm to outweigh the good. In the case of homœopathy, there are limited data regarding the harm caused and some data regarding the benefits (data which do not include patient outcomes or reports), particularly if we were to include broader notions of health and wellbeing. We believe that expanding evidence to include patient experiences, outcomes and preferences demonstrates an intrinsic ethical commitment and response to our patients' needs.

The link Freckelton draws with particular poor outcomes, such as the *Sam and Dingle* cases, might be made against any method of health care and is not therefore a valid epistemological critique of homœopathy exclusively. What, therefore, is unethical about the practice of homœopathy? Does the harm of isolated, extreme examples of homœopathic practice outweigh the benefits? Hardly, as Freckelton concedes. Many medications do not work for a lot of people and in the face of negative media coverage and scepticism from many conventional medical practitioners and the Friends of Science and Medicine (FSM), patients continue to turn to homœopathy. To imply that such patients are gullible and are being deceived does them a great disservice. Such a paternalistic stance challenges the view that the vast majority of patients are competent to be autonomous with respect to their own health care.

If homœopathy were charged with false claims, then the same would true if conventional medicine were to make false claims; nevertheless, this does not make conventional medicine unethical, only such claims. If homœopathy is charged with producing adverse effects, this is not a valid ethical argument, as the same is clearly true of conventional medicine, which often causes adverse effects yet does so in the pursuit of valid health goals; and only with the

informed consent of the patient, which is also the case for the homœopath. If it were claimed that homœopathy prevents appropriate care, this would also be true for conventional medicine; this may be a valid ethical critique of certain obstructive individuals, but not of the entire field of practice. Homœopaths are not expected to diagnose, but are trained to refer patients for diagnosis as well as for conventional care. If homœopaths were charged with lacking moral virtue, by which the field of practice is determined unethical, this would be impossible to sustain, as Freckelton has asserted.^[35] If it is claimed that the outcomes of homœopathy are harmful, either in all situations or in aggregate, then that is an empirical claim, which we have already suggested has no basis.

The problem in making an assessment of ethics is that Freckelton judges the field of practice rather than specific practices (which may be justifiable), specific behaviours (which may be unethical) or specific people (who may behave unethically). The latter judgments are fair and would apply equally to conventional medicine, and have led to the development of a system of laws and a regulatory framework. The former judgment, that the entire field of practice is unethical, is baseless and relies on a flawed understanding of both ethics and empirical data.

Conclusion

To prohibit homœopathic practice and research in Australia, as appears to be the remit of the FSM and the intention of the National Health and Medical Research Council, would be counterproductive to science, to the values of critical inquiry, to public discourse, as well as to patient autonomy. A judicious professional homœopath would not suggest the exclusive use of homœopathy or CAM therapies when conventional medicine and surgery are clearly preferred. Patients will continue to seek homœopathic treatment, and attempts to prevent patient choice, restrict appropriate clinical practice and limit research that may prove or disprove homœopathy would seem unnecessary and unjustifiable and may have the unintended consequence of increasing the potential risks that are highlighted in Freckelton's column.

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The editor's response

I welcome the constructive dialogue generated by the Levy and Gadd response to my column about legal issues latterly arising in relation to homœopathy. However, the debate that has emerged following my column needs to grapple with more than the Australian cases that were discussed. The English *Viegas* and Indian *Patel* cases that were also described in detail deserve attention as the results for patients from the errant practices in each were also fatal. Unfortunately, the issue is that when homœopathy substitutes for orthodox medicine, rather than acting as a benign placebo, or theoretically as a therapeutic agent, all too many cases have demonstrated the potentially fatal consequences. An important issue that arises from homœopathy cases in which patients have died transcends homœopathy and questions what are the responsibilities of complementary medicine practitioners when they proffer treatment for serious medical conditions for which they know or should know there are orthodox medical treatments.

Since the writing of the column, other developments have taken place which emphasise the need, especially in Australia, for homœopathy to do that which too often it has not done until now – function conservatively within its limited scientific base. In Australia's federal budget of 2012 there has been a crack down on taxpayers' funds being used to subsidise natural therapy services, except when there is clear evidence they are clinically effective ... Services that could be ineligible for the health insurance rebate include naturopathy, aromatherapy, ear candling, crystal therapy, flower essences, homeopathy, iridology, kinesiology, reiki and rolfing.^[1]

This is likely to impose an onus, legitimately, on homœopathy, among other health disciplines, to demonstrate their clinical efficacy.

In addition, in a decision handed down on 11 May 2012, Australia's most important appellate ruling was given on the potential for misleading representations about health services to constitute a breach of consumer protection legislation. In [*Noone, Director of Consumer Affairs \(Vic\) v Operation Smile \(Australia\) Inc \[2012\] VSCA 91*](#),^[2] the Victorian Court of Appeal made a very strong ruling in relation to the need for accuracy in what is communicated about such services. Its applicability to homœopathy is strikingly apparent. Justice Nettle, for instance, observed (at [60]):

A statement is misleading or deceptive or likely to mislead or deceive within the meaning of s 9 of the [*Fair Trading Act*] if there is a real and not remote possibility, be it more or less than a chance of 50 per cent, of the statement leading into error the readers at whom it is directed.

The court found that multiple statements of the Hope Clinic run by the disgraced dentist Noel Campbell in relation to its unorthodox cancer treatments were misleading and deceptive.

What has been absent in the responses of proponents of homœopathy to the debate following my column has been a scientific explication of how the processes of dilution and potentisation could possibly be efficacious, other than by reason of the trust reposed in them by those paying money for them and trusting in them, as well as how the procedures for provings have any potential for being rigorous and scientifically defensible. Rather, the critique has tended to be that allopathic medicine too has its fallibilities and is not always as evidence-based as it should be. This is a perfectly reasonable proposition. So too is criticism of Big Pharma for its excesses. But it does not justify the absence of an identifiable scientific base for homœopathy.

While patient satisfaction with any form of complementary medicine is a relevant consideration in evaluating its contribution to health care, it is not an objective or a sufficient yardstick. The numbers of persons who were satisfied by Dr Brinkley's transplantation of goat gonads to enhance virility during the Depression ^[3] is testament to the capacity for the public to be gulled by false promises. Misplaced hopes and aspirations can render vulnerable people even more vulnerable as patients. The fact that conventional medicine has had its own scandals also does not establish the scientific legitimacy of homœopathy. Nor does the fact that the class action litigation of *Gallucci v Boiron, Inc* Case No 11-cv-02039 (SD Cal) brought against a major French purveyor of homœopathic products was settled in 2012 for the modest sum of \$US12 million; no doubt a range of forensic exigencies contributed to the settlement figure.

Pinning down what lies at the heart of mainstream homœopathic practice is important but far from straightforward. The claim is made that my column extrapolates unfairly from individual instances of what may have been poor homœopathic practice. However, what is missing in homœopathic literature is unequivocal denunciation of the practitioners and their practices when there have been debacles such as instanced in my column. This leaves the inference that the conduct and the practitioners in question not only have not been deemed worthy of discipline or condemnation; they may well be standard practice.

What is even more concerning is the ubiquity and accessibility of proudly trumpeted, but scientifically parlous, claims continuing to be advanced on behalf of contemporary homœopathy. For instance, the first issue of *Spectrum of Homeopathy* for 2012 declaims that a range of homœopathic remedies have been shown to have an impressive spectrum of use – from wolf's milk for eczema and bulimia, cheetah's blood for multiple sclerosis, tiger's blood for dysmenorrhea and depression, to cat's milk for a screaming baby. At the homœopaths' Mental Health Congress 2012 in Bad Krozingen, Germany, speakers proclaimed the discovery of homœopathic remedies for schizophrenic disorders, depression, anxiety, autism spectrum

disorders, including Asperger's Syndrome, and insecurity. The question that arises once again is where the limits of the discipline lie and what steps are taken to verify remarkable and unlikely claims of therapeutic efficacy. This can be where the legal system can play a constructive role, as occurred, for instance, in the Victorian decision involving cancer therapies advanced by Noel Campbell.

My column referenced bizarre provings, including Venus beams and fragments of the Berlin Wall. Unfortunately, the truth is that the discipline is pervaded by such alleged discoveries for medical conditions. What follows is a proving triumphantly advanced in 2011 for car exhaust:

For this proving the exhaust of a 1962 Jaguar E-Type with no catalytic converter was gathered in a quart jar containing milk sugar. The jar was capped and allowed to sit for three days. The milk sugar was then ground to make the medicating potency.

Internal combustion engines require a combination of air and fuel to create an explosive charge in the engine's cylinders. When this combination is perfectly proportioned, the vast majority of the explosive charge is consumed in the cylinders, leaving little harmful waste products in the engine's exhaust. The ideal air-fuel ratio for complete combustion is 14.7:1 (stoichiometric ratio). Ideal hydrocarbon (unburned fuel) level is 10,000 ppm (parts per million). Ideal CO (carbon monoxide) level is 1 - 3%. During cold start up and acceleration the engine needs considerably more fuel to perform. At these times the air-fuel ratio is typically closer to 12.5:1, hydrocarbon levels are around 30 - 40,000 ppm, and CO increases to 5 - 6%. The exhaust sample from the 1962 Jaguar 3.8 liter E Type was captured at idle during engine warm up. Air-fuel ratio was around 10.5:1, with 60 - 70,000 ppm hydrocarbons, and 6 - 9% CO: an extremely fuel rich mixture creating a high level of harmful exhaust wastes. This type of mixture was typical of carbureted and early fuel injected engines, as well as the vast majority of vehicles used today in the third world.

The proving was conducted in the spring of 2011 at the Baylight School of Homeopathy in Portland ME USA; director Nancy Frederick. There were 5 provers ages 25 to 60; 4 female and one male.

Commentary:

During this proving there was a very clear progression from indignation, anger and frustration, to the feeling of apathy, indifference and depression, and ultimately a desire for eternal sleep. Many provers were frustrated with authority, money issues, work and family and felt powerless. Eventually the sense of powerlessness turned into boredom,

ennui and depression. Several provers described a sensation of letting go of work and family pressures, duties, discernment, and judgment of others.

Various provers felt calm and peacefulness, while others felt detached and emotionless, nowhere to go and nothing to be done, a desire to just be. Eventually this sense of depression and indifference was overwhelmed by the seduction of sleep.^[4]

That this proving could be thought to constitute anything related to legitimate methodology is nothing short of remarkable.

A few minutes' search on the internet reveals further provings said to have generated remedies available from pharmacies, including TV Emanation^[5] and a proving of the common house fly, auspiced by the New York School of Homeopathy.^[6] The absence of any form of intellectual rigour in such proclamations cannot but raise the potential for the legal system to contribute (constructively, as has the Victorian Court of Appeal decision referred to above) to the debate as to where any lines exist in terms of scientifically validated homœopathic remedies and methodologies.

Levy and Gadd properly point to the 2011 report on homœopathy as part of the Swiss Complementary Medicine Evaluation Programme: *Homeopathy in Healthcare – Effectiveness, Appropriateness, Safety and Costs*, edited by G Bornhoft, an Assistant Professor for Medical Theory and Complementary Medicine at Witten/Herdecke University, and P Matthieson, Head of Department for Plurality of Paradigms in Medicine at Witten/Herdecke University. The report is a collection of papers by pro-complementary medicine practitioners who were assembled after the Swiss Government in 1998 decided to give provisional inclusion of anthroposophic medicine, homœopathy, traditional Chinese medicine, phytotherapy and neural therapy among the list of services covered by the national statutory health insurance scheme. It is a report in need of careful scientific evaluation. No doubt that will emerge in time.

The Swiss report and the Levy and Gadd response to my column constitute the beginning of constructive dialogue between science, law and homœopathic medicine. However, it has a long way to go to avoid the legal system and appropriate financial exigencies perforce becoming major drivers in rendering the discipline intellectually accountable and thereby informing the general community about when they can safely repose trust in homœopathy and the claims of its practitioners.

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- 5 Jopes C, *TV Emanation*, <http://www.greatlakesprovings.com/tv-emanation.html> viewed 3 May 2012.
- 6 Sonz S and Stewart R, *Musca Domestica: A Proving of House Fly*, <http://www.nyhomeopathy.com/flysum.htm> viewed 3 May 2012).