

OBSERVATIONS ON THE REPORT *EVIDENCE CHECK 2: HOMEOPATHY* BY THE HOUSE OF COMMONS SCIENCE AND TECHNOLOGY COMMITTEE, FEBRUARY 2010

1. BACKGROUND

- 1.1. The report *Evidence Check 2: Homeopathy* was the second to be produced with the purpose of examining how the UK Government uses evidence to formulate and re-view its policies. It was not an inquiry into homeopathy as such. The House of Commons Committee asked two principal questions: What is the Government's policy? And on what evidence is that policy based? The point was whether the scientific evidence supported the provision of homeopathy by the NHS and the licensing of homeopathic products by the MHRA.
- 1.2. The report received much publicity because of its firm rejection of evidence for homeopathy's efficacy on its way to answering these questions. The aim of this paper is to focus on this one aspect of the Committee's work, in view of doubts voiced about the validity of its findings. Sections 2 – 5 below address this question.
- 1.3. The author served on the House of Lords Science and Technology Sub-Committee which in 1999-2000 inquired into complementary and alternative medicine (CAM). He was Co-Chairman of what used to be called the Parliamentary Group for Alternative and Complementary Medicine during the 1990s, and also served on the advisory board to the systematic review of water fluoridation which was conducted in 1999-2000 by the NHS Centre for Reviews and Dissemination (CRD) at the University of York. As a user of homeopathy he has failed to derive much benefit from it, but has supported its use and development in the UK.

2. THE SCIENTIFIC EVIDENCE FOR EFFICACY

- 2.1. There have been a number of systematic reviews and meta-analyses in this field, which as the Committee states are the best sources of evidence. The most recent review of substance is that by Shang *et al* in 2005, which it considered "the most comprehensive to date" and which compared 110 placebo-controlled trials of homeopathy [authors' spelling] with 110 trials of conventional medicine matched for disorder and type of outcome. The Committee cited a conclusion by the authors [paragraph 69] that "when analyses were restricted to large trials of higher quality there was no convincing evidence that homeopathy [*sic*] was superior to placebo". They did not also cite the authors' interpretation which followed these findings in the *Lancet* summary, which stated: "When account was taken for these biases [common to trials of both homeopathy and conventional medicine], there was weak evidence for a specific effect of homeopathic remedies, but strong evidence for specific effects of conventional interventions. This finding is compatible with the notion that the clinical effects of homeopathy are placebo effects."
- 2.2. This was no endorsement of homeopathy. But it was some way removed from the Committee's conclusion in paragraph 70 of their report, "In our view, the systematic reviews and meta-analyses conclusively demonstrate that homeopathic products perform no better than placebos." It also provides little support for that part of Professor Ernst's evidence to the Committee where he "pointed out that: . . . Shang *et al* very clearly arrived at a devastatingly negative overall conclusion" [67].
- 2.3. The exaggeration by the Committee of Shang's conclusions is worrying. It is difficult to see how a weakly supported positive effect, for which one explanation (possibly well-founded) is a placebo effect, can be translated into a conclusive demonstration

of this effect, with a “devastatingly” negative finding. No such firm claims can be found in Shang, who writes of finding “no strong” evidence, or “little” evidence, and who ends his paper with cautions about methodology and about the difficulty of detecting bias in studies, as well as the role of possible “context effects” in homeopathy.

- 2.4. The Committee’s overstatement is not helped by claiming Government support for its interpretation in paragraph 70, based on the Minister’s concession of no “credible” evidence that homeopathy works beyond placebo. If he meant persuasive evidence - and his guarded support for further research [75] supports this - that shows a confusion by the Committee between absence of evidence and evidence of absence. If however he was saying that all evidence was negative, this as Prof. Harper correctly stated [71] runs counter to the message from most reviews up to and including Shang, which is one of primary studies of insufficient quantity, rigour, size, homogeneity and power to give clear-cut answers.
- 2.5. It is the absence of reliable evidence that remains the problem, and this includes evidence of an absence of specific effects (while acknowledging the problem in proving a negative, an obstacle which did not deflect the Committee from its conclusive verdict in 70). The Committee itself writes in 69 of no “convincing” evidence from Shang, from higher-quality trials, which is not consistent with a claim of conclusive (dis)proof. Care with words can be as important as with figures, and can just as easily mislead.
- 2.6. In a search for best evidence in the early 2000s this author relied on the bulletin on homeopathy produced by the NHS CRD at York in 2002, one of an Effective Health Care series on “the effectiveness of health service interventions for decision makers”. This bulletin made a systematic assessment of the evidence to date. It advised “caution” in interpreting this evidence, and warned that many of the areas researched were “not representative of the conditions that homeopathic practitioners usually treat”, and that “the methodological problems of the research” should be considered. It found “insufficient evidence of effectiveness . . . to recommend homeopathy for any specific condition”. At the same time it could not conclude that homeopathy performed no better than placebo.
- 2.7. That was eight years ago. But it is notable that the more recent review by Shang, on which the Committee relied quite heavily, cited no reference to any placebo-controlled trial (i.e. of reasonable quality) subsequent to the CRD’s bulletin, in arriving at a suggestion, but not a conclusion, of a placebo effect. The House of Commons Committee’s verdict in 70 stands on its own in going beyond what either review found from the evidence before it.
- 2.8. In seeking an up-to-date assessment from the NHS CRD, this author was referred to the German researcher Klaus Linde as among the best of the objective sources of current evidence on homeopathy. Linde, who was the lead author of a major review in 1997 cited by the Committee, in turn recommended the statistician Rainer Lütke as an expert with a good overview of the current literature. Correspondence ensued with both researchers, who were aware of the Committee’s recent report.
- 2.9. Both Linde and Lütke hold that the Committee’s conclusion in 70 that reviews “conclusively demonstrate” a placebo effect is overstated and unsustainable on present evidence. They have further criticisms of the way in which evidence has been addressed.
- 2.10. Both are critical of Prof. Ernst’s evidence to the Committee as highlighted in 67. Prof. Linde confirms that his own 1999 re-analysis weakened the findings of his 1997 review and probably “at least overestimated the effects of homeopathic treatments”, but that his paper was “not ‘negative’” as stated by Ernst. He writes that “A more accurate interpretation is that the ‘re-analyses’ [by himself and 5 others, referred to by

Ernst] show that the (positive) evidence is not fool-proof. This applies still today (for example, to the Shang analysis)". Lütke draws attention to his own paper in 2002 which criticised many statistical errors in Ernst's 2000 re-analysis in the same journal, vitiating Ernst's negative conclusion, a published criticism which received no mention in Ernst's own evidence to the Committee. Ernst was correct to state in evidence elsewhere that the re-analyses of Linde came to a "less than positive" conclusion, and that further reviews "failed to conclude that homeopathy is effective". The Committee, while adopting Ernst's more absolute conclusions, has not resolved the contradiction between his statements.

- 2.11. Lütke, like Shang, has also drawn attention to the pitfalls in research into homeopathy, in a chapter in 'New directions in homeopathy research' (Witt C, Albrecht H, eds.) published in 2009. He counsels against including all types of homeopathy trials of reasonable quality in one review (such reviews tend to suggest that homeopathic medicines are not efficacious), since the pooling of so many different kinds of trial and type of homeopathy makes findings unreliable. He advocates restricting systematic reviews to clearly defined health conditions or to single homeopathic medicines, concluding that "the heterogeneity of trials is high and the meta-analysis results are not robust against small changes in study design or statistical analysis". In a paper published in 2008 he has argued that Shang's conclusions do not hold when slightly different selection criteria are applied, e.g. by redefining how large is a "large" study, or by including treatment trials but excluding prevention trials. Size is not the only factor in arriving at robust conclusions.
- 2.12. Context effects may play a part, according to both Shang and Lütke. Shang's "powerful alliances" between patient and carer, based on "shared strong beliefs", may not be as distinctive or as peculiar to homeopathy as the nature of the homeopathic consultation, with its wider range of questions than are addressed in a conventional context, and the lifestyle recommendations referred to by Lütke that often flow from it. There is overlap here with the placebo effect (see 4 below); but homeopathy as "a complex medical system of its own" may be responsible for some broader effects.
- 2.13. Linde writes that the "undecided fraction" to which he belongs is confused by "the notorious lack of predictable reproducibility" on the one side, and by "too many anomalous results in high quality studies to rule out a relevant phenomenon" on the other.

3. OTHER EVIDENTIAL CONSIDERATIONS

- 3.1 A conventional argument against CAM treatments is often that they are risky because they deny or delay a proper diagnosis and the adoption of tried and tested conventional treatments [105; 108; Ev 26-27]. But this is not an argument about (as here) homeopathy *per se*, and its side-effects which at such high dilutions are as implausible as its efficacy is claimed to be. The potential for harm however is real enough: but only if patients have not been in contact with their own doctors, which happens in a minority of cases; if homeopaths are not adequately trained to recognise 'red flags', and give bad advice; and if conventional treatment is likely to be successful and/or acceptably risk-free in the particular case, and indeed more successful than a homeopathic approach.
- 3.2. The argument for adopting one kind of treatment and not the other relates therefore to issues of practice, communication and training as well as of comparative efficacy (for patient choice see 6.1 below). These are highly important; but it is not legitimate to deploy the argument as the Committee did as a factor in the intrinsic risk/benefit ratio of a therapy, which it is not, adducing it as an additional negative element instead of as part of an efficacy argument which has already been addressed. (Suppose high-quality trials establish homeopathy's superiority over conventional treatment for a condition: this, with homeopathy's negligible side-effects, would make the conventional option the risky one.)

- 3.3. Nor is the argument even-handed if examination of true side-effects in homeopathic and conventional treatment is not addressed when discussing the comparative merits of the two approaches, patient satisfaction, and government policy. Shang *et al* gave “the exclusive focus on beneficial effects” as one of several limitations of their study. The extent of adverse clinical effects is as much a part of the evidence base as is benefit. If the Committee had looked at these it might have cast a different light on policy towards homeopathy in the NHS, and would almost certainly have highlighted public disquiet about some of the more aggressive conventional treatments as a reason for many patients preferring a CAM approach. This is a significant omission.
- 3.4. There may be no good conventional treatment for a condition. Alternatively, the standard treatment may be contraindicated. The Committee has not considered these reasons why some patients may welcome the continued provision of homeopathy.

4. THE PLACEBO EFFECT

- 4.1. The placebo effect, addressed at some length by the Committee (30–40), is not in dispute. Yet much about it is unknown. It may be premature to assume that patient expectations of modern medicine, with its erudition, structures, scientific approach and rituals which give it the intellectual and moral high ground in Western society, are of lesser force than those of a treatment which is commonly thought of as “implausible”, and not only by scientists. Belief in white coats is not weak. Furthermore patients are likely to resort to CAM on grounds of principle or safety as well as efficacy. The placebo as an explanation is sometimes reached for too readily off the shelf, when its applicability to the relevant condition, treatment and patient population is poorly understood. This gap in argument has not been closed by the Committee. The placebo effect in homeopathy needs more work before conclusions can be confidently drawn.
- 4.2. Empathy in a consultation is more than a matter of time given [81]: it also involves personality and training. This author has on occasion felt better heard in a ten-minute GP consultation than in an hour with a CAM therapist, although the latter have generally shown up well. The better comparator in CAM situations is probably the specialist consultation, since most patients will have initially visited their GPs. Nor is it always the fluctuating or self-limiting conditions [43, 81], as the Committee suggests, that send patients to unconventional providers; claimed relief from chronic complaints after a long period of failure with conventional treatment is not uncommon.
- 4.3. The surveys of homeopathic patients referred to in 80 suggest that self-reported benefit was not only at a high level but persisted beyond the limits of any placebo effect which, as the Committee states, is usually short-lived.

5. THE COMMITTEE’S WITNESSES

- 5.1. The Committee in two sessions called twelve witnesses to give oral evidence, all but one with relevant affiliations. Selection of witnesses can affect outcomes in the same way as selection of written evidence. It is therefore legitimate to examine the choices made.
- 5.2. It is not easy to see why a journalist doctor was invited to appear in preference to some other non-representative contributors to the inquiry. The written submission by Dr. Goldacre [Ev. 8] was notably short on supporting evidence, but contained unqualified statements on the ineffectiveness of homeopathy, forcefully expressed (“extreme quackery” was mentioned). By contrast, the submission by the Complementary Medicine Research Group from the Department of Health Sciences at the University of York presented a well-argued summary with 68 references [Ev. 143]. In this appears the statement “To date there are eight systematic reviews that provide

evidence that the effects of homeopathy are beyond placebo when used as a treatment for [five childhood conditions]”. This claim from a mainstream academic centre, rated joint first nationally for health services research in the latest Research Assessment Exercise, stands in stark contradiction to Prof. Ernst’s referenced claims, noted above, and to Dr. Goldacre’s unreferenced statements. It would have been illuminating if the Committee had probed the Group about this, face to face as a witness, and attempted some resolution before agreeing in unequivocal terms with the two witnesses who were invited to appear and were quoted favourably.

The Committee criticised the supporters of homeopathy for their “selective approaches” to evidence [73]. They could fairly be accused of the same. Unfortunately they did not (presumably) have the scope to solicit the views of Dr. Linde from Germany, which would have differed from those of Prof. Ernst with regard to the evidence.

- 5.3. Only one Primary Care Trust submitted a paper, and it was invited to give oral evidence on its decision that homeopathy did not provide value for money. Given the number of PCTs countrywide this is rather surprising. It might be wondered if some form of publication bias was in play, with the many PCTs who were happy with provision of homeopathy seeing no need to defend the *status quo*. At least one writer complained of the short timescale for submissions [Ev. 128]. It would have been interesting to know what steps the Committee took to obtain a range of views about the evidence, and whether West Kent was the only PCT to have done an assessment of the kind referred to in Ev. 134. Only a negative PCT view was recorded; and despite the Committee’s unequivocal conclusion even West Kent conceded “limited evidence in favour of homeopathy”.

6. SOCIETAL QUESTIONS

- 6.1. Since doctors exist for patients and not the other way round it is not self-evident that scientific evidence, important as it is, should be the sole determinant of what is provided to the public. If the patient is ultimately in the driving seat (s)he might wish on broader grounds than proven efficacy to finance this type of treatment rather than that (or in addition to that) from the public purse. This gives scope for political judgements which can set a government at odds with its medical advisers. This should be no surprise to a parliamentary scientific committee which sits at the border of these two worlds.
- 6.2. In the purely scientific field it is interesting that the present Committee should feel “troubled” [71] by two senior government scientists coming to different conclusions about the weight of homeopathic evidence. Such disagreement in interpretation is quite common in scientific debate, although life is undoubtedly easier where there is consensus. Premature consensus, however, has its own dangers, as is generally recognised. The Committee appears to require the scientists metaphorically to retire to a jury room and not come out until they agree [64, 72], presumably with the Committee’s view. This seems a step too far.
- 6.3. Pre-existing structures have some *de facto* claims. It is reasonable to decide that if something were not in existence one would not call it into being, but if it is already there one would not abolish it. While theoreticians might debate this, society as a whole can accept it. It is more easy to accept where the institution claims a minuscule proportion of the health and research budgets, which must be the case with homeopathy whatever precise figure the government comes to at the Committee’s request.

7. CONCLUSION

- 7.1. The evidence for homeopathy is not impressive, except possibly in terms of lack of adverse effects. The Committee however has been less than rigorous in its approach to this evidence. Its choice of witnesses favoured a medical media opponent

of homeopathy over a research centre of excellence. It was unwise to rely heavily on the interpretations of one professor of CAM, some of whose statements are unsound or in conflict with other statements of his, and who is not without his critics in the worlds of research and academia whose views were given less prominence. The 2005 review by Shang *et al* has been inaccurately represented as ruling out specific effects of homeopathy, in a summary statement by the Committee that goes beyond present evidence. The Committee's own statements show confusion between unconvincing evidence of a specific effect and disproof of it. The true risk profile of homeopathy, compared with conventional treatment, was not considered.

- 7.2. These limitations make the Committee's report an unreliable source of evidence about homeopathy. The jury must still be regarded as out on its efficacy and risk/benefit ratio. Whether more research should be done, and of what kind, is another question. But there can be no ethical objection to it since the principal questions have not, as the Committee claimed, "been settled already" [78].

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