Homoeopathy: The Evidence Puzzle

Foreword to August 2010 version

This is a personal set of notes rather than an academic publication, updating a March 02 Harvard Medical School lecture, and a previous published summary version titled "The Evidence for Homoeopathy" [1].

Does homoeopathy work? What evidence is there? Answering these seemingly simple questions provokes remarkable debate: the evidence needed, and its interpretation varying greatly with the needs and biases of the questioner – be they patients, practitioners, managers, academics or skeptics. This personal comment paper bears in mind some of the concerns of these differing interest groups. It draws on the developmental "Glasgow Model" from The Centre for Integrative Care at the Glasgow Homoeopathic Hospital, but the views are my own - a doctor studying human healing, and testing the validity of orthodox and complementary medicine. With an interest in placebo, I began skeptical of homoeopathy, but ran controlled trials that appeared to show that the medicines work over and above the evident healing effect of the general method of care.

Outline of the Paper and Questions Discussed:

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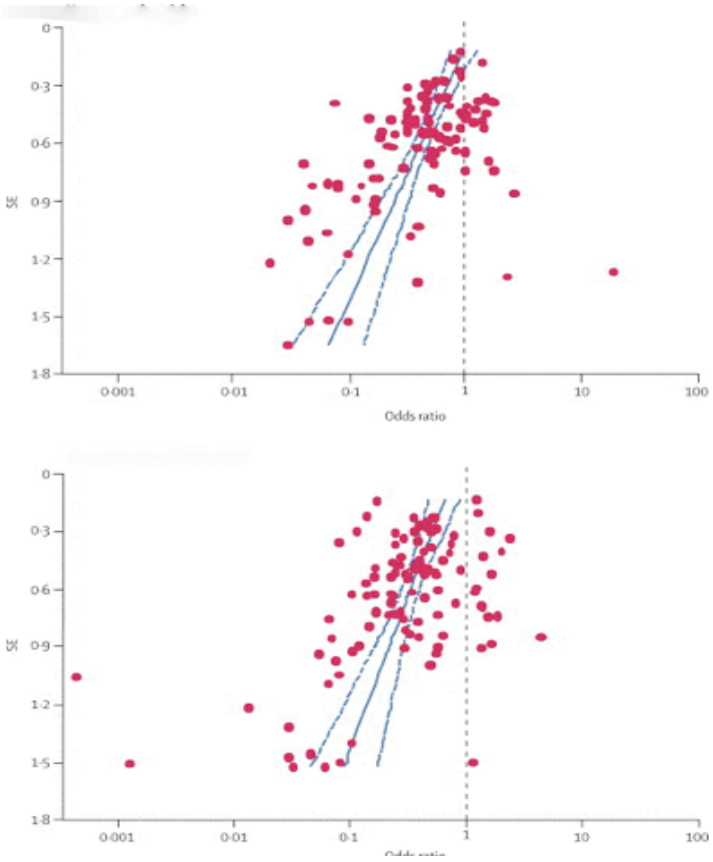
The traditional spelling of homoeopathy is used here, but it is increasingly also spelt homeopathy.

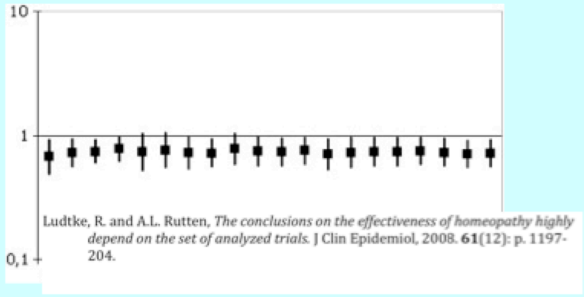
PART I: THE PUZZLE OF HOMOEOPATHY

Welcome to the puzzle of homoeopathy, one I have been intrigued and involved with for a long time. The puzzle brings questions like: Why do 49% of Scotland's general practices prescribe it, and doubled their prescribing for under 16s from 2000 to 2005? (Br J Clin Pharmacol 2006;62:6:647-652); Why do they describe better results, less side effects and reduced costs? Why is there so much polemic controversy interpreting the 100+ randomised trials to date? And, the key starting point for me with my interest in human healing capacity: Are the useful clinical effects all due to placebo responses? You must approach this puzzle in your own way. Some do so with confidant pre-assertion that homoeopathy cannot work, a stance that can even become a data-free scientism zone, others have an equal but opposite blind faith of belief, raising the system to a cure-all. I tackled the key placebo-only question with teams at Glasgow University in a series of four randomised double blind placebo- controlled trails - three of them published in the Lancet and BMJ. They failed to support the placebo-only hypothesis – and in fact they offered evidence that there was more than a placebo effect. Meantime, what ever "the solution", I have been struck by the rich contributions to the therapeutic encounter and relationship that some forms of homoeopathy have evolved - with much to teach us about holistic practice.

Does Homoeopathy work? Have a look at these two scatter plots analyzing placebo controlled trials - one shows 110 conventional trials, the other 110 homoeopathic trials – but I've removed the labels for now. If the oft-repeated statement *"There is no evidence for homoeopathy"* is true, then one set of dots should show this. (Dots to the left of the vertical dotted line are showing an effect greater than placebo). Is it clear to you that one set of data worked and the other did not? Do you think both show evidence of effect? Most meta-analyses have said "yes" to both sets working. But in 2005 Shang et al, having agreed both sets worked, went on to say so "no" to homoeopathy - based only on their small sub-group sub-analysis on 8 homoeopathy and 6 orthodox trials of their choosing. An accompanying high-profile editorial suggested "The End of Homoeopathy. In synchrony, some campaigners targeted removal of homoeopathy from the UK health service "because there is no evidence" What do you think? Which is which is shown in the article that follows (which also gives the references for this introductory section).



Bias? Later, other scientific groups noted that the authors choice of 8 homoeopathic trials in the sub-analysis was one of only 3 of the 20 possible cut-off points that could have been chosen to show a negative effect - with all the others showing a significantly positive effect (see the figure to the right here). This second paper did not get the same publicity as the first, and the dominant cultural impact of the first work was not reversed. The authors of the negative paper stated their *a priori* bias – that because they could see no plausible mechanism of action, then homoeopathy could not work, and any evidence that supports it must be wrong. Here they are part of a long-standing tradition in medicine.



Ludtke, R. and A.L. Rutten, *The conclusions on the effectiveness of homeopathy highly depend on the set of analyzed trials.* J Clin Epidemiol, 2008. **61**(12): p. 1197-204.

Figure 2. Indicates that all but 3 of 20 possible cut-off values lead to a significant effect if we consider all higher quality trials. The exceptions are *n = 144 (including 6 trials), n = 122 (7 trials) and n = 98 (10 trials). If the cut-off point is below n = 98 the pooled results of higher quality studies is consistently statistically significant.*

Theory or Data? Although Homoeopathy is a branch of western medicine, it has been mostly rejected by medical orthodoxy over its 200 years history because no clear mechanism of action has been identified. The argument against it then, and now, might be summarized as *'It can't work, so it doesn't work"*. Some then some inaccurately paraphrase this viewpoint as *"there is no evidence"*. Yet as you have just seen, there is evidence - with enough randomized trials to generate a number of meta-analyses, and a number of interpretations. Evidently, a lack of a mechanism for action is no argument for *a priori* rejection of evidence: you can't argue data out of existence - to do so is scientism, not science. So to consider homoeopathy, is also to consider the cultural processes of science.

From the mid-1980's public demand soared, and with it professional interest – by 2000, around 20% of Scotland's general practitioners had completed basic training, by 2003/4 49% of 323 general practices in Scotland prescribed homoeopathic remedies, and a survey of hospital consultants views suggested reduced medical skepticism. This rise in interest and use came partly from the growing public interest in a more whole person approach to medicine in general, the rise of complementary medicine, the more mind-body approach of homoeopathy, the limits of orthodoxy and concerns for side effects, and partly from growing scientific evidence with an increasing number of positive trials and meta-analyses. Then from 2005 a change in medical attitude began, perhaps precipitated by the negative conclusion of the first of the papers above. Some have argued this change was fueled by a media campaign from lobbying groups such as Sense about Science - who argue: *"homeopathy acts only as a placebo and there is no scientific explanation of how it could work any other way"* [2]. Indeed some homoeopathic dilutions are so extreme that on face value it is understandable that critics offer this argument. Yet data must trump theory – and the challenge is - most trials and meta-analyses of controlled trials have failed to support this "cannot work so must be placebo" hypothesis. In fact on balance these studies point towards real effects - mechanism of action unknown.

So What Is It? Homoeopathy varies from the dominant Western model in its approach to patients and illness in two fundamental ways. Firstly, its view of people differs – it never postulated a mind-body divide, and always took a whole person approach - which encourages enhanced therapeutic encounters. That however is hardly controversial, and is increasingly seen as a good thing. Secondly, its approach to treatment differs: it uses the potential of toxins (at controversially high agitated dilutions) to provoke defense and self-regulatory responses rather than the more orthodox

approach of blocking body reactions. To prepare a homoeopathic medicine, a toxic substance is studied to determine which body systems it can stress or derange. Then, if a patient's illness involves disturbances closely corresponding to this toxic pattern, the toxin is prescribed, attenuating through serially agitated dilution, to provoke homoeostatic responses - supporting the body's defense patterns – perhaps as a "toxic signal" lacking toxicity – analogous to low dose allergen desensitization (which homoeopathy was first to explore). Critics and advocates agree that the levels of dilution ensure the medicine is non-toxic, but critics argue they are too dilute to be active, drawing amusing metaphors – like one aspirin dropped in the ocean treating all the fish at once. Advocates argue a molecular concentration model is the wrong one, and we are in the realm of signal processing, more akin to how downloaded music has none of the original molecules in it but still works. The critics have the best jokes, but it is not clear who will have the last laugh.

This method of provoking body self-regulation gives a hint of its clinical scope: it claims to help, at times resolve, conditions which our natural healing mechanism can potentially reverse, but not mechanical problems, deficiencies or irreversible breakdowns in body functions, where it is only palliative or ineffective. Orthodox and homoeopathic approaches are complementary and can be used together.

Further discussion about the background, clinical systems or applications of homoeopathy are outside the scope of this paper, but a further reading list is given at the end.

So this puzzle brings a real scientific quandary, not easily resolved by reflex comment. The paper that follows will commenting on the controlled trial evidence, and also raise the challenge that clinical outcome studies show useful clinical impact, excellent safety and a potential to enhance patient care by integrating homoeopathic and orthodox medicine. But before that, let's talk about this word "evidence".

PART II: THE NATURE OF EVIDENCE

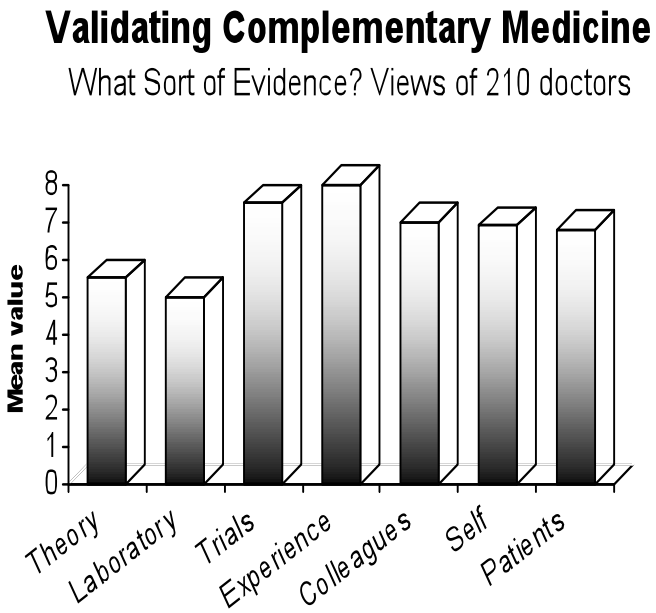
Professor Sackett opens his seminal book on Evidence Based Medicine (EBM) [3] with *"Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values."*. EBM is not a method to use the first of these to dominate the other elements (e.g. see http://www.cche.net/usersguides/ebm.asp#31).

In trying to find a balance between literature appraisal, clinical evaluation, and human caring, we are part of a larger cultural wave of change in medicine – explored in the 'The 5th Wave' [4] Report from The Public Health Institute of Scotland where it is argued that the cultural and conceptual divergence of 'objective' truth (nomothetic, scientific, falsifiable, reproducible) and 'subjective' truth (idiographic, personal experience) is not 'resolvable' - a balanced view must emerge embracing both with respect. No one experiences illness or care in the same way, our unique experience cannot be exactly replicated, and even the road to 'objective' science is approached via the idiographic route.

Asking if homoeopathy works brings these issues into sharp focus and it seems the time has not yet arrived when the homoeopathic puzzle is ready to be 'solved' in fact it is more in the nature of a "complex problem" than a puzzle with a solution. We are at a point when the RCT (randomised controlled trial) evidence is sufficient only to allow debate on whether homoeopathy varies from placebo, but not to comment on individual conditions. For that we need a synthesis of observational studies and qualitative work – which mostly show that patients are being helped and are satisfied. In fact, these are the sorts of dilemmas that General Practitioners (GPs) deal with daily – given that the majority of orthodox interventions do not have clear scientific evidence. Let's look at how they tackle this.

1. The Evidence Profile

When 210 GPs were asked to rated different forms of evidence that they would need before using or recommending an unorthodox therapy, their answers suggested that evidence forms a mosaic - an 'Evidence Profile' [5]. As this figure shows, theoretical factors are seen as least important, while a systematic examination of outcome ("Experience") is placed highest, with clinical trials next. Professional experience and patients' views are still rated very highly, well ahead of theoretical or laboratory evidence. Since this survey, the emphasis has if anything now grown stronger on patient's experiences.

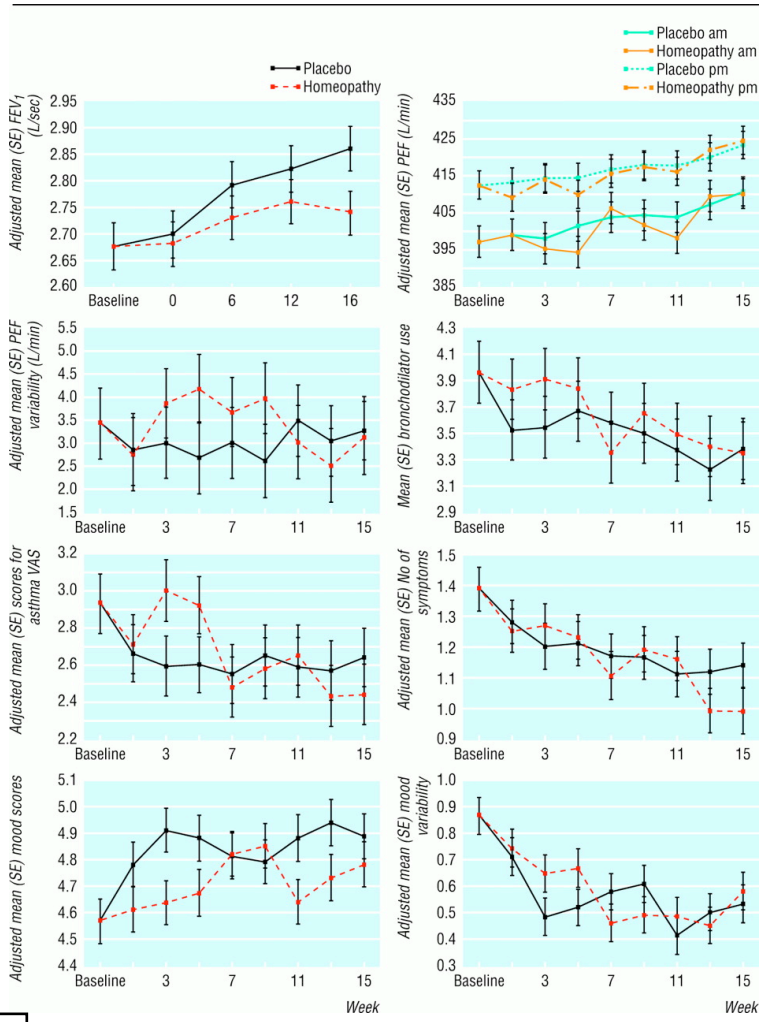


2. The Double Positive Paradox

Most agree that homoeopathy is good at inducing helpful changes – even if you call it - 'placebo, context-effects, context-enhanced effects, non-specific healing impact' or perhaps simply a 'healing response' [6]. But this success brings a problem by potentially creating *enhanced useful improvements from placebo* in trials, to such a degree at times that any therapy would be hard pressed to achieve any additional effect. This impacts the power (i.e. numbers) required to detect any such additional effect over the enhanced placebo effect. Take the Lewith et al trial that was reported as negative in asthma [7] with the BMJ commentary saying it 'did not work – so it was a waste of time'. In fact, (see figure/box below) *both* groups showed a clinically significant useful improvement. With such an enhanced placebo action, you need a very large study to tease out any action over and above this significant placebo response and avoid a false negative (Type II statistical error) because of inadequate numbers [8]. If say 50% of people respond to placebo and 80% to active, you would need 40 per group, or 50% Vs 70% needs 100 per group, but at 50% vs 60% you needs 400 per group (ref 32).

I've labeled this peculiar challenge - when a useful improvement is labeled a waste of time - "the double positive paradox" [9] [10]. If a trial is negative we need to ask - was it that both groups were negative, with no clinical effect, or were both groups positive? The latter calls for further enquiry. The rest of this paper now travels into that enquiry.

"Clinical efficacy of homoeopathy There was a significant increase from baseline in FEV_1 (P=0.006) and a significant decrease in asthma bother score (P=0.001) in both groups. There were also significant improvements in many of the diary measures. However, there was no significant difference between the groups in either of the two primary outcome variables."



Lewith et al. BMJ 2002;324:520-3.

PART III: THE EVIDENCE PROFILE FOR HOMOEOPATHY

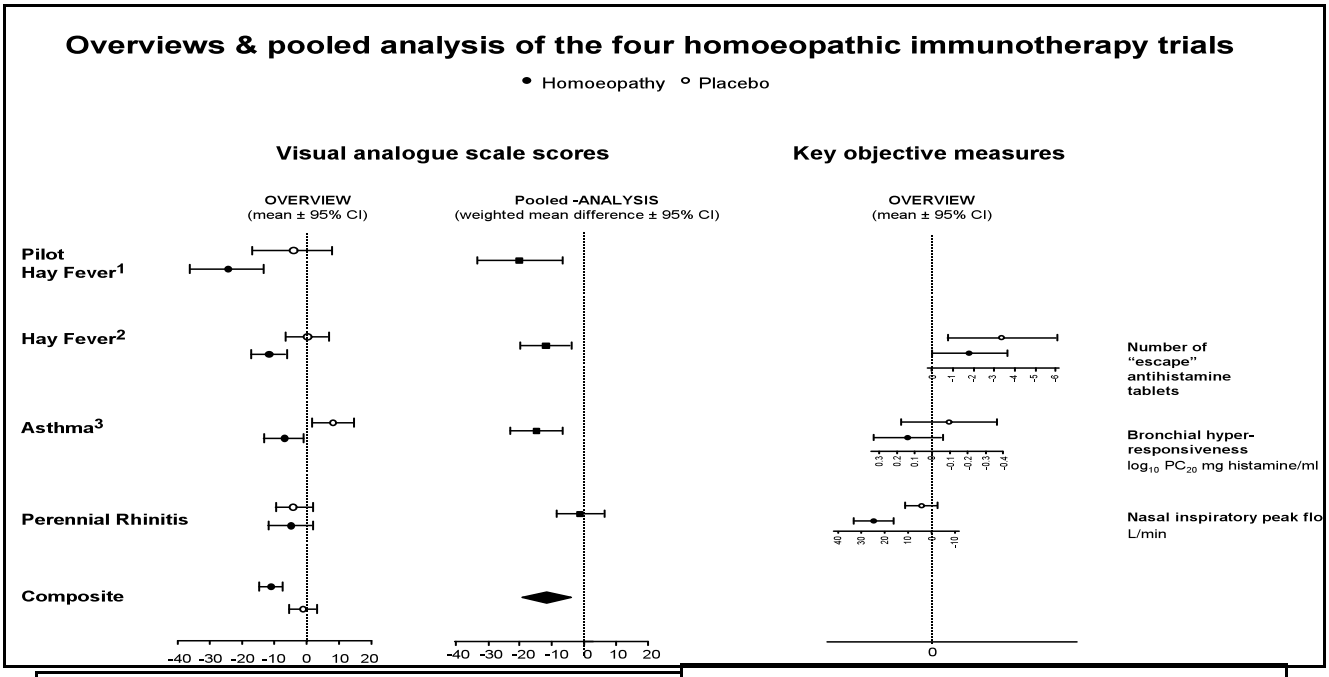
IS IT EFFECTIVE?

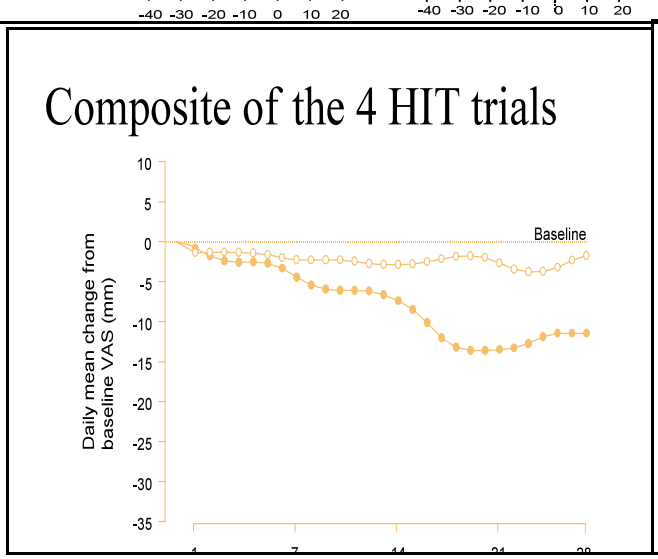
1. Is it effective when examined 'scientifically'? Is it a placebo response?

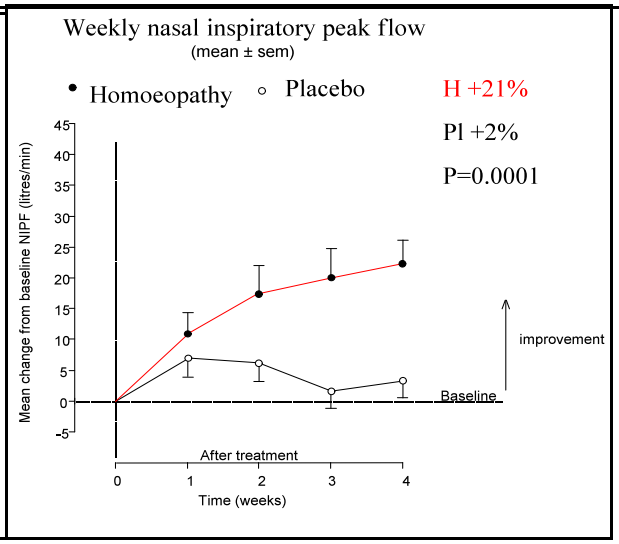
Skeptics may agree homoeopathy works, but say it's due *solely* to placebo. This is a hypothesis, not a fact. Hypotheses need tested. Assumed it was placebo, I set out to test my assumption. My bearings in this storm of controversy come from that part of the evidence mosaic that I can personally vouch for.

The 4 HIT Trials

With co-workers and independent colleagues at Glasgow University we conducted 4 double blind placebo controlled trials specifically designed to examine the evidence for the placebo hypothesis [11 12 13 14]. The initial bias was that placebo explained homoeopathy - but the results did not support this: all 4 trials produced patterns of results that clearly favoured homoeopathy over placebo.







Figures ref 13 BMJ 2000;321:471-6) 4 HIT trials (pilot & principle:hay fever, confirmatory: asthma & perennial rhinitis) using homoeopathic allergen desensitisation as a model to test a) the placebo hypothesis, and b) the reproducibility of the pilot's evidence in favour of homoeopathy. The top figure shows the patterns of the 4 trials. Bottom left is the composite of the symptom score (VAS) in all 252 patients, and bottom right shows the objective measure from the 4th trial.

So we were presented, and in turn presented the scientific community [15], with the challenge that either these results suggested that homoeopathy works, or, that the clinical trial is flawed - because - if homoeopathy is solely a placebo, then our experience was that the trial as a methodology was producing false positive results, with predictability and reproducibility, and at a rate which would undermine its use as a scientific tool for assessing orthodox treatments.

Major systematic reviews

Over the 18 year time frame of our 4 trail enquiry described above, many other researchers similarly attempted to address the placebo hypothesis using controlled trials, and a 1997 review found there had been over 180 controlled, and 115 randomized trials. By 2009 there had been 142 peer-reviewed RCTs in 129 papers reporting placebo controlled or non-placebo controlled RCTs of homeopathy: 63 (44%) had positive findings; 11 (8%) were negative; 68 (48%) were non-conclusive. These trials represent research in a total of 74 different medical conditions. Two or more studies are available for each of 28 conditions[16].

By 2006 there were four comprehensive (full data set of trials), independent systematic reviews or meta-analyses examining the question whether homoeopathic therapies behave like placebo in placebo-controlled RCTs. (The definition of meta-analysis is changing, and so the earlier overviews might better be called criteria based reviews. True meta-analyses, in the sense of combining original data from different trials, are rare beasts both in general and in homoeopathy (although in fact the pooled analysis shown in the Figure above achieved this to some degree, as did the European Commission review (see ref 20 below)).

On balance this evidence favours homoeopathy being more than a placebo (only 1 review concluded otherwise), and fails to strengthen the hypothesis that placebo is the sole explanation. However, overall there is insufficient data to comment on individual conditions, remedies or dosage regimes in any consistent way.

The first of these comprehensive reviews was published in the BMJ in 1991 by Kleijnen et al [17]. This team headed by Prof. Knipschild of the Department of Epidemiology at Limburg University was commissioned by the Dutch Government to independently review the evidence for homoeopathy. They spent two years assembling and analysing the trials. They found 107 controlled trials - 14 classical, 58 single remedy, 26 combinations, 9 isopathy. They commented 'Most trials seemed to be of very low quality, but there were many exceptions. There was a positive trend regardless of quality. Overall, of the 105 trials with interpretable results, 81 trials indicated positive results, in 24 no positive effects were found.' They concluded *"The evidence presented in this review would probably be sufficient for establishing homoeopathy as a regular treatment for certain indications... Based on this evidence we would be ready to accept that homoeopathy can be efficacious, if only the mechanism of action were more plausible."*.

In a fresh review of work up to 1996, published in the Lancet in 1997, Linde et al [18] found that 73% of trials to date were in favour of a greater than placebo action from homoeopathy. Their criteria based meta-analysis of 89 trials gave a pooled-odds ration of 2.45 with homoeopathy (showing twice the effects of placebo). The statistical significance proved robust when corrected for key variable including likely publication bias. They concluded that the *"results are not compatible with the hypothesis that the clinical effects of homoeopathy are completely due to placebo"*, noting that there was insufficient evidence to comment on individual conditions.

The next review was the independent one from The Homoeopathic Medicine Research Group ordered by the European Parliament to report to the European Commission Directorate General XII: Science, Research and Development. This again involved a fresh review and analysis, and like its predecessor concluded that the balance of evidence is in favour of homeopathy [19]. From this 17 trial comparisons in 2001 patients were deemed suitable for a pooled p-value meta-analysis and this gave a p-value of 0.0003, and the comment that *"it is likely that among the tested homeopathic approaches some had an added effect over nothing or placebo"*[20].

A 'critical overview of homeopathy' in the Annals of Internal Medicine reviewed the studies and systematic reviews up to 2003. The conclusion of their review of the whole data set echoed the now common view that

there is positive evidence for overall effect [21]. Overall we can perhaps say that trails to date make reasonable inroads into testing the 'placebo only' hypothesis - and have found that particular explanatory model lacking.

Specific Conditions Meta-analyses
The 2003 review mention above then considered the question of the evidence base for particular conditions and emphasized that *"limited number, and size, of trials to date, determine a lack of data to draw conclusive evidence on the effectiveness of homeopathy for most conditions"* . Their review of 12 systematic reviews of clinical trials of homeopathy for specific conditions suggested that homeopathy is effective for allergies, childhood diarrhoea, influenza, postoperative ileus, and not for migraine, delayed-onset muscle soreness, or influenza prevention. Other early attempts at assessing impact in specific conditions by selective meta-analyses (for example in osteoarthritis[22], post-operative ileus[23] rheumatoid arthritis [24]) mostly note the positive trend but have to conclude that there is not yet enough data to draw firm conclusions.

The latter failing arises primarily from the lack of sufficient number of trials in general and in any one focused context (only 6% of the studies in the 1997 review had >200 participants), and because most trials were not primarily designed to validate specific parts of the very mixed range of homoeopathic therapeutics, nor to compare homoeopathy to conventional therapy. This will take a long time and is mostly being tackled by other methodologies.

Some mis-report this as "there is no evidence it works" as opposed to "there is insufficient data to make comment". In fact this absence of evidence (not evidence of absence) caused the NHS Centre for Reviews and Dissemination in 2002 [25] to conclude in its own review that there was insufficient data to recommend homoeopathy for any specific condition. They commented that this would imply a 'no change' in the NHS funding – and the director Jos Kleinjnen clarified for me this meant no increase *or decrease* in funding (personal communication).

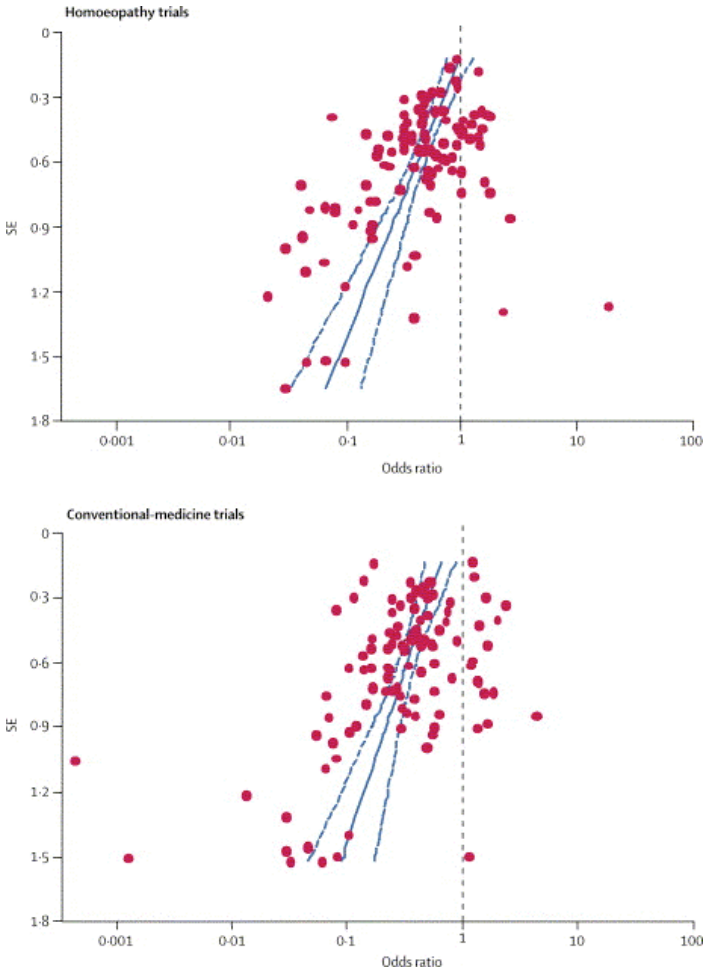
Given the subgroup/individual condition controversies, in 2003 Mathie backpedaled to the original trials and in a fresh assessment, emphasizing clinical effect, noted in 93 substantive RCTs that compare homeopathy either with placebo or another treatment, 50 papers showed significant benefit of homoeopathy in at least one clinical outcome measure, 41 showed no difference between groups, and 2 showed placebo better than homoeopathy [26]. (The 'no difference' group might now usefully be analysed for the double positive paradox mentioned above (ref 10) – in the 'no difference' trials did neither treatment work, or both work?). For now it seems that advocates and critics will continue to interpret, and sub-analyse, this raw data in very different ways.

Sub-analyses and 2nd 3rd and 4th order comments

A number of sub-analyses of the larger reviews have now taken place, for example in relation to trial quality. To put this in context, it is important to note that in both conventional and homoeopathic trials it has been show than smaller studies and those of lower quality tend to show greater effects [30], so that a reduced effect in quality-criteria selected subgroups could be predicted for any therapy. Also as *"… overall, the quality of clinical research in homoeopathy is low, but on average is higher than matched conventional trials"* [30] then any comparison is likely to show lower treatment effects from the data set with higher quality trials (ie homoeopathy). However, when only high-quality studies have been selected for analysis (such as those with adequate randomization, blinding, sample size, and other methodological criteria that limit bias), a surprising number still show positive results - for example in the Kliejnen et al review mentioned above a detailed quality evaluation of 60 trials still drew a positive conclusion. In the Linde et al Lancet review (ref 18 above), where 29% of trials were judged of 'high methodological quality', multiple subset and sensitivity analyses on many quality variables reduced, but did not eliminate, an effect in favour of homoeopathy. As expected, effects were reduced in larger studies and when there was inadequate blinding to outcome.

This Linde et al review in turn has been subject to various subset analyses by the original authors and others. These and other subsequent comments from this larger data set give progressively narrower and more partisan views of sub-sets, with Ernst even trying a one author 'systematic review of systematic reviews of homeopathy' [27] (using non-defined terms like no 'strong' evidence', not 'convincingly different') - and Bandolier then used this as the basis for adding to its own previously negative comments [28] (by now

being 3 to 4 steps away from actual data generating research, and deeper into personal opinion, and bias). Again, quoting from the Annals review (ref 21) the authors make reference to Ernst's review (ref 27) and their own 1998 subset analyses [29] (of just the 'classical' homoeopathy papers from their comprehensive 1997 review) *"one could eventually eliminate the effects in favour of homoeopathy by applying combinations of unusually selective criteria (such as picking a few of the very best studies and simultaneously adjusting their results for both small sample size and presumed publication bias), thereby decreasing the number of studies included"*.



This sub-set versus whole-set issue came sharply into focus in the 2005 Lancet paper from Mathias Eggar's team in Switzerland [30] which caused a media storm perhaps because the accompanying anonymous editorial was headed 'The End of Homoeopathy'. The work matched and analysed 110 homoeopathy trials (from around 200) with 110 conventional-medicine trials (from around 1/3 of a million). As the Figure shows 'most odds ratios indicated a beneficial intervention' (less than 1) – i.e. both approaches worked better than placebo, confirming the findings of the other large reviews. The homoeopathy trials were of higher quality than conventional-medicine trials (19% vs 8%). In both groups, smaller trials and those of lower quality showed more beneficial treatment effects than larger and higher-quality trials. This seems straightforward. Then warning that *'detection of bias is difficult when meta-analyses are based on small numbers of trials'* the authors did two such small scale subanalysis meta-analyses. The first analysed 8 respiratory trials and was "robustly positive" - and was therefore rejected by these authors as it was so positive: it *'might promote the conclusion that the results cannot be trusted'.* (Note, to make sense of this I should mention the authors' state in the paper their pre-existing bias that homoeopathy cannot work and any positive results must therefore reflect bias or artifact). Their second sub-analysis was restricted to their choice of large trials of higher quality, leaving them to comment on just 8 homoeopathic trials vs 6 conventional studies. The odds ratio was 0.88 (95% CI 0.65-1.19) for homoeopathy (eight trials) and 0.58 (0.39-0.85) for conventional medicine (six trials). In other words both worked, but the conventional trials showed a stronger effect. Their interpretation: there was *"weak evidence for a specific effect of homoeopathic remedies, but strong evidence for specific effects of conventional interventions. This finding is compatible with the notion that the clinical effects of homoeopathy are placebo effects."* The resultant extensive criticism might be summarized as - small data set, large bias – with no information or citation given for the 8 trials chosen, and that the data was 'dredged' to give the least positive result, with other data selections giving clear positive results (eg ref [31] as explored in Part I above of this article). The PEK management group of this Swiss project also offered significant criticisms of this work [32], and notes that other studies that were performed as part of the PEK program showed that homeopathic treatment is cheaper than conventional treatment, that patients treated with homeopathy show greater improvement than after conventional treatment, with less side effects and less hospitalization

Another approach is using only trials from the **same-experimental model in meta-analyses**. Some teams who have conducted repeat experiments of the same type (e.g. Reilly et al in atopic syndrome (see above

and ref 14) and Jacobs et al in childhood diarrhea [33]) have been able to combine their data, and the larger sample sizes have added weight to the individually positive trials.

The **veterinary research** has been interpreted as producing supportive evidence that homoeopathy has a greater than placebo effect, but again there is insufficient data to draw clear conclusions. An illustrative example is work suggesting that homoeopathy can reduce antibiotic use and still birth rates in commercial farming - see the work of Day in stillbirths in pigs and bovine mastitis [34] [35]. A list of 13 positive RCTs (of about 30 published papers) is available from here http://www.facultyofhomeopathy.org/research/veterinary_research.html.

Laboratory Evidence for Biological Effects

The laboratory evidence of biological effects is suggestive, controversial and not yet conclusive, and has shown inconsistent reproducibility. If homeopathy does work then some of this inconsistency may be methodological (likely the issue in a few 'science by TV' trials with new labs failing to get results (and follow the protocol) of established researchers), and some may be that the technology is as yet insufficiently advanced. Some have even suggested human 'operator' effects on the assays – but perhaps this is another marker of over delicate methods. A meta-analysis of 105 publications exploring the protective effects of serial agitated dilutions of toxic preparations noted that while most studies were of low quality, the high quality studies were more likely to show positive effects [36]. Some of the claims are extremely controversial, - an illustrative example: the late Jacque Benveniste (who stirred controversy from his earlier claims of homoeopathic action published in *Nature [37])* then claimed that he could use patterns of electro-magnetic fields signaling (which can be digitally recorded) to imprint patterns on water, with claims of delayed coagulation of plasma when mixed with water which was pre-exposed to the *"signal"* of heparin (ref originally on www.digibio.com - website, off-line since his death). In 2004, more conventional scientific workers from 5 countries published in *Inflammation Research* evidence of ultramolecular dilutions of histamine ability to inhibit basophil activation "in a reproducible fashion". It included one blind study multi-centred in 4 labs, and a second study confirmed the multi-centred study by flow cytometry independently in 3 labs [38]. A more recent meta-analysis evaluated 67 in-vitro biological experiments in 75 research publications and found that high-potency effects were reported in nearly 75% of all replicated studies; however, no positive result was stable enough to be reproduced by all investigators [39].

In 2009 Professor Luc Montagnier, a French virologist who co-discovered HIV and who won the Nobel Prize in 2008, made the radical claim that some bacterial DNA sequences are able to induce electromagnetic (EM) waves at high aqueous dilutions - if they were 'strongly agitated', a step 'critical for the generation of signals'. The effect needs excitation by the ambient electromagnetic background. Pathogenic bacteria and viruses show a distinct EM signature at dilutions ranging from 10^{-5} to 10^{-12} (corresponding to 5x to 12x in homoeopathic dilutions) and in one experiment at 10^{-18}. Small DNA fragments (responsible for pathogenicity) were solely accountable for the EM signal. These signals changed with dilution levels but was unaffected by the initial concentration, or destroying the remaining DNA fragments with chemical agents. The EM signal was destroyed by heating or freezing. A 'cross-talk' effect meant a negative sample inhibits a positive signal if left together overnight in a shielded container. The researchers propose the EM effects come from self-sustained nanostructures in the water, induced by the DNA during the dilution process. They detected the same EM signals in the plasma and in the DNA extracted from the plasma of patients suffering from Alzheimer disease, Parkinson disease, multiple sclerosis, and rheumatoid arthritis, suggesting bacterial infection may be involved [40]. The parallels to homoeopathy are evident: signaling from serially diluted/agitated 1in 10 and 1 in 100 solutions of signatures relevant to the pathological source, with negative samples able to cancel positive ones.

Up to now, the puzzle of homoeopathic evidence has had to rely on the clinical arena – if these new lab results prove sound, they may challenge that situation.

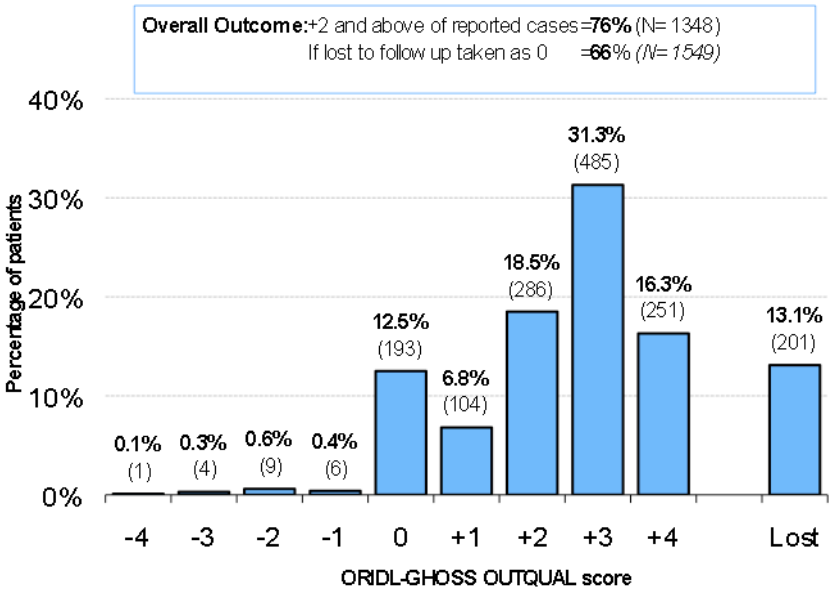
2. It is effective when applied clinically?

While clinical trials have mainly been used to test the placebo hypothesis, observational and outcome studies are being used to test the results of clinical care across the spectrum from primary to tertiary care. The Figure below is taken from an action research cycle tracking the results of prescriptions made in a primary care context using the ORIDL scale: Outcome Related to Impact on Daily Living (formerly GHHOS Glasgow Homoeopathic Hospital Outcome Scale). This is a patient recorded outcome measure where +2 or above is a response they deem to be of significant value, as described in the text box below. ORIDL has shown concurrent validity when compared to MYMOP and SF12 [41].

ORIDL Outcome Scale	
Cured/ Back to normal	**+4**
Major improvement	**+3**
Moderate improvement, **affecting daily living**	**+2**
Slight improvement, no effect on daily living	**+1**
No change/Unsure	**0**
Slight deterioration, no effect on daily living	**-1**
Moderate deterioration**, affecting daily living**	**-2**
Major deterioration	**-3**
Disastrous deterioration	**-4**

Primary Care

This figure shows the results of 1348 prescriptions in primary care (1036 patients), tracked prospectively [42]. These results appear to confirm the traditional claims of important beneficial impact on clinical outcome, with less cost and reduced iatrogenesis.



A 2005 study from the Institute for Social Medicine, Epidemiology and Health Economics, Charite University Medical Center in Berlin compared conventional and homoeopathic care over 1 year in 493 patients (315 adults, 178 children) presenting with 1 of 8 common chronic diagnoses – headache, lower back pain, depression, insomnia, sinusitis, and in children asthma, atopic dermatitis and allergic rhinitis. This showed patients seeking homoeopathic treatment had a better outcome overall compared with patients on conventional treatment, for a similar level of cost. [43]

Secondary Care

Good results are being obtained in more complex problems when treated by a medical homoeopath in an out-patient (ambulatory) setting. Table 1 shows results, as rated by patients, 1 year after out patient care at Glasgow Homoeopathic Hospital [44]. Subsequent work has shown that the effect increases in the second and then again in the third year follow-ups.

Table 1: Audit of Outcome of Care - 100 Out Patients at GHH

100 sequential patients followed up after 1 year with 80% returns.

At presentation:
81% had failed to conventional treatment
47% had seen a Consultant for the problem
After 1 year*: ORIDL*
60% improved in the presenting complaint
61% in well being
49% has a sustained improvement of value in daily living (≥ +2)
37% had a sustained reduction in conventional therapy.

An outcome study at the Bristol Homeopathic Hospital in 6544 consecutive follow-up patients (>23,000 consultations), using an ORIDL form measure, found that 70.7% (4627) reported improvement, with 50.7% (3318) rated at better (+2) or much better (+3) [45].

Data collection across all five homeopathic hospitals in the UK NHS in 2007 confirmed that after a series of appointments, a high proportion of patients, often representing "effectiveness gaps" for conventional medical treatment, reported improvement in health affecting their daily living. The study tracked consecutive patient of 51 medical practitioners over 4 weeks using ORIDL and its derivative, the ORIDL Profile Score (ORIDL-PS) in 1797 patients reporting 235 different medical complaints (see the box for top 30). The proportion of patients with important co-morbidity was 60% with more than 6. Patients reporting an improvement affecting daily living (ORIDL-PS ≥+2) increased from 34% at visit 2 to 59% at visit 6. In the four most frequently treated complaints, outcome varied between 59.3% (CFS) and 73.3% (menopausal disorder) [46].

30 most commonly treated complaints: eczema; chronic fatigue syndrome(CFS); menopausal disorder; osteoarthritis; depression; breast cancer; rheumatoid arthritis; asthma; anxiety; irritable bowel syndrome; multiple sclerosis; psoriasis; allergy(unspecified); fibromyalgia; migraine; premenstrual syndrome; chronic rhinitis; headache; vitiligo; seasonal allergic rhinitis; chronic intractable pain; insomnia; ulcerative colitis; acne; psoriatic arthropathy; urticaria; ovarian cancer; attention-deficit hyperactivity disorder (ADHD); epilepsy; sinusitis. Ref 46

Tertiary Care.

In-patient care at the Centre for Integrative Care at GHH is showing that even after conventional care had proved ineffective, or has plateaued in its effect, patients can be significantly helped by a holistic care approach with an integrative care programme which includes judicious blending of a conventional perspective with homoeopathy and other complementary approaches. Table 2 shows two surveys, each of 100 sequential in-patients with advanced and complicated illness, who were treated in this way [47]. Typically these patients have multiple problems, with mixed chronic pathologies and psychological distress.

Table 2 Summary from Audits of 200 In Patients at GHH

At presentation:

100% had already had conventional care
97% has seen a Consultant for the problem
85% rated the problem as causing major disruption to daily living
67% had previously needed hospitalised for the problem

At a range of 3 -6 months after treatment(94% response rate):
Clinical Outcome (>=2 on ORIDL-GHHOS scale)
73% had a useful improvement in the presenting complaint
70% had a useful improvement in general mood and well-being.

Impact on conventional care:
41% reported ↓ consultations with GP.
41% reported ↓ conventional drugs
53% reported ↓admissions to hospital
39% reported ↓outpatient visits

3. Is it relevant in today's care? Who might benefit? For what?

As the above spectrum of results show, homoeopathy can offer therapeutic options where:

- conventional care has failed or plateaued, after best evidence based medicine has failed
- or conventional can be supplemented with added benefit
- or no conventional treatments exist,
- or they are contraindicated,
- or they are not tolerated from side effects,
- or where patients are reluctant to accept conventional treatment, perhaps from worry about side effects, or as a matter of choice
- when homoeopathy is better than the conventional option.

Collectively these have been labeled the 'efficacy gaps' of conventional treatments.

Two dimensions of care need considered - the direct effects of the remedy, and, the therapeutic impact of the *method* – the approach to the patient. At times homoeopathy is supportive rather than curative and in addition to specific effects it also shows the positive effects of the 'non-specific'/context/values' dimensions. Many general practitioners (GPs) report opting for homoeopathy as first line in certain problems, keeping the more costly and potentially risky conventional treatment as second line [48]. Some practical examples that these GPs say are of value might help illustrate this (bear in mind these are clinical observations, as mentioned above, there are mostly insufficient data from trials to give further scientific comment):

- GPs and practice nurses can use remedies like Colocynthis for colic in infants less than 6 months of age when no conventional drugs are available [48].
- The therapy can reduce allergic sensitivity (eg see The HIT trials above) and conventional desensitization injections are now thought to be too dangerous for primary care use.
- The complications of surgery can be reduced, e.g. by using Arnica cover at the time of dental extraction [49]
- Intensive care challenges – like reducing tracheal secretions to aid extubation with Kali Bic [50] and survival in life-threatening sepsis evidence of increased survival - at Day 30 homeopathy 81.8%, placebo 67.7%, p = 0.19. Day 180 homeopathy 75.8%, placebo 50.0%, p = 0.043 (1 patient saved for every 4 treated) [51]
- Recombinant activated protein C NNT = 16, bleeding event 1:665.
- Useful care in degenerative illness where conventional care is often failing, e.g. rheumatic illness. Or
- In viral illnesses where no drug treatments exist, and
- In those instances of anxiety or depression when psychotropics are best avoided, for example in 'stuck' grief reactions, helping avoid suppression of emotions with psychopharmacology.

Some conditions where there is at least positive 1 RCT would be (some referenced in this paper and full list in ref 26): hay fever, post-operative ileus, rheumatoid arthritis, asthma, fibrositis, influenza, glue ear, muscle soreness, pain (miscellaneous), radiotherapy side-effects, sprains, upper respiratory tract infections, anxiety, ADHD, chronic fatigue syndrome, IBS, insect bite-induced erythema, migraine, osteoarthritis, PMS, seborrheic dermatitis, tissue trauma, vertigo. Clinical outcome studies preceding trial evidence (eg ref 45) have also highlighted conditions such as Crohn's disease, depression, eczema, headache and menopausal syndrome.

4. What can it not do? What are its limits?

The approach seems to rely on defense and self-regulatory responses, unlike the usual orthodox approaches of blocking body reactions or replacing deficiencies. This indicates its clinical scope: while it is claimed it can help, at times resolve, conditions which are intrinsically reversible, the medicines cannot achieve things beyond the healing potential of the body – for example it will not help mechanical problems, deficiencies or

irreversible breakdowns in body functions - where it is only palliative or ineffective. So in conditions such as cancer it is unlikely to directly affect longevity, but it may help quality of life and symptom control. Where cells have been irreversibly destroyed e.g. Islet cells of the pancreas in insulin dependent diabetes it will not work. The whole person approach is often generally helpful, but vigilance is required for when an orthodox approach is also needed. Then there are the multiple spheres of health care that lie beyond the issue of prescribing. Since its beginnings Homoeopathy has explored general health issues, under terms like 'obstacles to cure', and non-prescription factors in health such as nutrition, and attention to social, psychological and environmental barriers to recovery. There is a risk that if the homoeopathic practitioner does not link their care to these general health issues, their practice may become mechanical and prescription focused.

5. Is it cost effective? Is it time-effective?

The main cost of homoeopathic care is in the increased practitioner time. The resultant **prescription costs** are low, on average a quarter of the normal reimbursable medicines charge [52]. A French survey (quoted in ref 52) suggested 87% of patients prescribed homoeopathy did not see another physician for the same problem. In the UK NHS on average less than 4 pounds (8 US dollars), and unit dispensing from stock is even more economical in dispensing practices and clinics.

Compared to conventional care: some studies show results as good as, or better than conventional care at no increase in costs (eg ref 43 above), while others have shown a reduction in orthodox drug and procedure bills after the introduction of homoeopathy, with monitoring suggesting homoeopathic doctors issue fewer prescriptions and at lower cost than their colleagues [53]. An observational study of homeopathy in primary care at a University Paediatric Clinic, Berne on 230 consecutive consultations for acute otitis media showed evidence of averting antibiotics, with resolution considerably faster than in reported series, at a 14% cost savings [54]. A non-randomised, pragmatic cost-effectiveness study of antibiotic' v 'homeopathic' strategies in 529 children with recurrent upper respiratory tract infections treated by French GPs with and without 'homeopathic orientation' showed the homeopathic strategy superior in respect of medical effectiveness, complications, number of consultations, quality of life, and parental time off work with equivalent direct medical costs [55]. One GP monitored 100 patients over 4 years, got good results, and estimated he saved on average 60 pounds per patient [56].

As reported in Tables 1 & 2 above, we have found that one year after beginning **specialist out patient** care, 41% of patients have a sustained reduction in their conventional medications, similar to a survey of 500 out-patients attending the Royal London Homoeopathic Hospital: 29% of patients had stopped and 32% decreased their usage (33% were the same, 6% had increased). The biggest benefits were amongst patients attending for musculo-skeletal, skin and podiatry, genito-urinary, neurological and respiratory conditions [57].

These costs savings are increasingly important at a time of soaring conventional drug costs and budget deficits – the UK NHS Drug bill was £4.9bn in 2000 and £11bn by 2008 (BMJ 2 Feb08).

The experience of GHH is that the all-too-common downward and costly spiral for many patients in conventional care of multiple specialist opinions and investigations can often be interrupted when a whole person integrative approach is adopted, using homoeopathy where appropriate as the first choice drug therapy if a prescription is needed. Certainly, the absence of significant side effects means that the costs of iatrogenic illness are also significantly reduced – and there can be no one who is not worried about the massive burden of drug side effects [58] including the 250,000 UK hospital admissions a year [59].

WHAT OF SAFETY?

6. Are the medicines safe?

The therapy lacks the potential for life threatening side effects - a view accepted by users and critics alike. It can be used in pregnancy, and the extremes of life without harm. A prospective observational tracking of over 1000 acute prescriptions in primary care has recorded all possible adverse events at less than 2% (see Figure above). Follow up case studies of each of these reports did not revealed any damaging reactions. A

review of safety using a world literature search from 1975-1995 and enquiries with regulatory agencies (MCA and FDA), and companies concluded that homoeopathy is generally very safe with incidences of adverse effects being very low and mostly minor and some are errors in recorded with mistaken identity with herbal products. Main risks are indirect due to the practitioner, not the medicine. Another risk is from unscrupulous individual or groups producing contaminated products, making it necessary to use only reputable manufacturers that follow their National Pharmacopoeias.

In chronic conditions there can be an initial aggravation of symptoms that can be distressing, and although part of this is likely from the participants expectations (a nocebo action), the controlled trials lend weight to the reality of this phenomenon [12 14 60]. The healing reaction provoked by the medicine can also lead to a temporary recurrence of old symptoms. In fact the aggravation phenomenon would be interesting to explore in an RCT programme.

7. Are the professionals and system of delivery safe?

There is a risk in homoeopathy being misapplied, a risk not intrinsic to homoeopathy, rather to the given system of medical delivery in which it may be used. Homoeopathy is unique among complementary treatments in the UK in having an official place in the National Health Service (NHS), and a Faculty of Homoeopathy established by Act of Parliament to regulate its practice. Many other countries do not have adequate regulation. Homoeopathy is a therapy and an approach to care, it is not a whole system of medicine, and if misapplied by a therapist overstepping the bounds of their medical competence it can place the patient at risk, as can over narrow emphasis at the expense of general care. Thus the Faculty trains only statutorily registered health professionals, who must use the therapy within the accepted boundaries of their given professional competence and discipline. There are over 1000 members, licensed associates and associates in the UK, principally doctors, along with dentists, pharmacists, nurses, midwives, veterinary surgeons and podiatrists.

In March 1995 a first level qualification of a Licensed Associate (LFHom) was introduced for candidates who had passed The Primary Health Care Examination [61]. This is an inter-professional qualification which enables the practitioner to offer patients and clients an informed view on the role, and the limits, of homoeopathy in their care, recommending specialist advice where appropriate, and applying simple application of homoeopathy within their discipline. The exam is now used internationally (e.g: Japan, South Africa, Russia, Portugal and an equivalent qualification from the American Board of Homeotherapeutics).

All doctors working at a specialist referral capacity in the UK must have passed the more advanced Membership examinations (MFHom) and gained further supervised clinical experience before going on the Faculty of Homoeopathy's Specialist Register. A nationwide network of specialists has now been created supplying local clinics to the standards defined in the Clinical Standards Policy produced by the Faculty of Homoeopathy [62].

Homoeopathy can also be practiced by common law right by any one in the UK, and although the organisations such as the Society of Homoeopaths are making significant progress towards achieving professional standards for non-statutorily registered practitioners, the situation remains unregulated.

8. Can it be safely integrated with orthodox approaches?

This is established. Since 1948 extensive clinical experience within the UK National Health Service (NHS) has demonstrated a useful and safe role for homoeopathy across the spectrum of medicine and professional disciples from primary care to tertiary care. Auditing of the integrative care programmes of GHH, and its linked clinics have demonstrated a capacity for safe integration at secondary and tertiary level care [63].

In the 1990's, an inter-professional postgraduate education programme in homoeopathy (ADHOM The Academic Departments of GHH) became the most popular postgraduate medical course in the UK, orthodox or otherwise. In a decade, around 20% of Scottish GPs completed basic level training, and according to one survey's finding, two years after attending this foundation course 78% were still integrating elements of homoeopathy in their NHS [48, 64].

These experience suggest that integrated care combining orthodox and homoeopathic approaches can often enhance the care of a given patient. They can safely and effectively be used together. It is important that that patients do not experience a fragmentation of their care through an "either/or" mentality, placing them in positions of conflict between different therapies, or therapists.

INDIVIDUAL'S EXPERIENCES & SYSTEM LEVEL ISSUES

9. Do patients want it, and are their expectations met?

For years, whenever surveys are conducted, like the one by Grampian's Local Health Council in 1993 that stimulated that health authority's consensus assessment, they point to a sizable demand for homoeopathy. When Lothian Health Board in Scotland opened a new homoeopathic clinic 1999 within 4 weeks 40% of every GP practice in Lothian had referred a patient, and every practice had done so within 8 months. The demand at GHH increased (40% rise from 1995 to 2000) to around 150 referrals per month. Of these, 87% are coming from GPs, and about half of these are patient initiated.

Surveys from elsewhere in the UK suggest that around 75% of the public want complementary therapies in the NHS [65], and The Consumer Association surveys have shown a doubling of the use of complementary medicine by its members from 1986 to 1991 [66]. It has grown still further from then and studies across Europe [67] and in the USA [68] have similarly pointed towards a large, and growing demand for complementary medicine.

Consumer surveys affirm that patients are in general satisfied, with 4 out of 5 users claiming significant benefit or cure, and 75% saying they would use complementary medicine again [66]. Our out-patient surveys showed that 81% of patients rate the care as very good or excellent, and only 9% would choose to be treated only by conventional means in the future, the vast majority of patients would wish both forms of care to be integrated. The patient enablement results and qualitative research described below confirm these results.

10. Do health care workers want it, and are their expectations met?

When GP registrars' views were sampled in 1982 over 80% expressed an interest in training in a complementary medicine [69], and 5 years later the figure was over 90% [70]. This was then reflected in the multidisciplinary postgraduate courses, or the Distant Learning version with students in over 20 countries, and the demand by other professions increased in parallel. Surveys have suggested that around 3/4s of GPs want complementary therapies in the UK NHS. Since the negative publicity stemming from the Shang et al Lancet paper explored earlier, the numbers attending post-graduate courses has dropped significantly.

In 2003/4 49% of 323 general practices in Scotland prescribed homoeopathic remedies , and the prevalence of homoeopathic prescribing in those under 16 years has doubled since 2000 [71] . Practitioners are rating the treatment as useable and useful in NHS practice with around 80% reporting continued integration of homoeopathy in their NHS general practice 2 years after basic training (ref 48). Hospital doctors have been less involved, but some work suggested they had an unexpressed interest [72]. Hospital doctor referrals to the GHH Integrative care unit grew from 5% of referrals in 1990 to 20% on 2005.

Research at Glasgow University in 1993 showed a very high demand for training in complementary medicine by medical students,[73], and the proposed curriculum for an undergraduate familiarisation course was subsequently adopted by the British Medical Association's report [74]. Since then several American medical schools have offered courses in Complementary and Integrated Medicine. Now however, the drop in postgraduate demand for training from 2005 is also reflected in reduced student interest.

11. What of health authorities?

The traditional delivery of homoeopathy in the UK NHS has been sustained through its many structural changes (like the now defunct purchaser-provider environment, and the subsequent Trust structures). NAHAT (The UK National Association of Health Authorities and Trusts) reported in its Research Paper No.10 1993 that the vast majority of the then providing Trusts had a positive attitude towards complementary

medicine including homoeopathy. Yet while some have increased commissioning, e.g. Lothian Health Board, this is uneven, others have argued for decreases. It is a challenging reflection on the processes of decision making in this area to see the opposite conclusions being drawn from the same data by different authorities - each claiming their decisions are scientific. Private insurance companies in the UK continue to pay for homoeopathy from recognised homoeopathic medical specialists. In 2005 there was an unprecedented debate provoked by NHS Glasgow's examination of the integrative care in patient beds at GHH, with a proposal to remove them. The extensive civic debate involved reviews in public, professional and parliamentary forums. The result was a withdrawal of the proposal and a positive statement by NHS Glasgow on the quality of care and results, saying it "offered a valid and important model of care" [75]. Since then, a concerted media and lobbying campaign by a group calling itself 'Sense and Science', claiming there is no evidence at all for homoeopathy, has damaged homoeopathy's standing with several Health Authorities, especially in England, and threatened the continued availability of homeopathy for some patients. At a Scottish level, there has been no formal change in policy since the Scottish Office Department of Health's report [76] recommending that here should be further exploration of the integration of some complementary therapies, including homeopathy, more fully into health care. They called for more support for education and research in this area and recommended that providers "*endeavour to achieve a controlled exploration of the costs and benefits of integrating complementary medicine with conventional medicine….and should ensure that the service is accessible to all who need It"* .

12. Is it patients' entitlement?

The question of people's right to choose their form of health care is becoming more important. When we, and our health carers, are well motivated and confident we respond better to the care we are given. Health care systems throughout the world are now beginning to respond to the call for a more pluralistic and individualised approach to care, integrating traditional and contemporary approaches, and based more on partnership between patient and health care worker. In the UK, under parliamentary law, reaffirmed by questions in the House of Commons, homoeopathy must be supplied as part of NHS care and purchasers are free to meet the need in their area. The Select Committee on Science and Technology of the House of Lords affirms *"We recommend that if a therapy whose mechanism of action is unclear does gain sufficient evidence to support its efficacy, then the NHS and the medical profession should ensure that the public have access to it and its potential benefits".*[77] A 2010 House of Commons Science and Technology Committee's report on Homoeopathy drew a different conclusion – and so the long-standing controversy continues [78].

DEVELOPMENTAL ISSUES

13. Is it rational and scientific? How might it work?

All medical care has its mystery and confusion, and homoeopathy is no exception. However homoeopathy compares very well to orthodoxy in the way in which history taking, drug selection and follow up is well systemetised and structured. In fact the PG education audit has shown the extent to which doctors find that even an introductory homoeopathic training can enhance the rational basis of their clinical perceptions and decisions (see ref 48 and Table 3).

The approach rests on a basic testable premise that drugs prepared in a homoeopathic manner can helpfully modify disease processes when selected on the basis that in higher doses they would produce a similar physiological disturbance to the one that is to be treated. The analogy with allergen desensitisation and immunotherapy is well placed: the homoeopaths introduced the former with pollen therapy for hay fever, and presaged the latter.

The materia medica of the drugs prescribed in this way is developed from an experimental base, and while that work needs to be re-assessed, much of it is noteworthy. The homoeopaths were using placebo controlled clinical trials as early as 1911 as part of the technique of "proving", an on-going method for evaluating the prescribing indications for their drugs.

While there are conventional frameworks within which the counter-stimulant effect of homoeopathy can be understood (for example with the concept of hormesis [79]), the action of the medicines which have been

serially vibrated and diluted to extremes beyond likely biochemical effects presents far more of a challenge. The positive double blind trial results mentioned lead us to consider that these ultramolecular medicines have a greater than placebo effect: raising speculation on **biophysical changes** in the water used to make the medicine - an unproven idea for which some tentative theoretical and laboratory evidence exists [80] - an example, described in the New Scientist (7 November 2001) as a possible "first scientific insight into how some homoeopathy works", discovered from studies on cluster-cluster aggregation phenomena in aqueous solutions, that as you make a dilution more dilute there are almost instantaneous developments of very stable larger aggregates, more so in the dilute solutions than in the more concentrated solution [81]. The possibility of EM signatures was raised earlier (ref 40). Unconfirmed claims of biophysical changes in agitated serial preparations are also being made, e.g. in NMR [82] and thermoluminescence spectra of ultramolecular dilutions of 10^{-30} of LiCl and NaCl having similar spectrum to dilutions containing molecules of the same substances, and different from D2O likely to be due to broken H-bonds. [83]. Now scientists are claiming they can store a digital image in a single liquid crystal using electron spin states[84]. Analogies might include other examples of complex information coding not dependant on biochemical changes, for example images recorded on magnetic media or the endlessly unique patterns of snow flakes, and transmission of replicated patterns without using molecules – like downloaded digital media. These things do *not* explain homoeopathy as yet – but they hint at the possibility of types of mechanisms that may be relevant.

14. Is it progressing and contributing to medical advance?

New remedies and approaches are being developed, e.g. earlier we saw the studies on allergic desensitization; and the results from the conventional research labs where Jonas and colleagues have shown reduced stroke damage in rats using the conventional knowledge of the toxicity of the released glutamate from the damaged brain, and the application of the homoeopathic principle with ultra-low dose glutamate [85].

Innovations in computing and coding are making a contribution to the body of medicine - such as the influence on READ coding, and the developments at the University of Namur, Department of Informatics on expert diagnostic systems. Speculation on mechanisms of action are encouraging theoretical discourse, e.g. on the biophysical nature of dilutions (see section above).

The field has developed important insights of relevance to the emerging field of mind-body medicine and psychoneuroimmunology, e.g. in seeing the relationship between emotional suppression and ill health.

More importantly, the approach is contributing significantly to the reintroduction of a holistic perspective in medical practice. The comments in Table 3 were made by practitioners who had completed the postgraduate foundation training [48].

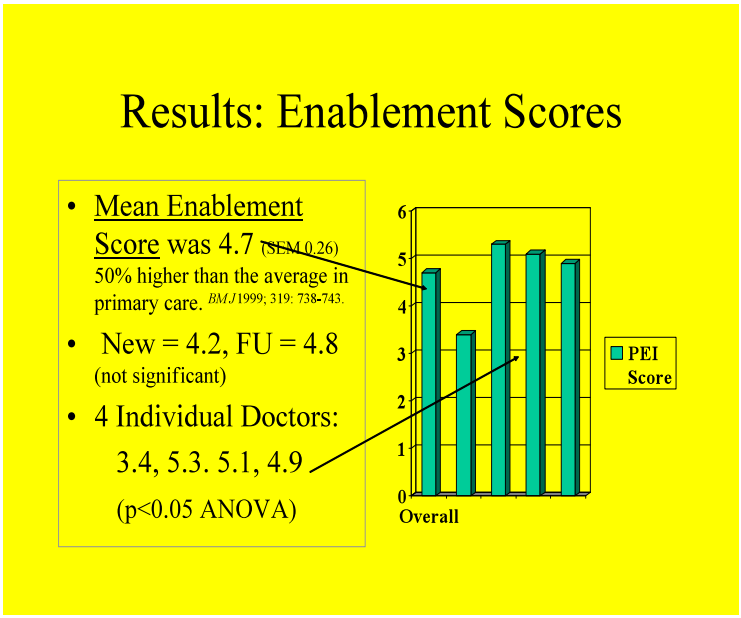
Table 3: Influence Of Homoeopathy: The Views Of 40 NHS General Practitioners Ref 48

- "Relearned" history taking. (x 2)
- Listen more / less dismissive. (x4)
- Now find patients expectations for NSAIs, antibiotics, psychotropics difficult. (x4)
- Now want to refer patients.
- New outlook on chronic disease.
- More broad-minded in medicine in general.
- More aware of natural healing.
- Now see patient as a whole & not as much at cellular biochemical level.
- Now see people more as individuals & see the whole person for whom I seek a treatment.
- More aware of patient dissatisfaction with conventional medicine.
- It has saved my brain from fossilising.
- Rekindled interest in Clinical Medicine.
- Find practice richer & more fascinating.
- I marvel at my lack of knowledge.

- How did I manage without it?.
- Should be in undergraduate or GP training.

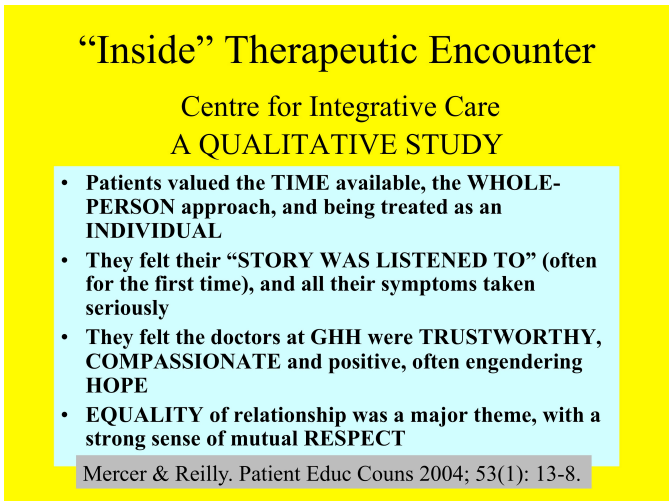
15. Is it a different way to consult – is that not the secret of its success?

Some critics have said the positive results are 'only' due to the time taken and the whole person approach. It is very true that these factors are making a major impact – and this suggests that conventional models of care and clinical encounter could be usefully changed to follow suit. In addition to the specific effects shown in the controlled trials for the remedies, it is clear that an individualized homoeopathic approach enhances the therapeutic encounter. The remarks in the Table above highlight the fact that practitioners report that even basic training in the subject can encourage a form of consulting which is therapeutic in its own right. The image on the right shows the Patient Enablement Instrument results from 200 patients treated by 4 senior doctors at GHH – showing high levels of empowerment after the consultations. This correlated with high levels of empathy established in the therapeutic encounter [86] [87], and in turn was a predictive variable for the one-year health gain outcome results. We have also demonstrated an impact on these key factors and outcome, from the length of the first consultation [88].



Qualitative research summarized in the next Figure has explored what factors may have affected the high 'enablement/empowerment' scores achieved by the consultations by asking patients about their experience and what patients value in the GHH approach [89].

This care is in turn has contributed to stimulating medical educational models e.g. with patient-centred teaching, taking account of the emotional and general physical aspects of health in tandem with the patient's local complaints. This has been used to enrich undergraduate education modules examining holism and human healing responses [90]. It has also contributed to the development of PROMS –patient recorded outcome measures – and their adoption by Scottish Government's Quality Strategy, along with the call for a more patient centred health system built on enabling partnership with people with long term conditions, and founded on a caring and compassionate approach.



CLOSING REMARKS

Well, does homoeopathy work? As you have seen that is complex and fascinating enquiry, and you need to draw your conclusions from this evidence mosaic for homoeopathy. I think a picture emerges that re-enforces the experiences of the clinicians and patients who say this approach can make a valuable contribution to care, especially when applied with a whole person perspective, integrated with conventional knowledge.

PART IV: Further Information & References

Web & Library Services

1. A variety of information and support resources including updates on evidence are available from the Faculty of Homeopathy and The British Homoeopathic Association - www.facultyofhomeopathy.org
2. Further info from the library and reference services of www.Hom-Inform.org.

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Acknowledgment

The librarians of www.Hom-Inform.org the Glasgow Homoeopathic Hospital helped in earlier updates. My thanks to those who have offered feedback on earlier versions of this article.

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