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DEBATE

Priorities and methods for developing the evidence profile of homeopathy *Recommendations of the ECH General Assembly and XVIII Symposium of GIRI*

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To achieve scientific acceptance, homeopathy must investigate several questions:

1. **The activity of very highly diluted preparations. The consensus of the meeting was that there is clear evidence of this.**
2. **The content of very highly diluted homeopathic preparations. More research is needed but evidence exists that a specific signal is present in homeopathic preparations.**
3. **A theoretical framework in which the effects of homeopathic diluted preparations can be explained. The 'Body Information Theory' is such a theory.**
4. **The clinical effectiveness of homeopathy. Because they avoid the placebo effect, animal studies are a priority.**

For human trials using Quality of Life questionnaires, studies on the activity, content and theoretical basis of homeopathic preparations were reviewed approximately 70% of cases; more in children showed improvement. Homeopathy reduced costs and allowed a better improvement in work-days lost compared with conventional practice. Randomised controlled trials (RCTs) implicitly test the placebo hypothesis; RCTs have been performed and meta-analyses conclude that there is clear evidence of efficacy which cannot be attributed to placebo effect.

Priorities depend on the audience. More research is needed especially regarding the content of homeopathic preparations and the transmission of information. Theoretical issues are also important to avoid incorrect design of research protocols. More effort should be dedicated to veterinary research. Clinical effects analysis in humans remains important. Many other questions should be prioritised, such as the potential of homeopathy to avoid invasive procedures in children and the long-term effects of homeopathy in preventing chronic complications. *Homeopathy* (2005) **94**, 107–124.

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Introduction

During a 3-day meeting in Brussels in November 2004, organised jointly by the European Committee for Homeopathy (ECH) and Groupe International de Recherche sur l'Infinitésimal (GIRI), 90 invited researchers came together to discuss the evidence profile of homeopathy. Four questions were prioritised: the activity of very highly diluted homeopathic preparations, the content of these preparations, the theoretical framework needed for further research, and the clinical evidence.

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The activity of very highly diluted homeopathic preparations

Homeopathic practitioners argue that preparations diluted beyond Avogadro's number (ie above 11c) are

used in only about 25% of homeopathic prescriptions. Nevertheless, for some ultramolecular dilutions is the most important obstacle to the acceptance of homeopathy.

Professors Marcel Roberfroid and Jean Cumps of the Institute of Pharmacy at the University of Louvain, coordinated an European multi-centre (4 centres) trial and performed the statistical analysis, explained the protocols and discussed the results. The work demonstrates a significant inhibition of human basophil degranulation, as measured by Alcian blue staining, by high dilutions of histamine (10^{-30}–10^{-38} M). The results were subsequently confirmed in three laboratories by flow cytometry analysis and in one laboratory by measuring histamine release. Molecular theory cannot explain these findings, but the facts are indisputable.[1,20] These experiments are based on the Human Basophil Degranulation Test, but measure inhibition of degranulation by high dilutions of histamine, rather than stimulation of degranulation by high dilutions of IgE, as in the work of Benveniste,[21] which has proved to be irreproducible.[22,23]

Research on high dilutions has been conducted since the 1950s, but the number and quality of publications has increased in the last decade. Reviews and meta-analyses have been performed but often ignored or denied.[24] This research is not encouraged or even deemed inadvisable by academic authorities. Professor Jean Cambar, Dean of the Faculty of Pharmacy at the University of Bordeaux, reviewed the most important published models that confirm the effects of very highly diluted homeopathic preparations.

The efficacy of very high homeopathic dilutions of human or natural animal molecules (also called endogenous molecules) has been demonstrated by publications including: Thymulin in mice, (Bastide M[25]) α/β interferon, (Carriere V[26]) Thyroxine, (Endler PC[27–30]) Bursin, (Youbicier-Simo BL[31–33]). During the meeting Dimitris Zienkiewicz, an immunologist at the University of Edinburgh, presented preliminary findings assessing, by immunosorbent assay and flow cytometry, alteration in activation and function of dendritic cells as a result of treatment with homeopathic dilutions of a bacterium. Dendritic cells play a role in both activation and regulation of the immune system. Systematic changes in the profile of cytokines IL-10, IL-11 and IL-12 cannot be explained by the molecular theory. Effects of very high homeopathic dilutions using pharmacological models has also been published in peer-reviewed journals. Examples include: Acetylsalicylic acid in a vessel model.[34–39]

The longest-used type of model is the toxicological model, examples include: Arsenic,[40–46] Phosphorus,[47–50] Mercury,[51] Cadmium,[52–54] Cisplatinum,[55] Glutamate,[56,57] Cuprum sulphate,[58–62], and others.[63–65] It has been applied to vegetable, animal, cell culture material or even clinical studies. Such models are still in use and are the theme for collaboration between the Universities of Berne and Bologna, testing homeopathic arsenic trioxide treatments in plant-based bioassays. The working variables are the germinated seeds or the stem length on the seventh day. At least 6 experiments by this team have been published (Dr Lucietta Betti. DISTA-Department of Agro environmental Science and Technology, University of Bologna).[41,42,45]

Professor Wolfgang Süß, Institute of Pharmacy at the University of Leipzig, has used acetylcholine-induced contraction of the rat ileum to test the transfer of the activity of a homeopathic remedy (Atropinum sulphuricum D60) from the original liquid form to the homeopathic tablet. Several controls were used. Lactose tablets impregnated with highly diluted atropine showed systematic activity, compared with anhydrous lactose tablets. This simple model has the potential to remove doubts about the activity of very highly diluted homeopathic medicines.[66–74]

Many of these experiments are well conducted, in controlled conditions, with sufficient numbers and with correct statistical analysis. The facts are indisputable, statistically significant and reproducible, even if they cannot be explained by the molecular paradigm.

The content of very highly diluted homeopathic preparations

Professor Cambar introduced the theme by asking what are the contributions of spectroscopy (Raman, Ultraviolet, X-ray or Magnetic Nuclear Resonance)[75–83] in revealing the structure of water and solvents in high dilutions? What is the relevance of Avogadro's number in evaluating the precise pattern of molecules? Can a dilution work without molecules? One of the most innovative perspectives in this last decade was the demonstration that high dilutions can have as much without any solute molecule as when molecules are present.

Professor Louis Rey of Lausanne, a specialist in low-temperature thermoluminescence, presented the latest results of the experiments he carried out with Dr Philippe Belon on the thermoluminescence of ultra-high dilutions of lithium chloride and sodium chloride. Ultra-high dilutions of lithium chloride and sodium chloride (10^{-30} g cm^{-3}) were irradiated by X- and γ-rays at 77 K, and then progressively re-warmed to room temperature. During that phase, their thermoluminescence was studied and it was found that, despite dilution beyond the Avogadro number, the emitted light was specific to the original salts dissolved. Much to the authors' surprise, the experimental results showed, without ambiguity, the specificity of the contained information. The findings proved to be reproducible in the course of many experiments. As a working hypothesis, the researchers propose that this phenomenon results from a marked structural change in the hydrogen bond network initiated at the onset by the presence of the dissolved ions and maintained in

the course of the dilution process, and probably due to the successive vigorous mechanical stirring.[84-89]

Professor Guadalupe Ruiz-Vega, Universidad Michoacana de San Nicolás de Hidalgo, Morelia, Mexico, presented her most recent publications in the field of thermodynamics. She was able to demonstrate the biological effect of two ultra-low dose compounds.[90]

The use of modern techniques by specialists is the best way to show sceptics that the experimental facts are well grounded and confirmed by reproducible experiments. Even in ultra-molecular homeopathic dilutions, information specific to the original dissolved substance remains and can be detected.

The theoretical framework for the effects of homeopathic diluted preparations

Two members of GIRI, Professor Madeleine Bastide (University of Montpellier) and Agnès Lagache (Professor of Philosophy, Paris) have been working on this topic for 16 years. A new theoretical framework is needed to explain the facts described above and to inform improved research models in the future. A working group applied this theory to experimental results. 'When the observed fact does not correspond to a famous theory, the fact has to be accepted and the theory rejected'; 'A theory must be modified to be adapted to nature and not nature to adapt itself to the theory'. (*Claude Bernard 'Introduction à la Médecine Expérimentale'*). And when a new theory is supported by experimental results it became a new paradigm. Professor Bastide explained that homeopathy and research models are based on the observation of 'symptoms'. Asymptomatic pathologies exist, they provoke 'biological scars' (*Charles Nicolle, Nobel Prize 1929, Life and Death of Illness*). Symptoms and biological modifications are not the same and concern different levels in the body. The symptom may be an expression of the body when it cannot respond adequately, for example Rubella in a normal subject, no apparent illness; Rubella in immune-deficient subject, symptoms, illness.

For homeopathy symptoms are idiosyncratic: specific to the patient. They are the personal expression of sickness by the patient. They are used to choose the specific remedy according to the similarity of the symptoms observed by 'proving' in a healthy subject. The living body is in an irreversible learning process; it communicates at every level with its environment. It is able to receive and process semantic and corporeal information; it is not an inert object.

The paradigm of corporeal signifiers

Three principles define homeopathy: the similia and holism principles, and the use of very high dilutions. The effects of high dilutions cannot be explained by a simple molecule-receptor interaction. Bastide and Lagache propose an epistemological approach to homeopathy based on body information processes following the rules of information exchange, the paradigm of corporeal signifiers.[91-96] Exchange of objects between a giver and a receiver is simple: one loses, the other gains, and the sum is constant. On the other hand, information is not an object but the trace of an object—mediation between object and receiver is required for a signal to be transmitted. For example, the story of Robinson Crusoe: Crusoe sees Friday's footprint in the sand but not the foot itself. For him, this footprint means 'there is another man on this island'. Friday's foot is the originator (matrix) of the information; the footprint is information but is not an object; the sand is the carrier of the information (the mediator). When the carrier disappears, the information disappears too. The information is understood only by the receiver and the understanding of the information depends on its context. Crusoe believes that he is alone on the island. Bastide and Lagache therefore suggest that in homeopathy, the originator of the information is the starting material of the remedy; succussed dilutions of the starting material in a solvent are mediators. High dilutions contain only information but no molecules from that material. This mediation results from the succussed solvent being in a specific state, implying perhaps electro-magnetic processes. The receiver (the whole living body) receives and processes the information in the remedy according to its state, whether healthy ('proving') or sick (therapy).

The clinical effect of homeopathic preparations

An experimental design is relevant only if it takes into account the observed phenomenon within its specific framework and if the subject addressed can be isolated from all external influences. In human medicine medication effects are known as specific effects. Whatever the research model, taking into account the homeopathic approach, the idiosyncratic symptoms (specific to the patient) must be considered.

Professor Leoni Bonamin, Paulista University (São Paulo, Brazil) and president of GIRI, reviewed studies in veterinary homeopathy. Such studies are relevant for homeopathy because it is easier to isolate the effects of the treatment: the placebo effect is almost nihil and there are fewer ethical constraints. Moreover, herd studies can include an homogeneous sample of a large number of animals. Nevertheless, the rules for well-designed studies must still consider the particularities of homeopathic research (including idiosyncrasy). Veterinary studies are important for organic farming regulation. In Europe, only homeopathic treatments are authorised for organic farming. The use of homeopathy is aimed at avoiding chemical residues in the food chain. More institutional support is needed.

In recent studies, homeopathic complexes have been tested with good results using parallel placebo groups, blinded design, large homogenous samples and a protocol that is easy to manage in the farming context. The use of homeopathic complex reduced the incidence of haematomas in turkeys during transportation by about 30%.[97] The use of a complex (with endogenous and exogenous substances) to improve oestrus manifestation in female pigs induced a reduction of the repetitions of inseminations and semen loss.[98] Veterinary studies are also useful for developing study design. In psychogenic dermatosis in dogs and cats 6 months of treatment with the simillimum shows 70% success.[99] The prolonged effect of homeopathic treatment makes cross-over design dubious. Because veterinary pathogenetic studies are very rare, veterinarians often extrapolate from human pathogeneses.

Research protocols in experimental animals include, for example, the effects of nosodes *vs* allopathy and indicated homeopathic medicine using as model experimental urinary infection in rats. The results showed control > pooled autonosode > individual autonosode > antibiotic > *Phosphorus* 30c.[100] The antidepressive effect of *Hypericum perforatum* in rats was better in 200cH than 30cH.[101] With such studies it is possible to evaluate parameters such as the criteria for the choice of the best homeopathic dilution. Experimental animal studies have limited application to veterinary or to human homeopathy but veterinary studies minimise placebo effects and confirm the efficacy of homeopathic treatments. Experiments in laboratory animals help improve research design in homeopathy.

Finally, human studies were considered. A working group was dedicated to clinical research, and particularly considered the issues of individuality and complexity. Evidence Based Medicine (EBM) gives priority to 'Therapeutic Effects Testing' (TET), starting from laboratory studies to Randomized Clinical Trials (RCTs), and finally reviews or meta-analyses of RCTs. The achieved level of TET determines the level of evidence for a medicinal product. 'Clinical Use Testing' (CUT), starting with case reports, epidemiological and cost benefit studies, is not sufficient to provide evidence as defined by EBM. No real bridge exists between these two approaches.

EBH starts and ends with the individualised patient. In order to understand the patient, we must consider his totality, understand his basic vulnerability, latent or manifest. This totality is qualitatively modalised with chronological assessment to get the Minimal Syndrome of Maximal Value. The therapeutic instrument can be self-healing (no medication), or management of life-style or nutrition. A homeopathic medicine can be considered after study of its physico-chemical characteristics, its toxicology, and clinical experience: this is the first step, the hypothesis. The second step is the probability by a first proving on healthy volunteers; third is the confirmation by further provings; fourth is the corroboration by physio-pathological study; and last is the clinical verification in daily practice. But the keystone is the Law of Similars. Research in homeopathy must concentrate on qualitative proving on healthy volunteers and clinical verification in daily practice. Therefore after many years of studies, our first priority must be systematic clinical files collection. A statistical approach (likelihood ratio), can help establishing a scientific base for repertories. This approach was presented by Dr Lex Rutten.

Dr Harald Walach, University of Freiburg, presented an overview of published papers. Homeopathy is popular (used by 50% of the population in France) and is historically successful, both individually (by Fieldmarshal Radetzky, Paganini, etc.) and generally (in cholera and other epidemics all over Europe). Homeopathy remained effective in the face of adversaries and is growing despite (or because of?) modern medical technology.

Publications between 2000 and 2004[102-129] using validated Quality of Life questionnaires, 6915 patients showed clinically significant improvement (approximately 70%; more in children). Homeopathy reduced costs and was associated with improvement in workdays lost compared with conventional practice. For specific diagnoses such as bronchial asthma (89% improvement; even better after 2 years), palliative care in cancer (improvement of quality of life, fatigue and anxiety but not pain), hyperactive children (after 3 months, 75% improvement *vs* 65% for conventional treatment), Upper respiratory tract infections (67.3% improvement with homeopathy, 56% with conventional treatment; side effects 7.8% homeopathy *vs* 22% conventional), homeopathy generally gives better results (including safety) for equivalent costs.

An 'efficacy paradox' can be perceived. In the hierarchy of evidence, RCTs and meta-analyses/systematic reviews of RCTs are of the highest value the best rigour and internal validity but have low external validity and may not be generalisable. On the other hand the applicability of case series and outcome studies is greater, with higher external validity and generalisable conclusions. RCTs implicitly test the placebo hypothesis: 'Is homeopathic therapy different from placebo?' They presuppose a local-causal model of homeopathy, that the physical presence and 'information' of a remedy is decisive (without considering the 'receiver' health status), and that a 'true' effect would be detectable through replication. It is apparent that discrepancies exist regarding homeopathy in daily practice and the RCT approach.

Nevertheless RCTs have been performed and meta-analyses of these studies have concluded that there is clear evidence of efficacy in favour of homeopathic treatments that cannot be attributed only to a placebo effect.[130-139] For some diagnoses, the same level of evidence has been reached: rheumatoid arthritis (6 studies); childhood diarrhoea (3 studies); postoperative ileus (8 studies); hayfever, asthma (4 studies). For

migraine, results of RCTs are disappointing. In children, using comparison groups, significant results have been obtained for recurrent infections, post-operative agitation, adenoids, otitis media, and stomatitis in patients with cancer (complication of conventional treatment). There are promising pilot studies on low back pain, premenstrual syndrome and chronic fatigue.[140 453]

The problems with RCTs are:

- they are difficult to replicate (true also for conventional treatment: only 48% of all SSRI studies are significant);
- they are invasive and expensive, inducing lack of interest due to a lack of funding;
- blinded RCTs answer only the placebo question;
- they make unwarranted presuppositions.

Nevertheless, clear indications exist of the clinical effectiveness of homeopathy; homeopathy is effective in outcome studies or *vs* comparison groups. Placebo phenomena are an insufficient explanation for the effects of homeopathy. Homeopathy can be similar or better in effectiveness than conventional treatment and, where it has been studied, cheaper. Many other questions not so far asked should be prioritised, such as the potential of homeopathy to avoid invasive procedures in children and, in primary care settings, the long-term effect of homeopathy in preventing chronic complications.

Priorities and recommendations

Priorities depend on the audience. The fact the activity of very high diluted preparations is evident does not mean that further research is not required. On the contrary more research is needed especially regarding the content of homeopathic preparations and the transmission of the information. Theoretical issues are also important to avoid unnecessary or incorrect design of research protocols. More effort should be dedicated to veterinary research.[454 474] Clinical effect analysis in humans remains important.[475]

Dr Galen Ives (Priority Research, Sheffield) made recommendations for future surveys on homeopathic practice. Questionnaire design should be driven by requirements for data analysis, and professional advice sought before starting, in particular thinking carefully about measurement scales. It is best to include only new patients. If the aim is to look at the daily practice, a large sample is needed. The question about why patients choose homeopathy must be addressed. The aims of the study must be kept clearly in mind. For example: analysis of effectiveness or cost effectiveness compared to conventional medicine. Patient satisfaction is not the same as treatment effectiveness. Effectiveness can best studies through Quality of Life studies.

Dr Spiros Kivellos (Athens) introduced a severity scale that aims to embody the principles of classical homeopathy in clinical study protocols. He proposed a classification of 'level of health', starting on level 1 (healthy) down to level 12 (irreversible internal lesions). The homeopathic prognosis can be estimated using such a scale and group classification has been elaborated.

Conclusions

- There is evidence that highly dilute homeopathic preparations have biological activity.
- The presence of a 'footprint' of the original substance can be detected in the high diluted homeopathic preparations.
- A paradigm to explain these observations exists.
- Veterinary studies confirm the clinical effectiveness of homeopathy.
- Human studies reveal clinically significant improvement in 70% of patients; these effects cannot be attributed to placebo effect. For some indications the efficacy of homeopathy reaches a high level of statistical significance.
- Future studies should investigate the preventive effects of homeopathy in children and chronic diseases. Funding of research into homeopathy must be considered as vital.

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