A Review of *Homeopathy in Healthcare*

by William Alderson

Gudrun Bornhöft and Peter Matthiessen (eds), *Homeopathy in Healthcare – Effectiveness, Appropriateness, Safety, Costs: An HTA report on homeopathy as part of the Swiss Complementary Medicine Evaluation Programme*, trans. from the German by Margaret M Saar (Berlin, Heidelberg, New York: Springer-Verlag, 2011).

Homeopathy in Healthcare is important for three reasons, and before going into the detail, it is worth establishing these.

1. Firstly, this is a report on homeopathy which has been produced according to scientific principles by appropriately qualified professionals without a vested interest.

2. Secondly, this report clearly concludes "that the individual CAM interventions, especially homeopathy, were effective, under Swiss conditions safe and, as far as could be judged from the trial situation, also cost-efficient." (p. 2[*])

3. Thirdly, this report utterly rejects the meta-analysis by Shang et al.,[1] which has been used as the basis of attacks on homeopathy ever since 2005.

What this means is that there is expert evidence in favour of homeopathy as an effective, safe and economic approach to medicine, and that the arguments attacking homeopathy are confirmed to have been founded on an invalid and inappropriate source.

The nature and authorship of the report

Homeopathy in Healthcare is the first publication in English of the health technology assessment of homeopathy commissioned by Swiss Federal Office of Public Health as part of its programme of evaluation (PEK) of a number of complementary and alternative medicine (CAM) therapies. The original report was submitted in 2004, and an abbreviated version was published in German in 2006 in the journal *Forschende Komplementärmedizin*.[2]

The health technology assessment (HTA) is

> an established scientific procedure which, in contrast to the meta-analyses and systematic reviews specified by the Cochrane Collaboration Standards, examines not only the efficacy of a particular intervention, but especially also its 'real world effectiveness', its appropriateness, safety and economy. HTAs are therefore much wider in scope and politically more informative. (p. 2)

In other words, it addresses issues relevant to the use of homeopathy in practice, the issues which are most relevant to those who commission medical services, such as GPs, Primary Care Trusts and the NHS generally, or other national health insurance programmes, such as the one in Switzerland. As such this report is fully in line with the principles of evidence based medicine (EBM), unlike assessments based only on randomised controlled trials (RCTs).

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[*] All page references are for *Homeopathy in Healthcare* unless otherwise stated.

Homeopathy in Healthcare explains the problems of different types of research and the basis on which research has been included or excluded. It also presents a clear explanation of how the various types of research have been used for the purpose of this assessment.

Of the 13 authors 10 have qualified in medicine and 6 of these have subsequently qualified in homeopathy. The three authors not trained in medicine have backgrounds in physics, electronic engineering or sociology, but have worked in medical fields. 8 authors hold academic positions, and 6 of them have worked with CAM issues. As regards conflicts of interest, *Homeopathy in Healthcare* states that

> Compilation, evaluation and revision of this report were carried out in adherence to the commission documents and the FSIO [Swiss Federal Insurance Office] specifications on behalf of the FSIO. Nobody involved in the compilation had any financial or other conflict of interest. Whenever expert advice was sought from a physician who himself uses the method in question, independent experts were also consulted. (p. 230)

From this it is clear that the authors have the appropriate expertise to undertake an assessment of homeopathy, have no vested interests, and have used an appropriate and scientific approach to the available evidence.

In these respects *Homeopathy in Healthcare* is very different from the House of Commons Science and Technology Committee report *Evidence Check 2: Homeopathy*,[3] although the Swiss HTA actually performed for the Swiss government the very function which the *Evidence Check* was allegedly intended to perform for the British government. In the case of the *Evidence Check* there was no evidence that the authors had appropriate expertise. Indeed, not only was there evidence suggesting that they lacked impartiality, but they also relied heavily on the evidence of witnesses who were unqualified and known to be partial. In addition, the *Evidence Check* used inconsistent arguments to justify the position that evidence from randomised controlled clinical trials (RCTs) is the only valid evidence, despite the fact that there is no scientific rationale to support this position. This position is also rejected by the dominant paradigm of evidence based medicine (EBM), which appeared to be the nominal basis for the *Evidence Check*.

Evidence based medicine

Homeopathy in Healthcare points out that

> Evidence-based medicine (EBM) has as its aim and concern the identification and evaluation of the entire body of published evidence concerning a medical problem with a view to making the results available, accessable and easily usable in medical practice. (p. 28)

It goes on to note that

> Sackett [one of the founders of EBM] had pointed out that EBM was not limited to randomised trials and their meta-analyses, but in the wake of the ensuing EBM euphoria it has become established practice to rely solely on the results of randomised controlled clinical trials (RCTs) and their meta-analyses. (p. 28)

Finally it notes that there is a danger of

> distortions and a systematic error potential once the methodic tool has become independent and claims universal validity. (p. 28)

Where the *Evidence Check* ignored this danger, the Swiss HTA specifically applies the full principles of EBM and addresses the whole range of evidence.

It is interesting to note that the only mention by the Commons Science and Technology Committee of the original publication of the Swiss HTA is (in reference to a comment by Professor Edzard Ernst) that "the 'reviews' on upper respiratory tract infections were health technology assessments, not systematic reviews, and mostly contained uncontrolled data".[4] No explanation was provided as to the nature of an HTA, and in fact *Homeopathy in Healthcare* shows that the Swiss HTA was an extremely thorough review and assessment of the available evidence.

The review of the evidence

Before looking at the available evidence *Homeopathy in Healthcare* sets out the context for study. It explains the nature of homeopathy, the problems of research into homeopathy, the problems of clinical trials in general, and the process of gathering and selecting evidence. The explanation of the principles of homeopathy is extremely succinct and clear, outlining the key issues which must be taken into account when conducting trials of classical homeopathic treatment. In particular, emphasis is put on individualisation, the 'Law of Similars' and the use of a single remedy.

In discussing homeopathic research, *Homeopathy in Healthcare* points out that

> Many experimental and clinical trials that were based on the methods of conventional medicine have been carried out in homeopathy over the past decades with a view to gaining scientific and political recognition. From a homeopathic point of view, it was justification research more than anything else and did not provide any new insights into homeopathy as such. (p. 16)

It continues:

> Homeopathy experts continue to claim that the great majority of existing homeopathy trials were conducted with inadequate means, that their designs ignore central principles of homeopathy and thus increase the likelihood of false-negative results. The trials have almost nothing in common with the actual practice of homeopathy in Switzerland; their external and model validities are very low. (p. 16)

These issue were taken extremely seriously in the assessment of the evidence in the HTA, and after a detailed discussion the authors concluded

> We therefore consider the following tacit assumptions in the usage and interpretation of RCTs to be questionable or false:
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> - The treatment reality can be adapted to the RCT model and allow for an assessment that corresponds to the model.
> - The RCT result can be projected back to the treatment reality and is valid there (external validity).
> - A formally correct RCT is equally safe from false-positive and false-negative results (internal test validity). (p. 30)

What this means is that, unlike the Commons Science and Technology Committee, the Swiss HTA did not simply accept the results of trials and meta-analyses at face value. It not only took into account the extent to which the studies met the formal requirements for such trials and meta-analyses (internal validity), but it also considered whether the studies employed methods appropriate to homeopathy (model validity) and whether the studies reflected real clinical practice (external validity). The authors concluded that

> In contrast to the now customary view that the reliability of results grows with internal validity, we think that – roughly speaking – there is a risk of false positive results if the external validity is overrated and a risk of false negative results if the internal validity is overrated. From the homeopathic point of view, the external validity is low with most studies (apart from the newer, more practice related outcome studies) because they tend to ignore the essential foundations of classical homeopathy. (p.201)

An example of trials ignoring "the essential foundations of classical homeopathy" can be seen in the assessment of clinical trials of homeopathic treatment for upper respiratory tract infections and allergies. The HTA considered the extent to which these trials took into account individualisation and the Law of Similars. As can be seen from the table below, of 29 trials less than one third definitely observed these basic principles.

Table 1: Application of the similarity rule and individualisation in 29 trials of treatment for upper respiratory tract infections/allergies		Similarity rule			
		Observed	Partly observed	Not observed	No documentation
Form of treatment used	Individualised homeopathy	9	1	0	1
	Isopathy	0	1	4	2
	Complex homeopathy	0	2	3	2
	Clinical homeopathy	0	0	3	1

Source: *Homeopathy in Healthcare*, Table 10.4, pp. 152-154.

Preclinical research

The authors point out that pre-clinical research – physio-chemical research, trials on plants and animals, and trials on isolated human tissues – cannot assess the effect of individualisation and the Law of Similarity, but only the properties and actions of homeopathically potentised substances. In 2004, when the HTA was completed, there was no physio-chemical explanation for the action of homeopathic remedies, though the evidence suggested that "homeopathic potentisation most probably involves a principle of action that is different from the 'usually' assumed molecular, often receptor-mediated, modes of drug action" (p. 18). Since 2004 there have been various advances in the identification of the physio-chemical properties of potentised substances, but there is still no certain explanation of their biological action.

Homeopathy in Healthcare notes that experiments on plants show that potentised substances have regulatory effects on plants, in that the effects are minimal on healthy plants, but greater on stressed or sick plants. It also notes that the effects "are not in line with the classical pharmacological view" (p. 18).

With animals, the approach used is frequently that of isopathy, in that "test animals are poisoned with toxic substances and then protected or detoxified with homeopathic potencies of the same poison" (p. 18). The authors note that "These studies also support the proposition that homeopathic potencies have primarily a regulatory effect, i.e. they restore balance to destabilized organisms" (p. 19).

In respect of trials on human tissues "The most proven in-vitro model … is the human basophil degranulation test (HBDT) known from allergology" (p. 19). The authors note that "in countless trials with several variations it was possible to supply significant, multiply reproduced evidence that the BDT was influenced by high homeopathic potencies of histamine, bee poison and other substances capable of inducing allergic reactions" (p. 19).

Homeopathy in Healthcare concludes that

> The tenet that very high dilutions of medicinal substances (homeopathic potencies) are able to induce specific effects in living organisms is supported by quite a large number of high quality trials in fundamental pre-clinical research. (p.19)

Clinical trials

As regards clinical trials, *Homeopathy in Healthcare* notes general problems relating to their purpose and conduct, in that

> In contrast to mainstream medicine, the practice of homeopathy gains little from conventional trials. There is no interested pharmaceutical industry nor are there potent sponsors; research infrastructures and appropriate research concepts are also lacking. (p. 22)

It adds that

> The standard methods applied in recent years are so incompatible with the homeopathic approach that a qualified comparison of systems remains imposiible if there is no adaptation and integration of homeopathic methods. Because such studies have hardly anything in common with homeopathic practice – a fact that considerably reduces their external and model validity – they increase the likelihood of false-negative results. (p. 22)

The only systematic review of clinical trials of homeopathy conducted as part of the HTA was one for upper respiratory tract infections and allergies (mentioned above). Taking into account the problems with such trials, the authors concluded that

> Even considering the reduced external validity of randomised studies which is caused by non practice-related methodology, the selection of study participants and blinding and which reduces their appropriateness in evaluating classical homeopathy, the study results still clearly demonstrate clinical efficacy for homeopathy. The positive effect is not only apparent in placebo controlled studies, but especially also in the comparison with conventional treatments. (p. 199)

In short, *Homeopathy in Healthcare* argues that both pre-clinical and clinical studies indicate that homeopathy is efficacious and effective, but expresses concerns about the inadequacy of research which ignores principles of fundamental importance to actual homeopathic practice.

Systematic reviews and meta-analyses

In assessing published systematic reviews and meta-analyses of clinical trials of homeopathic treatment, *Homeopathy in Healthcare* notes that

> The large majority of studies mentioned in systematic and other reviews were carried out according to conventional medical standards as justification research, with a view to attaining outer recognition for homeopathy. Homeopathically speaking, most of these studies were conducted with inadequate, not pratice-relevant methods, because their design ignored essential tenets of homeopathy, thus causing low model validity and a high risk of false-negative results. (p. 118)

In addition to such methodological flaws, the authors came across other problems, including:

- Inadequate information about the criteria for including or excluding studies;
- The application of unusual demands or overly restrictive arguments;
- Inappropriate evaluation processes, including overemphasis on internal validity;
- Conclusions being affected by the researchers' reservations.

As a result there is a detailed discussion of the studies and of the use of "three-tier evaluation scale ('likely, questionable, unlikely')" (p. 117) in the HTA. On the basis of this scale, and despite the issues noted above, *Homeopathy in Healthcare* concludes that "the effectiveness of homeopathy has to be rated as 'likely'" (p. 117).

Shang et al.

Homeopathy in Healthcare makes a point of discussing "The danger of biased evaluation due to one-sided focus on purely formal criteria without thematic differentiation" because it "has been confirmed in the PEK project" (p. 39) [the programme of evaluation of which included the HTA of homeopathy]:

> Before the overall project was finalised, the results of the smaller quantative sub-study, which – contrary to the explicit intention of an HTA – had evaluated only experimental trials (randomised double-blind trials), became known out of context. (p. 2)

This meta-analysis is known as Shang et al. (2005), and it was published alongside "the unfortunately titled Lancet editorial 'The end of homeopathy'" (p. 2). The repudiation of this meta-analysis by the authors of the HTA is of enormous importance, since Shang et al. has been the crucial basis both for propagandising against homeopathy internationally, and for a specific campaign against the provision of homeopathy in the NHS in the UK. *Homeopathy in Healthcare* deals clearly and in detail with the profound criticisms of this study, all of which were published in 2005, but have been systematically ignored or belittled by individuals (including Edzard Ernst, Simon Singh[5] and Ben Goldacre[6]) and organisations and bodies (including Sense About Science, the Commons Science and Technology Committee, the BBC and the Advertising Standards Authority).

The propaganda campaign against homeopathy has been led by Sense About Science, an organisation which received more than 37% of its donation income from the pharmaceutical industry in the years 2004-2009. In 2006 it published a briefing document for the public and journalists, *Sense About Homeopathy*,[7] in which only one piece of research on homeopathy was cited: Shang et al. The author of this document was Chris Tyler, who has provided no evidence of having qualifications or experience in medicine or homeopathy. He went on to work as advisor to the House of Commons Universities, Innovation and Skills Committee which subsequently became the House of Commons Science and Technology Committee. Here he "pioneered the Science and Technology Committee's 'Evidence Check' programme".[8] This committee called as a witness the Managing Director of Sense About Science (Tracey Brown), who also has provided no evidence of having qualifications or experience in medicine or homeopathy. Simon Singh, who has provided no evidence of having qualifications or experience in medicine or homeopathy, is a trustee of Sense About Science, and he has close links with the BBC, having worked there as a producer.

In the context of closely linked organisations and individuals promoting the conclusions of one particular study, the systematic rejection of those conclusions as invalid is important. The fact that the rejection comes from the authors of the full HTA, of which that study formed a small part, is of major significance. It is to be hoped that all those organisations which have relied on Shang et al., whether directly or indirectly, will revise their policies in the light of this new, more thorough and better-informed assessment of the facts.

Conclusion

Homeopathy in Healthcare summarises the conclusions of the Swiss programme of evaluation, stating

> that the individual CAM interventions, especially homeopathy, were effective, under Swiss conditions safe and, so far as could be judged from the trial situation, also cost effective. (p. 3)

Again and again it presents the same analyses about homeopathy and homeopathic research as Homeopathy: Medicine for the 21st Century (H:MC21) has provided on its website and in its

publications. As such, *Homeopathy in Healthcare* is an authoritative and detailed corroboration of H:MC21's arguments over the last five years. It is a shame that this full publication in English was not available many years ago, since it would have enabled homeopaths and patients to be better armed from the start against those propagandising against homeopathy. It is a report which needs to be publicised as widely as possible as the most thorough and thoroughly legitimate assessment of homeopathy within the paradigm of evidence based medicine.

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1 Aijing Shang, Karin Huwiler-Müntener, Linda Nartey, Peter Jüni, Stephan Dörig, Jonathan A.C. Sterne, Daniel Pewsner and Prof. Matthias Egger, 'Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy', *Lancet*, 366 (2005), 726-732.

2 G. Bornhöft, U. Wolf, K. Ammon et al., 'Effectiveness, safety and cost-effectiveness of homeopathy in general practice – summarized health technology assessment', *Forschende Komplementärmedizin*, 13 (2006) Suppl. 2, 19-29, available at <http://content.karger.com/ProdukteDB/produkte.asp?Aktion=ShowAbstract&ArtikelNr=93586&Ausgabe=231996&ProduktNr=224242>.

3 House of Commons Science and Technology Committee, *Evidence Check 2: Homeopathy* (London: The Stationery Office, 2010).

4 House of Commons Science and Technology Committee, *Evidence Check 2: Homeopathy* (London: The Stationery Office, 2010), p. 19.

5 Simon Singh and Edzard Ernst, *Trick or Treatment? Alternative medicine on trial* (London: Bantam Press, 2008), pp. 135-139.

6 Ben Goldacre, *Bad Science* (London: Fourth Estate, 2008), p. 56.

7 Chris Tyler, *Sense About Homeopathy* (London: Sense About Science, 2006).

8 'CSaP Appoints New Executive Director', Centre for Policy and Science, Cambridge University, 15 March 2010 at <http://www.csap.cam.ac.uk/news/article-csap-appoints-new-executive-director/>.