

UNDERSTANDING THE EVIDENCE BASE FOR HOMEOPATHY

The evidence base for homeopathy is a controversial topic, with ‘experts’ on both sides of the debate drawing differing conclusions from the existing data. It is often reported that there is no evidence homeopathy works or that the current evidence base shows homeopathy is no better than placebo. Neither statement is correct.

Such misconceptions stem largely from the House of Commons Science and Technology Committee Evidence Check 2: Homeopathy report,¹ which has influenced decision-making within the NHS.

Reliability of the House of Commons Science and Technology Committee Evidence Check 2: Homeopathy report

As this document is widely referred to, its reliability needs to be considered. Although described by some as a ‘comprehensive review’ of the evidence, the Evidence Check 2 report is not a scientific document and therefore should not be used as evidence in decision-making. No systematic scientific method was applied, it was not carried out by expert academics in the field and the choice of evidence included showed a disturbing bias – both in terms of written submissions and the choice of witnesses permitted to give oral evidence.

Such fundamental flaws have been widely acknowledged: whilst 3 out of 4 MPs voted in favour of the report, one member of the Select Committee (Ian Stewart MP) abstained, dissenting from the report because he was concerned by the “balance of witnesses”; 70 MPs expressed their concern by signing an Early Day Motion (EDM 908) and an independent critique by Earl Baldwin of Bewdley concluded that the report was “an unreliable source of evidence about homeopathy”.² Earl Baldwin’s opinion is of particular interest as he served on the House of Lords Science and Technology Sub-Committee that inquired into complementary and alternative medicine in 1999-2000 and so was familiar both with correct S & T Committee procedures and the topic in question.

These facts can be verified in more detail at www.homeopathyevidencecheck.org.

What evidence is covered by the Evidence Check 2: Homeopathy report?

Reliability aside, a second pertinent issue is that the Evidence Check 2 report only considered *efficacy* of homeopathy, not real world *effectiveness* assessing the ‘whole treatment package’ as provided by homeopaths in everyday practice. They therefore excluded all observational studies and pragmatic randomised controlled trials and only considered five comprehensive meta-analyses of randomised controlled trials (RCTs).^{3,4,5,6,7} From this evidence the four meta-analyses which found in favour of homeopathy were excluded,^{3,4,5,6} based on the testimony of Prof Edzard Ernst that, in his opinion, they were unreliable. This left only one study to inform the report’s conclusions – the comprehensive comparative meta-analysis known as The Lancet study by Shang et al. published in 2005.⁷

Considering that this single paper is the only ‘global study’ to conclude that homeopathy is no more than a placebo effect, its role in the debate cannot be overstated, so once again quality and reliability are paramount.

Multiple concerns have been raised about the Shang et al. study, particularly the fact that it’s conclusions were based on only 8 trials out of the 110 available at the time and that it fails a sensitivity analysis⁸ i.e. if you remove just one of the 8 trials they used in the analysis, the result is reversed, showing that homeopathy works beyond placebo. Furthermore not one of those 8 trials used involves individualised homeopathic treatment – the form of homeopathy considered to be ‘usual care’, as practiced by most homeopaths.

Reliability of the analysis is not the only problem with the Shang paper. As we take a fresh look at the evidence in 2015, we also need to consider how well this study reflects the entirety of today’s evidence base.

The sixth and most recent comprehensive meta-analysis by Mathie et al., published in 2014, found that **homeopathic medicines, when prescribed during individualised treatment, are 1.5 to 2.0 times more likely to have a beneficial effect than placebo.**⁹ This study includes 151 placebo-controlled randomised trials – 41 more than Shang’s team identified in 2005, but which would have met their inclusion criteria if available at the time.

This demonstrates the extent to which the 10 year-old Shang et al. paper, which now covers only 73% of the eligible trials, has been superseded by the Mathie et al. paper – evidence of the highest academic quality which did not even exist at the time of the House of Commons Evidence Check.

High quality primary RCTs that show efficacy of homeopathy

As there are grave concerns about the reliability of both the Evidence Check 2 report and Shang et al. paper, when considering RCT evidence, it is more helpful to take a step back and look at the primary data rather than these documents which have taken the unusual approach of assessing homeopathy, in all its forms, for all conditions, by doing a combined analysis of all trial results.

In conventional medicine the usual research question which is, “*Is treatment X effective for condition Y?*” not, “*Is conventional medicine effective when you combine all trial results on all drugs for all conditions?*” When looking at the evidence base from this more usual perspective, we find that there are some high quality RCTs showing that certain homeopathic treatments are effective e.g. the homeopathic medicine *Oscillococcinum* for the treatment of influenza¹⁰, individualised homeopathic treatment for childhood diarrhoea¹¹ and both individualised homeopathic treatment¹² and homeopathic ear drops for acute otitis media in children.¹³

Basing decisions on the most relevant evidence

The best evidence for assessing the *efficacy of homeopathic medicines* comes from trials that are as similar as possible to “real world” practice. Evidence from such trials of individualised homeopathy suggest that homeopathic medicines are more effective than placebo.⁹

When assessing the *effectiveness of treatment by a homeopath* (i.e. the combined impact of consultations and homeopathic medicines delivered in a “real world” clinical setting), the best evidence comes from pragmatic randomised controlled trials. This is an active area of homeopathy research, with several publications due in the next 12-18 months.

Additionally, evidence from uncontrolled observational studies provides insight into changes in patients who have received treatment provided by homeopaths. The available observational data from such studies shows that a significant proportion of patients improve significantly during a course of homeopathic treatment. A selection of the most directly relevant studies is provided below.

United Kingdom

Four published studies carried out from 1999 to the present day have tracked the outcome of patients being treated at **NHS homeopathic hospitals**:

Liverpool (2001)

An outcome survey carried out at the Liverpool department of homeopathic medicine over a 12 month period in 1999-2000 surveyed **1,100 patients¹⁴**; **76.6% reported an improvement** in their condition since starting homeopathic treatment and **60.3% regarded their improvement as major**. 814 patients were taking conventional treatment for their condition and 424 [52%] of these were able to reduce or stop conventional medication. The main conditions treated were osteoarthritis, eczema, chronic fatigue syndrome, asthma, anxiety, headaches, inflammatory arthritis and irritable bowel syndrome.

Royal London Homeopathic Hospital (2003)

A **500-patient survey** at the RLHH showed that many patients were able to reduce or stop conventional medication following homeopathic treatment.¹⁵ The extent of improvement varied between diagnoses e.g. 72% of patients with skin complaints reported being able to stop or reduce their conventional medication; for cancer patients there was no reduction. The study also showed that many patients seek homeopathy because of their concerns about the safety of conventional treatment.

Bristol Homeopathic Hospital (2005)

An observational study at Bristol Homeopathic Hospital included over **6,500 consecutive patients** with over 23,000 attendances in a six-year period;¹⁶ **70% of follow-up patients reported improved health, 50% major improvement.** The largest improvements were reported in childhood eczema or asthma, and in inflammatory bowel disease, irritable bowel syndrome, menopausal problems and migraine.

Bristol, Glasgow, Liverpool, London and Tunbridge Wells (2008)

In this pilot study, data from **1602 follow-up patient appointments** at all five NHS homeopathic hospitals were collected together over a one-month period.¹⁷ At their second homeopathic appointment, 34% of follow-up patients overall reported an improvement that affected their daily living. For patients **at their sixth appointment**, the corresponding **improvement rate was 59%**. Eczema, chronic fatigue syndrome, menopausal disorder, osteoarthritis and depression were the "top five" most referred conditions.

Patients referred to NHS homeopathic hospitals typically have chronic conditions for which available conventional treatments have not been sufficiently effective. In total, the study identified 235 separate medical complaints treated at the hospitals during one month. Many patients had multiple pathologies. The study showed that reported health benefits may occur more quickly in some medical conditions than in others. The pilot findings are informing a programme of standard setting for treatment outcomes in the NHS homeopathic hospitals.

France

'EPI3' Project (2008-2012)

Homeopathy is widely used in France and a major study following 8559 patients attending GP practices was used to assess the effectiveness of homeopathic treatment. This 'EPI3 study'¹⁸ is managed by LA-SER a UK-based company specialised in scientific evidence for medicine and health technologies (<http://www.la-ser.com/>). The project team includes individuals from high-profile institutions such as the Institut Pasteur in Paris, University of Bordeaux and McGill University, Montreal; Lucien Abenham is the French General Director of Health (Surgeon General).

Key findings of the EPI3 project:

- **Upper respiratory tract infections (URTIs)**

Patients treated by GPs trained in homeopathy did as well clinically as those treated with conventional medicine, but used fewer conventional drugs.¹⁹ This study investigated the

use of antibiotics and antipyretic/anti-inflammatory drugs use for the treatment of upper respiratory tract infections (URTIs). 518 adults and children with URTIs were included. Patients who consulted with GPs certified in homeopathy showed significantly lower consumption of antibiotics (OR=0.43, CI: 0.27–0.68) and antipyretic/anti-inflammatory drugs (OR=0.54, 95% CI: 0.38–0.76), with similar evolution in related symptoms.

- **Musculoskeletal disorders (MSDs)**

Patients treated with homeopathy did as well clinically as those treated with conventional medicine, but used only half the amount of non-steroidal anti-inflammatory drugs (NSAIDs) and had fewer NSAID-related side effects.²⁰

1153 eligible patients with MSD were followed for 12 months, comparing groups who received homeopathy (N=371) or conventional medicine (CM; N=272), or a mixed approach involving both approaches (N=510). Patients did not differ between groups except for chronicity of MSDs, which was higher in the homeopathy group (62.1%) than in both the CM (48.6%) and mixed (50.3%) groups. The twelve-month development of specific functional scores was identical for all groups ($p > 0.05$). After adjusting for propensity scores, NSAID use over 12 months was almost half in the homeopathy group (OR, 0.54; 95%CI, 0.38-0.78) as compared to the CM group; no statistically significant difference was found in the mixed group (OR, 0.81; 95% CI: 0.59-1.15). MSD patients seen by homeopathic physicians showed a similar clinical progression when less exposed to NSAID in comparison to patients seen in CM practice, with fewer NSAID-related adverse events and no loss of therapeutic opportunity.

Germany

Comparing homeopathy and conventional care (2005)

A study commissioned by a German health insurance company to determine whether to continue covering homeopathic treatment assessed the value of homeopathy in treating chronic conditions commonly seen in general practice.²¹ **493 patients** (315 adults, 178 children) treated by general practitioners received either conventional medicine or homeopathy. **Patients in the homeopathy group reported greater improvement than the conventional medicine group ($p=0.002$) with no significant difference in cost.**

The physicians' assessments showed that children who received homeopathy had a better clinical response than those who received conventional medicine ($p<0.001$). Conditions treated included headache, low back pain, depression, insomnia and sinusitis in adults, and atopic dermatitis, allergic rhinitis and asthma in children. Following this study, Innungskrankenkasse Hamburg decided to continue to cover homeopathic treatment.

Eight-year follow up of chronically ill patients treated with homeopathy (2008)

This study which followed over 3500 adults and children receiving routine homeopathic care from GPs,²² found that **"patients who seek homeopathic treatment are likely to improve considerably"**. At the start, 97% of participants were diagnosed with a chronic complaint, with 95% declaring prior conventional treatment for their condition. Disease severity decreased significantly ($p < 0.001$) between the start of the study, after 2 years and after 8 years of homeopathic treatment. Notably, after 8 years, figures were almost identical to 2-year follow-up, indicating steady long-term health benefits.

This multi-centre 8-year longitudinal cohort study concentrated on patients in routine care treated by GPs with additional qualifications in homeopathy. The study included 3,709 patients, 73% of which contributed data to the 8-year follow-up i.e. 2,722 adults (72.8% female, age at baseline 41.0 ± 12.3) and 819 children (48.4% female, age 6.5 ± 4.0). The most frequent diagnoses were allergic rhinitis and headache in adults, and atopic dermatitis and multiple recurrent infections in children.

Main outcome measures, utilising conventional medical research instruments, included quality of life (QoL) and numerical severity scale assessments. One in two patients experienced reductions of 50% in symptom severity after 8 years, with corresponding changes in QoL measures. Of adults, almost 50% of responders (67.4% total study population) experienced "clinically relevant treatment success" (complaint severity reduced 2 points or more on a 10-point scale); in children the figure was 80%. Younger age, female gender and more severe disease at baseline were factors predictive of better therapeutic success.

What motivates patients to use homeopathy?

Qualitative research carried out at Glasgow Homeopathic Hospital found that those motivated to seek this form of treatment may achieve an empathy with their homeopathic doctor that can make a positive contribution to the enablement and health change they feel as a result of their appointments^{23,24} Patients attributed key importance to the length of consultations, the whole-person approach, being treated as an individual, and telling and having their "story" listened to in depth.²⁵

Acknowledgments

Our thanks to Hugh Nielsen whose summary of UK observational data we edited and added to.

For further information visit www.hri-research.org or contact info@hri-research.org

References

1. Evidence Check 2: Homeopathy, Report by the House of Commons Science and Technology Committee, February 2010
2. Earl Baldwin of Bewdley, June 2010: Observations on the report *Evidence Check 2: Homeopathy* by the House of Commons Science and Technology Committee, February 2010
3. Kleijnen, J., Knipschild, P. & ter Riet, G. Trials of homeopathy. *BMJ* **302**, 960 (1991).
4. Linde, K. *et al.* Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trials. *Lancet* **350**, 834–843 (1997).
5. Linde, K. *et al.* Impact of study quality on outcome in placebo-controlled trials of homeopathy. *J. Clin. Epidemiol.* **52**, 631–636 (1999).
6. Cucherat, M., Haugh, M. C., Gooch, M. & Boissel, J. P. Evidence of clinical efficacy of homeopathy. A meta-analysis of clinical trials. HMRAG. Homeopathic Medicines Research Advisory Group. *Eur. J. Clin. Pharmacol.* **56**, 27–33 (2000).
7. Shang A, Huwiler-Muntener K, Nartey L, *et al.* Are the clinical effects of homeopathy placebo effects? Comparative study of placebo-controlled trials of homeopathy and allopathy. *Lancet*, 2005; **366**: 726–32
8. Lütke, R. & Rutten, A. L. B. The conclusions on the effectiveness of homeopathy highly depend on the set of analyzed trials. *J. Clin. Epidemiol.* **61**, 1197–1204 (2008).
9. Mathie RT, *et al.* Randomised placebo-controlled trials of individualised homeopathic treatment: systematic review and meta-analysis. *Systematic Reviews*, 2014; **3**:142.
10. Mathie, R. T., Frye, J. & Fisher, P. Homeopathic Oscilloccinum(®) for preventing and treating influenza and influenza-like illness. *Cochrane Database Syst. Rev.* **12**, CD001957 (2012).
11. Jacobs, J., Jonas, W. B., Jiménez-Pérez, M. & Crothers, D. Homeopathy for childhood diarrhea: combined results and metaanalysis from three randomized, controlled clinical trials. *Pediatr. Infect. Dis. J.* **22**, 229–234 (2003).
12. Sinha, M. N. *et al.* Randomized controlled pilot study to compare Homeopathy and Conventional therapy in Acute Otitis Media. *Homeopat. J. Fac. Homeopat.* **101**, 5–12 (2012).
13. Taylor, J. A. & Jacobs, J. Homeopathic ear drops as an adjunct to standard therapy in children with acute otitis media. *Homeopat. J. Fac. Homeopat.* **100**, 109–115 (2011).
14. Richardson W R. Patient benefit survey: Liverpool Regional Department of Homoeopathic Medicine. *Br Homeopath J* 2001; 90: 158-162.
15. Sharples F, van Haselen R, Fisher P. NHS patients' perspective on complementary medicine. *Complement Ther Med* 2003; 11: 243-248.
16. Spence D, Thompson E A, Barron S J. Homeopathic treatment for chronic disease: a 6-year university-hospital outpatient observational study. *J Altern Complement Med* 2005; 5: 793-798.
17. Thompson E A, Mathie R T, Baitson E S, Barron S J, Berkovitz S R, Brands M, Fisher P, Kirby T M, Leckridge R W, Mercer S W, Nielsen H J, Ratsey D H K, Reilly D, Roniger H, Whitmarsh TE (2008). Towards standard setting for patient-reported outcomes in the NHS homeopathic hospitals. *Homeopathy*, **97**:114-121.
18. Grimaldi-Bensouda, L. *et al.* Benchmarking the burden of 100 diseases: results of a nationwide representative survey within general practices. *BMJ Open* **1**, e000215 (2011).
19. Grimaldi-Bensouda, L. *et al.* Management of upper respiratory tract infections by different medical practices, including homeopathy, and consumption of antibiotics in primary care: the EPI3 cohort study in France 2007-2008. *PloS One* **9**, e89990 (2014).

20. Rossignol, M. *et al.* Impact of physician preferences for homeopathic or conventional medicines on patients with musculoskeletal disorders: results from the EPI3-MSD cohort. *Pharmacoepidemiol. Drug Saf.* **21**, 1093–1101 (2012).
21. Witt C, Keil T, Selim D, et al. Outcome and costs of homeopathic and conventional treatment strategies: a comparative cohort study in patients with chronic disorders. *Complement Ther Med*, 2005; **13**: 79-86
22. Witt, C. M., Lüdtke, R., Mengler, N. & Willich, S. N. How healthy are chronically ill patients after eight years of homeopathic treatment?--Results from a long term observational study. *BMC Public Health* **8**, 413 (2008).
23. Mercer S W, Reilly D, Watt G C (2002). The importance of empathy in the enablement of patients attending the Glasgow Homoeopathic Hospital. *British Journal of General Practice*, **52**:901-905.
24. Bikker A P, Mercer S W, Reilly D (2005). A pilot prospective study on the consultation and relational empathy, patient enablement, and health changes over 12 months in patients going to the Glasgow Homoeopathic Hospital. *Journal of Alternative and Complementary Medicine*, **11**:591-600.
25. Mercer S W, Reilly D (2004). A qualitative study of patient's views on the consultation at the Glasgow Homoeopathic Hospital, an NHS integrative complementary and orthodox medical care unit. *Patient Education and Counselling*, **53**:13-18.