

The Evidence for Homoeopathy

Foreword to Version 8.2 September 05

(update of March 02 Harvard Medical School Course version and Reilly D. *Alt Ther Med Health* 2005;(11)2:28-31). Does homoeopathy work? What evidence is there? Answers these seemingly simple question provokes remarkable debate: the evidence needed, and its interpretation, varying greatly with the needs and biases of the questioner – be they patients, practitioners, managers or academics. This personal comment paper attempts to briefly address the demands 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 those of the author - I am a doctor studying human healing testing the validity of orthodox and alternative medicines. I began skeptical of homoeopathy, but spent 15 years doing controlled trials that appear to demonstrate the remedies work over and above the useful healing effect of the general method of care.

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ABSTRACT

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 might be summarized as ‘It can’t work, so it doesn’t work’. In addition, it varies in its approach to patients and illness in two fundamental ways. Firstly, as it never postulated a mind-body divide it always took a whole person approach. Secondly, it varies in its approach to treatment: it uses the potential of toxins (at controversially low dilutions,) to provoke defense and self-regulatory responses rather than the more orthodox approach of blocking body reactions. This method gives a hint of its clinical scope: it can help, at times resolve, conditions which are natural healing mechanism can potentially reverse, but not mechanical problems, deficiencies or irreversible breakdowns in body functions, where it is only palliative.

Public demand has soared, and with it professional interest – by 2000, around 20% of Scotland’s general practitioners had completed basic training, and hospital consultants views suggested reduced medical resistance¹. Partly this comes from the public interest in complementary medicine, and a sympathy with the more mind-body approach of homoeopathy, and partly from recent scientific evidence. Some homoeopathic dilutions are so extreme critics assume they only placebos - yet trials and meta-analyses of controlled trials have mostly failed to show this, in fact on balance they are pointing towards real effects - mechanism of action unknown. So that is a scientific quandary. Meantime, clinical outcome studies show useful clinical impact, excellent safety and a potential to enhance patient care by integrating homoeopathic and orthodox medicine.

A. INTRODUCTION & BACKGROUND COMMENTS

1. Some Background Comments on Homoeopathy

Over 200 years, and despite, until recently, strong orthodox rejection, this therapy has established itself throughout much of the world. Its use is steadily increasing, and it is claimed to be an effective, safe and acceptable form of care in acute and chronic problems, both physical and mental. Using an outline structure, this paper examines the evidence for these claims through the sort of questions that might be asked when judging any form of care, preceded by some comments on research into the nature of evidence in today’s health care which has helped shape the emphasis of this paper.

In essence, homoeopathy differs from conventional approaches because much of orthodox treatment is designed to directly limit, block or mimic body reactions, while homoeopathy provokes the body’s own defense and self-regulating, homeostatic responses. The two approaches are complementary, they can be used together. To prepare a homoeopathic medicine, a toxic substances 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 dilution, to provoke homoeostatic responses - supporting the body’s attempts to correct the disease. 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. In addition to the medicines, there are also differences in the homoeopathic approach to the patient. The homoeopathic clinical method in chronic or complex problems involves a whole person history which encourages enhanced therapeutic encounters. Further discussion about the background, clinical systems or applications of homoeopathy are outside the scope of this paper, and you may wish to follow up the ‘further reading’ list given at the end.

2. The Nature of Proof: An Evidence Profile

When I asked 210 primary care doctors to rate different forms of evidence that in practice they would want before using or recommending an unorthodox therapy their answers suggested that evidence forms a multi-dimensional mosaic - an ‘Evidence Profile’². As Figure 1 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.

Professor Sackett opens his seminal book on Evidence Based Medicine ³ "Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values." Perhaps that's our best guide at a time when the RCT (randomised controlled trial) research evidence only allows some comment on whether homoeopathy varies from placebo, but is not good enough to comment on individual conditions, and observational studies and qualitative work show that patients are satisfied. In the 'The 5th Wave' ⁴

document The Public Health Institute of Scotland argued that we are struggling in another wave of change in medicine when the cultural and conceptual divergence of 'objective' (nomothetic, scientific, falsifiable, reproducible) truth and 'subjective' (idiographic, personal experience) truth 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. The time has not yet arrived when the homoeopathic puzzle is ready to be 'solved'.

Validating Complementary Medicine What Sort of Evidence? Views of 210 doctors

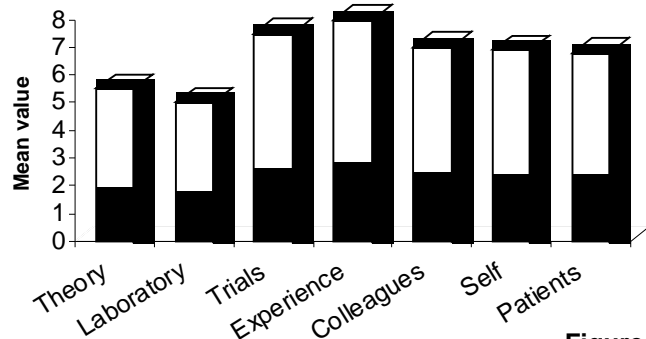


Figure 1

B. THE EVIDENCE PROFILE FOR HOMOEOPATHY

IS IT EFFECTIVE?

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

Few argues that homoeopathy is wholly ineffective, but scientific scepticism, stemming mostly from a lack of a plausible mechanism of action, has led many commentators to confidently assume that homoeopathy's clinical success is due *solely* to placebo responses. I will comment briefly later on the data from trials in general, but here I'll begin with that part of the evidence mosaic that I can personally vouch for.

The 4 HIT Trials

With my co-workers and independent colleagues at Glasgow University over 18 years we conducted 4 double blind placebo controlled trials specifically designed to examine the evidence for this placebo hypothesis ^{5 6 7 8}. The initial bias was that placebo explained homoeopathy - but all 4 trials refuted this and produced patterns of results which clearly favoured homoeopathy over placebo (as summarized in Figure 2).

So we were presented, and in turn presented the scientific community ⁹, with the challenge that either these results suggested that homoeopathy works, or, that the clinical trial is flawed. If homoeopathy is solely a placebo then our experience is that the trial as a methodology is producing false positive results, which are predictable and reproducible, and at a rate which would undermine its use as a scientific tool for assessing orthodox treatments.

Homoeopathy certainly brings into focus issues of trial design and interpretation, not least the power (i.e. numbers) required to detect a change over placebo in the presence of any 'placebo/context-enhanced non-specific healing impact' – when the placebo group shows good improvement: take the Lewith et al trial which was reported as negative in asthma ¹⁰ – in fact *both* groups showed a significant clinically useful improvement, and it was clear that avoiding a 'Type II' (false negative) statistical error because of inadequate numbers ¹¹ needs a very large study to tease out any homoeopathic action over and above its significant placebo response (I've labeled this the "double positive paradox"^{12 13}),. 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 25).

Figure 2

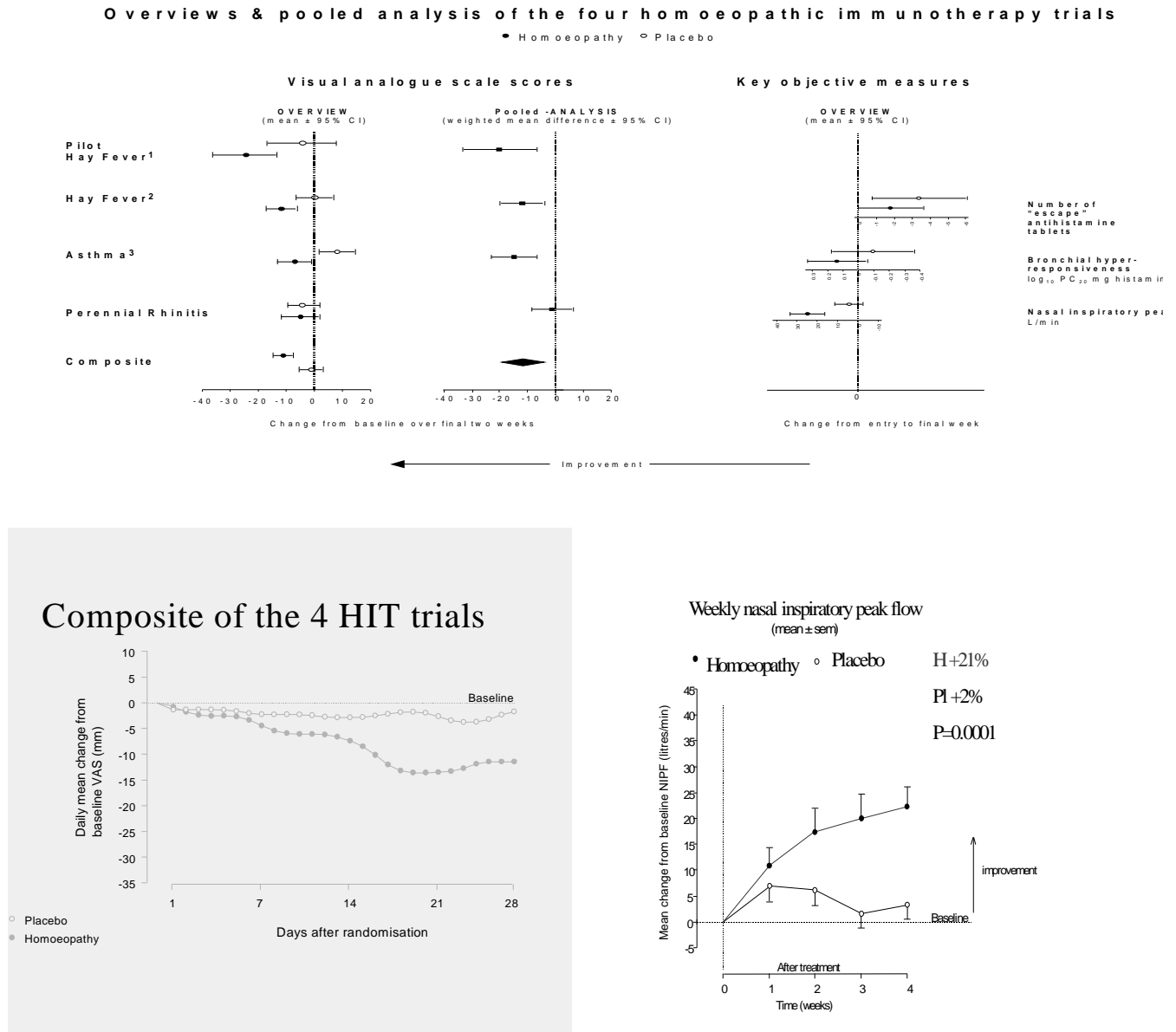


Figure 2: Figures (from ref. 8 BMJ 2000;321:471-6) summarising the 4 HIT trials (pilot and principle in hay fever, confirmatory in asthma and perennial rhinitis). All used homoeopathic allergen desensitisation as a model to test a) the placebo hypothesis, and b) the reproducibility of the pilot's evidence 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.

Major systematic reviews

Over the 18 year time frame of our 4 trial 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 – and some 50+ trials have been published since. By 2003 there were four comprehensive, 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 Figure 2 achieved this to some degree as did the European Commission review (see ref 16 below)).

On balance this evidence favours homoeopathy being more than a placebo, 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 comprehensive review was published in the BMJ in 1991 by Kleijnen et al¹⁴. 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 al¹⁵ 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 ratio 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. They also selected from the trials 17 comparisons in 2001 patients deemed suitable for a pooled p-value meta-analysis. 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*"¹⁶.

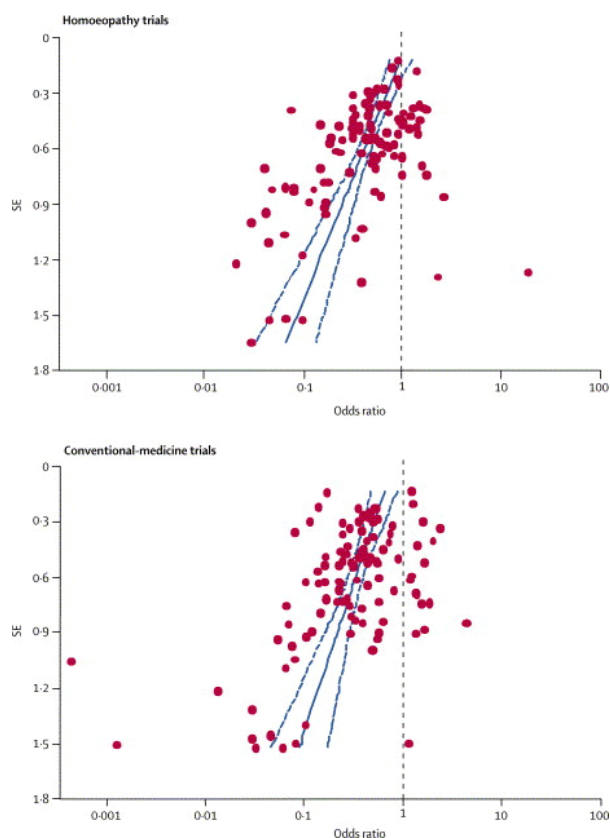
In 2003 a 'critical overview of homeopathy' in the Annals of Internal Medicine reviewed these studies and the other systematic reviews to date and their conclusion echoed the now common view that there is positive evidence for overall effect, but the limited number, and size, of trials to date, determine a lack of data to draw conclusive evidence on the effectiveness of homeopathy for most conditions¹⁷. 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. For now then, these trials make reasonable inroads into testing the 'placebo only' hypothesis - and they have found that particular explanatory model lacking. Early attempts at assessing impact in specific conditions by selective meta-analyses (for example in osteoarthritis¹⁸ and post-operative ileus¹⁹) mostly note the positive trend but have to conclude that there is not yet enough data to draw firm conclusions. 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 2002²⁰ 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 Kleijnen clarified for me this meant no increase or decrease in funding (personal communication).

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 shown that smaller studies and those of lower quality tend to show greater effects²⁴, 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"²⁴ 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 and still drew a positive conclusion. In the Linde et al Lancet review (ref 15 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 review in turn has been subject to various subset analyses by the author and others. These and other subsequent comments from this larger data set give progressively narrower and more partisan views of subsets, with Ernst even trying a 1 man 'systematic review of systematic reviews of homeopathy'²¹ (using non-defined terms like no 'strong' evidence', not 'convincingly different') - and Bandolier then using this as the basis for add to its own previously negative comments²² (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 17), the authors make reference to Ernst's review (ref 21) and their own 1998 subset analyses²³ (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 Switzerland²⁴ which caused a media storm perhaps because of the accompanying anonymous editorial being headed 'The End of Homoeopathy' ! 110 homoeopathy trials (from around 200) and 110 matched conventional-medicine trials (from around 1/3 of a million) were analysed. As the Figure to the right 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 2 such small scale subanalysis meta-analyses. One (of 8 respiratory trials) was robustly positive - and was therefore rejected 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? "This finding is compatible with the notion that the clinical effects of homoeopathy are placebo effects." Small data set, large bias. The PEK management group of this Swiss project has offered significant criticisms of this work²⁵, 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 adding trials from 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 8) and Jacobs et al in childhood diarrhea²⁶) have been able to combine their data, and the larger sample sizes have added weight to the individually positive trials.

Given the subgroup/individual condition controversies, 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 homoeopathy²⁷. (The 'no difference' group might now usefully be analysed for the double positive paradox mentioned above (ref 13) – 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.

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 would be 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^{28 29}.

Laboratory Evidence

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 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 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 effects³⁰. Some of the claims are extremely controversial, - an illustrative example: the late Jacques Benveniste (who stirred controversy from his earlier claims of homoeopathic action published in *Nature*³¹) then claimed that he can 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 www.digibio.com). 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 1 study blinded multi-centred in 4 labs, and a second study confirmed the multi-centred study by flow cytometry independently in 3 labs³². Up to now, the puzzle of homoeopathic evidence has had to rely on the clinical arena – these new lab results may challenge that situation.

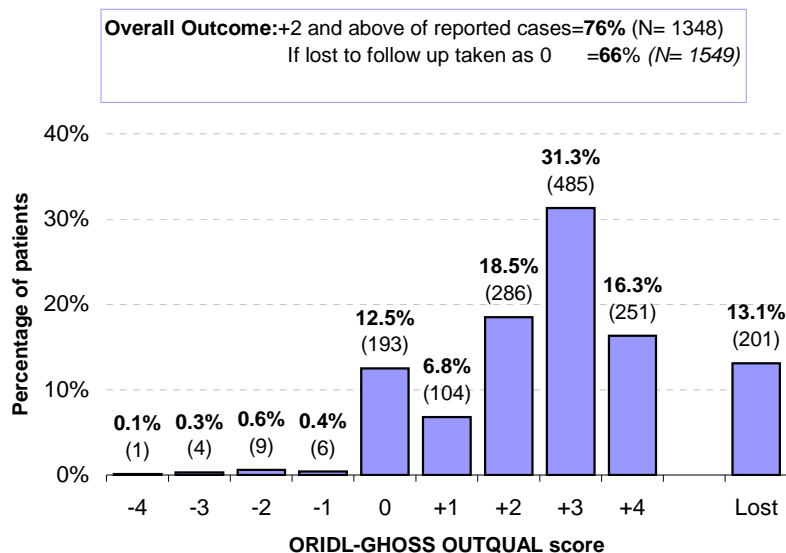
2. It is effective when applied clinically?

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. Figure 3 is taken from an action research cycle tracking the results of prescriptions made in a primary care context using the ORIDL “Outcome Related to Impact on Daily Living” scale (aka ‘GHHOS Glasgow Homoeopathic Hospital Outcome Scale’) where +2 or above is a response deemed to be of significant value, as described in the text box below. ORIDL-GHHOS has shown concurrent validity when compared to MYMOP and SF12 (Reilly, Bikker and Mercer – *in preparation*)

GHH 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

Figure 3: Shows the results of 1348 prescriptions in primary care, tracked prospectively³³. These results appear to confirm the traditional claims of important beneficial impact on clinical outcome, with cost and reduced iatrogenesis.



Beyond such simple primary care applications, 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 Hospital³⁴. 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:

60% improved in the presenting complaint
 61% in well being
 49% has a sustained improvement of value in daily living
 37% had a sustained reduction in conventional therapy.

At a tertiary care level, 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 a conventional perspective with complementary approaches, including homoeopathy. Table 2 shows two surveys, each of 100 sequential in-patients with advanced and complicated illness, who were treated in this way³⁵. Typically these patients have multiple problems, with mixed chronic pathologies and psychological distress.

A 2205 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.³⁶

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, if 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

The two dimensions of care need considered - the direct effects of the remedy, and, the therapeutic impact of the *method* of approach to the patient. At times homoeopathy is supportive rather than curative and in addition to the specific effects it shows the positive effects of the 'non-specific'/context/values' dimensions. Many general practitioners (GPs) are now opting for homoeopathy as first line in certain problems, keeping the more costly and potentially risky conventional treatment as second line³⁷. This will likely become increasingly common for homoeopathy and other complementary therapies. Some practical examples these GPs say are of value might help illustrate this trend (bear in mind these are clinical observations, as mentioned above, there are mostly insufficient data from trails to give further scientific comment) :

- GPs and practice nurses can use remedies like Colocynthis for colic in infants under 6 months of age when no conventional drugs are available³⁷.
- The therapy can reduce allergic sensitivity^{5, 6, 7, 8} (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 extraction³⁸
- Intensive care challenges – like reducing tracheal secretions to aid extubation with Kali Bic³⁹.

- 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.

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 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. 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 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.

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 charge⁴⁰. A French survey (quoted in ref **Error! Bookmark not defined.**) suggested 87% of patients prescribed homoeopathy did not see another physician for the same problem. In the UK NHS on average less than 2 pounds (3 US dollars), and unit dispensing from stock is even more economical in dispensing practices and clinics.

Some studies show results as good as, or better than conventional care at no increase in costs (see ref 36 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 colleagues⁴¹. For example, 1 GP monitored 100 patients over 4 years, got good results, and estimated he saved on average 60 pounds per patient⁴². As reported above (see Tables 1 & 2) we have found that one year after beginning specialist out patient care, 41% of patients have a sustained reduction in their conventional medications. This is increasingly important at a time of soaring conventional drug costs and budget deficits – the UK NHS Drug bill recently soared by nearly 50% in 3 years, rising by 2.3bn to 7.2bn pounds (Independent. 8 Dec 2003). 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 approach, using homoeopathy as the first choice drug therapy, is adopted. 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 effects⁴³

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 3). Follow up case studies of each of these reports did not reveal any damaging reactions.

However, in chronic conditions there can be an initial aggravation of symptoms which 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^{6, 8 44}. The healing reaction provoked by the medicine can also lead to a temporary recurrence of old symptoms.

Another risk is from unscrupulous individual or groups producing contaminated products, making it necessary to use only reputable manufacturers which follow their National Pharmacopoeias.

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, 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. 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 new first level qualification of a Licensed Associate (LFHom) was introduced for candidates who had passed The Primary Health Care Examination⁴⁵. This is an interprofessional 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 Homoeopathy⁴⁶.

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 disciplines from primary care to tertiary care. More recent auditing of the integrative care programmes of GHH, and experimental linked clinics such as the Pain Relief Clinic and General Medical Clinic in the Glasgow Royal Infirmary, have again demonstrated a capacity for safe integration at secondary and tertiary level care⁴⁷.

In the 1990's, an interprofessional 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^{37, 48}.

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 as complementary therapies become more popular 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 which 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 in 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, 87% coming from GPs, about half of these being patient initiated.

Surveys from elsewhere in the UK suggest that around 75% of the public want complementary therapies in the NHS ⁴⁹, and The Consumer Association surveys have shown a doubling of the use of complementary medicine by its members from 1986 to 1991 ⁵⁰. It has grown still further from then and studies across Europe ⁵¹ and in the USA ⁵² 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 ⁵⁰. 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 enablement results and qualitative research described below confirm these results.

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

Surveys have suggested that around 3/4s of GPs want complementary therapies in the UK NHS. And as well as demanding clinical services, many are seeking training. When GP registrars views were sampled in 1982 over 80% expressed this view ⁵³, and 5 years later the figure was over 90% ⁵⁴. This has now been borne out in practice. Doctors form the majority (85%) of the current students on the multidisciplinary CME/CPD approved postgraduate course in Glasgow, or its Distant Learning version with students in over 20 countries, and the demand by other professions has increased in parallel.

Research at Glasgow University showed a very high demand for training by medical students, suggesting that this trend will increase further ⁵⁵. and the proposed curriculum for an undergraduate familiarisation course which emerged was adopted by the British Medical Association's report ⁵⁶. Several American medical schools now offer courses in Complementary Medicine. Hospital doctors have been less involved but some work now suggests that they have an as yet unexpressed interest ¹. Hospital doctor referrals to the GHH Integrative care unit have grown from 5% in 1990 to 20% on 2005.

The rise in referral rate from GPs, and in the numbers trained in the UK reflects the positive attitude which many doctors now have towards this treatment. Practitioners are rating the treatment as useable and useful in NHS practice (eg ref 37) with around 80% reporting continued integration of homoeopathy in their NHS general practice 2 years after attending basic training.

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" ⁵⁷.

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. 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 that "*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”.*⁵⁸

DEVELOPMENTAL ISSUES

13. Is it rational and scientific?

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 ref37).

The approach rests on a basic testable premise that drugs 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. Indeed 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), 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 above force us to consider that these 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 exists⁵⁹ - 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 in the dilute solutions than in the more concentrated solution⁶⁰. Unconfirmed claims of biophysical changes in such preparations are also being made, e.g. in NMR⁶¹ and thermoluminescence spectra⁶². Now scientists are claiming they can store a digital image in a single liquid crystal using electron spin states⁶³. 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. see the immunomodulation research in references 5 to 8, and the results from the state-of-the-art 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 glutamate⁶⁴.

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).

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 training³⁷.

Table 3: Influence Of Homoeopathy On Practice & Outlook:

The Views Of 40 NHS General Practitioners.

- "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.

Ref 37

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

15. Is it a different way to consult – and 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 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 Table 3 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. Figure 4 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^{65 66}, and in turn was a predictive variable for the one year outcome results. We have also demonstrated an impact on these key factors and outcome, from the length of the first consultation⁶⁷.

Results: Enablement Scores

Figure 4

- Mean Enablement Score was 4.7 (SEM 0.26) 50% higher than the average in primary care. *BMJ* 1999; 319: 738-743.
- New = 4.2, FU = 4.8 (not significant)
- 4 Individual Doctors: 3.4, 5.3, 5.1, 4.9 (p<0.05 ANOVA)

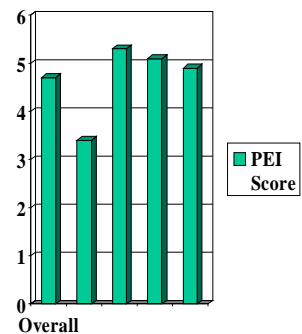


Figure 4

Figure 5 summarises qualitative research showing what patients value in the GHH approach and highlights the factors affecting the high 'enablement/empowerment' scores achieved by the consultations.

“Inside” Therapeutic Encounter

Glasgow Homoeopathic Hospital

A QUALITATIVE STUDY

- **Patients valued the TIME available, the WHOLE-PERSON approach, and being treated as an INDIVIDUAL**
- **They felt their “STORY WAS LISTENED TO” (often for the first time), and all their symptoms taken seriously**
- **They felt the doctors at GHH were TRUSTWORTHY, COMPASSIONATE and positive, often engendering HOPE**
- **EQUALITY of relationship was a major theme, with a strong sense of mutual RESPECT and SHARED DECISION MAKING**

Figure 5. Reference ⁶⁸ and full report download from www.adhom.com

This care is in turn 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 ⁶⁹ and formed the basis of the Scottish Executive's request for a GHH doctor to help launch their 'Patient Centred Care' initiative.

CLOSING REMARKS

The evidence mosaic for homoeopathy summarised here tends to re-inforce clinicians and patients experience that this approach can make a valuable contribution to care, especially when applied with a whole person perspective, integrated with conventional knowledge. Now reports from the Scottish Office Department of Health ⁷⁰ and The Working Party chaired by HRH Prince Charles ⁷¹, have recommended further exploration of the integration of some complementary therapies, including homeopathy, more fully into health care. They have 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”*⁷⁰.

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Web & Library Services

5. A variety of information and support resources are available from the Faculty of Homeopathy and The British Homoeopathic Association - www.trusthomeopathy.org
6. Further academic and education materials available from ADHOM The Academic Departments of GHH on www.adhom.com which also has links to the library and reference services of www.Hom-Inform.org.

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David Reilly can be contacted via the Homoeopathic Hospital at the address at the beginning of this article. Those readers interested in evaluating the subject can write to The Academic Departments at the same address for details of its training and distant learning evaluation course or visit www.adhom.com where any updates of this article will be posted.

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