

Evidence profile for the efficacy of homeopathy – A new paradigm for medical sciences:
“The Body Information Theory”.

• **First question addressed: The activity of very highly diluted preparations.**

Homeopathic practitioners will argue that the use of preparations that are diluted beyond Avogadro’s number (i.e. potencies greater than C10) happens in only 25% of the prescribed homeopathic medications. Nevertheless, for some people this question is the most important obstacle to the acceptance of homeopathy.

A/ The experimental model that is cheapest, most reproducible and also the most easily researched is probably the “acetylcholine-induced contraction of the rat ileum”. It is a well-recognized scientific model (Chang FY, Lee SD, et al. Rat gastrointestinal motor responses mediated via activation of neurokinin receptors. *J.Gastroenterol Hepatol* 1999; 14: 39-45). This model has been devised for the verification of very high dilutions of Belladonna by A. Cristea, a Romanian researcher; results have already been published (*Bastide M (ed). Signals and Images. Kluwer Academic Publishers* 1997: 161-170).

Professor Wolfgang Süß, Institute of Pharmacy at the University of Leipzig, has used this model to test the transfer of the activity of a homeopathic remedy (in this case Atropinum sulphuricum D60) from the original liquid form to the homeopathic tablet. As usual, several controls were performed. A-lactose monohydrate tablets impregnated with the highly diluted Atropinum had systematically efficacy, on the contrary with anhydrous α -lactose tablets no effect can be ascertain. Thus, the quality of homeopathic tablets can be tested before daily use in pharmacy (constant reproducibility). This very simple model therefore has the potential to remove doubts about the activity of very highly diluted homeopathic remedies (Schmidt F, Süß WG, Nieber K. In-vitro Testung von homöopathischen Verdünnungen. *Biol. Med./Heft* 1/February 2004;32-37).

B/ It has taken much more time for another model to be accepted by the scientific community. The first publications appeared in 1991 but it is only in 2004, after an international cooperation, that the results have finally been accepted in a high-standard peer-reviewed journal, *Inflammation Research*. This model is different from the Benveniste model; he used the same control but not the same activator.

Professors Marcel Roberfroid and Jean Cumps of the Institute of Pharmacy at the University of Louvain, who respectively coordinated the 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). This multi-centre research has subsequently been confirmed in three laboratories by applying flow cytometry analysis and in one laboratory by measuring histamine release. Even if, at present, the molecular theory cannot explain these findings, the facts remain indisputable as recognized by the editor of *Inflammation Research*. (Belon P, Cumps J, Ennis M, Mannaioni PF, Roberfroid M, Sainte-Laudy J, Wiegant FAC. Histamine dilutions modulate basophil activation. *Inflamm. Res.* 2004; 53: 181-188.)

C/ Research on high dilutions has existed since the 1950s, but the number and quality of publications has increased in the last decade. Reviews and meta-analyses have even been performed but often ignored or even denied (see *COST B4 supplement report EUR 19110 ISBN 92-828-7434-6*). This research is not encouraged and even deemed inadvisable by academic authorities.

Professor Jean Cambar, Dean of the Faculty of Pharmacy at the University of Bordeaux, described the most important models that have been published previously in international journals, confirming the effects of very highly diluted homeopathic preparations.

The efficacy of very high homeopathic dilutions of human or animal natural molecules (also called *endogen molecules*) has been published several times in prestigious journals. Examples include the following: *Int J Immunotherapy* 1987; 3: 191-200 (Thymulin in mice. Bastide M); *Int J Immunopharm* 1990; 6: 211-214 (α/β interferon, Carriere V); *J Vet Human Toxicol* 1995; 37(3): 259-260 (Thyroxine, Endler PC); *Int J Immunopathol Pharmacol* 1996; 9: 43-51 (Bursin, Youbicier-Simo BL). During this meeting Dimitris Zienkiewicz, immunologist at the University of Edinburgh, presented preliminary findings assessing, by immunosorbent assay and flow cytometry, the alteration in activation and function of dendritic cells that comes about as a result of their treatment with homeopathic dilutions of a bacterium. Dendritic cells play an instrumental 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.

Efficacy of very high homeopathic dilutions using *pharmacological* models has also been published in peer-reviewed journals. Examples include the following: *Thrombosis. Res.* 1994; 76: 225-229 (Acetylsalicylic acid in a vessel model. Doutremepuich C); *Haemostasis* 1990; 20: 99-105 (Acetylsalicylic acid in healthy volunteers. Doutremepuich C); *Thrombosis. Res.* 1987; 48: 501-504 (Acetylsalicylic acid in healthy volunteers, Doutremepuich C).

The longest-used model, published frequently all over the world, is the *toxicological* model (Arsenic, Phosphorus, Mercury, Cadmium, Cisplatina, Glutamate, Cuprum sulphate, etc). It can be applied to vegetable, animal, cell culture material or even clinical studies. This model is still used and indeed is the theme for a collaboration between the Universities of Bern and Bologna, testing homeopathic arsenic trioxide treatments by plant-based bioassays. The working variables are the germinated seeds or the stem length on the seventh day. At least 6 recent experiments by this team are published (Dr Lucietta Betti. DISTA-Department of Agro environmental Science and Technology, University of Bologna.).

Experiments are well conducted, in controlled conditions, with a sufficient number of plants, animals or cells, and with a fair statistical treatment. *The facts are indisputable, statistically significant and reproducible*, even if they cannot be explained using the molecular paradigm.

- **Second question addressed: The content of very highly diluted homeopathic preparations.**

Professor Jean Cambar introduced the theme by asking what are the contributions of the different spectroscopies (Raman, Ultraviolet, X-ray or Magnetic Nuclear Resonance) in revealing the structure of water and solvents in high dilutions? What is the real relevance of Avogadro's number in evaluating the precise pattern of molecules? Can a dilution work without any molecule? One of the most innovative perspectives in this last decade was the demonstration that high dilutions have as much activity and effectiveness in an organized structured solvent without any solute molecule as they do when molecules are present (even only some molecules).

Professor Louis Rey, Doctor of Sciences, Lausanne, a specialist in low temperature thermoluminescence, has published on this topic in the international journals *Nature* (1988; 391: 418) and *C.R.Physique* (2000; 1: 107-110). He presented the latest results of the experiments he carried out together 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 77K, then progressively re-warmed to room temperature. During that phase, their thermoluminescence was studied and it was found that, despite their dilution beyond the Avogadro number, the emitted light was specific of the original salts dissolved initially. 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 different identical 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 stirrings. (*Physica* 2003; A323: 67-74).

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. (Publication in process.)

The use of modern techniques in the hands of 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, specific information of the prime dissolved substance still remains in the preparation and can be detected experimentally.

- **Third question addressed: The theoretical framework in which the effects of homeopathic diluted preparations can be explained.**

Two members of G.I.R.I. (Groupe International de Recherche sur l'Infinitésimal; see www.giriweb.com), Professor Madeleine Bastide (University of Montpellier) and Agnès Lagache (Professor of Philosophy, Paris) have been working on this topic for 16 years. A new paradigm for medical science is needed to explain these facts and to allow more precise research models in the future. A working group of 7 members applied this new paradigm to the analysis of 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).*

Prof. Bastide explained that homeopathy and research models are based on the observation of “symptoms”. Asymptomatic pathologies exist that provoke “biological scars” as a proof of the self-treated organism without showing the illness symptoms (*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 find any answer whatever the situation (infection, stress, strong emotion...).

Example: Rubella in a normal subject: no apparent sickness. Rubella in immuno-deficient subject: symptoms, apparent sickness.

For the allopathic research approach, the symptoms are pathognomonic, specific to the illness; they are used to diagnose the pathology. When the diagnosis of the pathology is performed, the treatment is chosen accordingly; classical therapy may be also targeted against symptoms. For the homeopathic research approach, considered symptoms are idiosyncratic; specific to the patient. They are the personal expression of the 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 a lasting and irreversible learning process; it communicates at every level with its environment. It is able to receive and treat semantic and corporeal information; it is not an inert object.

The paradigm of corporeal signifiers (Bastide M., Lagache A. *Revue Intern. Systémique* 1995; 9: 237-249 and *Altern Ther Health Med.* 1997; 3: 35-9).

Three principles define homeopathy, based on clinical and experimental analysis: the similia and whole person principles, and the use of very high dilutions. The effects of high dilutions cannot be explained by a simple molecule-receptor interaction (mechanistic paradigm), the “*well established theory*” of modern science. Prof. Bastide & Lagache propose an epistemological approach to homeopathy based on body information processes received and interpreted by the living organism; this follows the rules of information exchange. Exchange of objects between a giver and a receiver is very 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, take 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 – he knows that he is alone on the island. Prof. Bastide & 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 from that material and no molecules remain. 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 bases of this paradigm are verified by the systematic experimental results obtained as described in the first parts of the conference.

This new paradigm is needed to explain the experimental facts and to understand the failure of research models that do not fit it.

- **The final question addressed: The clinical effects of homeopathic preparations.**

An experimental design is only relevant if it takes into account the observed phenomenon within its specific framework and if the subject addressed can be isolated of all external influences. Considering human medicine, the psychological factors are responsible for non-specific effects and the medication effects are called specific effects. Whatever the research model, taking into account the homeopathic approach, the idiosyncratic symptoms (specific to the patient) must be considered excluding pathognomonic symptoms.

A/ Professor Leoni Bonamin, Paulista University (São Paulo) and president of G.I.R.I., 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 nil and there are fewer ethical considerations. Moreover, studies in well-defined herds and features can include a very homogeneous sample from a large number of animals. Nevertheless, the rules for well-designed studies must still consider the particularities of homeopathic research as regards the Similia principle (considering idiosyncratic symptoms).

Veterinary studies are very important for organic farming regulation. In Europe, only homeopathic treatments are authorized for biological farming. The use of homeopathy is aimed at avoiding chemical residues in the food chain. More institutional support is certainly needed.

In recent studies, the use of homeopathic complexes has been tested with very good results using parallel placebo groups, blinded design, homogeneity of samples with sufficient animals, and a protocol that is easy to manage in the farming context.

Filliat C. Particularité de l'utilisation de l'homéopathie en production avicole. *Annals of the "Entretiens Internationaux de Monaco 2002"*, 5-6 October 2002. <http://www.giriweb.com>. The use of homeopathic complex reduced the incidence of haematomas in turkeys during transportation by about 30%.

Riauourt A. L'Exemple de la Filière Porcine. *Annals of the "Entretiens Internationaux de Monaco 2002"*, 5-6 October, 2002. <http://www.giriweb.com>. 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.

Veterinary studies are also useful for questioning homeopathic study design. Using the model of psychogenic dermatosis in dogs and cats (Torro, et al. *In press*), six months of treatment with the simillimum shows 70% success. One year after finishing the treatment there was no recurrence. The entire study duration is six years. The very long efficacy of the homeopathic treatment is a reason for questioning cross-over design.

Because veterinary pathogenetic studies are very rare, veterinarians often need to do extrapolations from human pathogenesis and their *Materia medica* is based on classical studies performed in humans.

Research protocols in experimental animals. For example, the effects of nosode (isopathic homeopathic remedy) versus allopathy and similar homeopathic remedy using as model the experimental urinary infection of rats (Gonçalves *et al.* O uso da homeopatia no tratamento da infecção urinária em ratas. *Anais do VIII SINAPIH*; 20-22 May, 2004: p.25-26. <http://climed.epm.br/sinapih/index>). This study compares nosode from individual or collective samples. It is a blinded study; the presence of *E. coli* in gall bladder of rats is evaluated after 12-16 days of treatment: Untreated control, 100% of bacteria colonies (no spontaneous healing), second control is the vehicle (alcohol 5%) 94%, comparison group treated with Antibiotic (levokinolone) 33%*, treated group with nosode from a pool of urines (30D) 73%*, treated group with a self-nosode (30D) 39%*, and treated with a similar homeopathic remedy Phosphorus 30CH (the incorporation of rats in this group happens observing their individual behavior) 22%* (* Fisher test, p=0.05).

With such studies it is possible to evaluate some homeopathic parameters such as the criteria for the choice of the best homeopathic dilution. The general rule is to use high potencies for chronic / mental disturbances and low potencies for acute / organic disturbances. The anti-depressive effect of *Hypericum perforatum* in rats was better in 200CH than in 30CH: tested by the Porsolt forced swimming method (Goulart *et al.* Avaliação dos efeitos de *Hypericum perforatum* (Hp) dinamizado homeopaticamente em comportamento de ratos. *Anais do VIII SINAPIH*, 20-22 May 2004: p.14. <http://climed.epm.br/sinapih/index>); this was a blinded, well designed study.

Experimental animal studies have limited application to veterinary or to human homeopathy.

Veterinary studies minimize placebo effects and confirm the efficacy of homeopathic treatments. Experiments in laboratory animals help improving research design in homeopathy.

B/ Last, but not least, the *human studies* were considered.

B.1) A second G.I.R.I. working group was dedicated to clinical research, and particularly considered the issues of individuality and complexity.

Evidence Based Medicine (EBM) gives first priority to “Therapeutic Effects Testing” (TET), starting from the work of basic scientists in laboratories up to clinical researchers doing Randomized Clinical Trials (RCTs), and finally reviews or meta-analyses of several RCTs. The achieved level of TET determines the level of EBM for a medicinal product. “Clinical Use Testing” (CUT), starting with case reports, epidemiological outcomes and cost-benefit studies, is only interesting for public health authorities and patients but it is never sufficient to reach EBM. No real bridge exists between these two approaches.

Evidence Based Homeopathy (EBH) starts and ends with the individualized patient. It can be represented as the arch of homeopathy: at one side there is the examination of the patient, and at the other side the therapeutic instrument. In order to understand the patient, we must consider his totality in time and space to be able to understand his basic vulnerability, latent or manifest. This totality must be qualitatively modalized with chronological assessment to get the Minimal Syndrome of Maximal Value. The therapeutic instrument can be self-healing (no syndrome, no medication), or management of life-style or nutrition in order to avoid obstacles to cure. A homeopathic remedy can be considered after study of its physico-chemical characteristics, its toxicology, its usual therapeutic use: this is the first step, the hypothesis. The second step is the probability by a first “proving” (blinded protocol) 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. For the remedies we must have the same qualitative assessment as for the patients. But the keystone of the whole homeopathic process, without which the arch will crumble, is the Law of Similars. Research in homeopathy must be concentrated 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 (CLIFICOL project). The Bayesian statistic, a statistical approach (likelihood ratio), can help establishing a scientific base for our symptoms’ repertoires. This approach was presented by Dr Lex Rutten from The Netherlands.

Can one get over the gap that exists between EBM and EBH?

B.2) Dr Harald Walach, University of Freiburg, presented an overview of the already published papers.

Homeopathy is certainly popular (used by 50% of the population in France) and is historically successful, both individually (by Fieldmarshall 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.

Looking only at the latest publications and using validated Quality of Life questionnaires (between 2000 and 2004), 6915 patients presented clinically significant improvement (approximately 70% of cases; more in children). Homeopathy reduced costs and allowed a better improvement in work-days lost compared with conventional practice. For specific diagnoses such as bronchial asthma (89% improvement; even better after 2 years), cancer patients in palliative care (improvement of quality of life, fatigue and anxiety but not pain), hyperactive children (after 3 months, 75% improvement versus 65% for conventional treatment), URTI (67.3% improvement with homeopathy, 56% with conventional treatment; side effects 7.8% homeopathy versus 22% conventional), homeopathy is at least as effective as conventional therapies, but costs are lower and the safety of homeopathy is greater.

On the other hand, an “efficacy paradox” can be acknowledged. Using the hierarchy of evidence, for conventional medicine the RCT is of the highest value – the best rigour and internal validity – but it has a low applicability score, a low external validity and its conclusions are generalized with great difficulty. On the contrary the applicability of case series is great, showing a high external validity and its conclusions generalized easily. RCT implicitly tests the placebo hypothesis; the question is only: “Is the homeopathic therapy different from placebo?” It presupposes 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 (Linde K, Clausius N, Ramirez G, Melchart D, Eitel F, Hedges LV, Jonas WB. *Lancet* 1997; 350: 834-43 and Dean M.E. *Hans Walz Preisschrift, Essen:KVC Verlag*, 2004.) For some specific 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 are obtained for recurrent infections, postoperative agitation, adenoids, otitis media, and stomatitis in patients with cancer (complication of the conventional treatment). There are promising pilots studies on low back pain, premenstrual syndrome and chronic fatigue.

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.

Conclusions: Clear indications exist about clinical effectiveness of homeopathy; homeopathy is effective in uncontrolled practice or versus comparison groups; enough indications exist that “placebo” is 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, it is cheaper in the long run. Many interesting questions not even asked should be prioritized, 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.

B.3) Future projects were discussed.

▪ Surveys on homeopathic practice have already been published. Dr Galen Ives (Priority Research, Sheffield) made some recommendations for future projects. Questionnaire design should be driven by requirements for data analysis, and professional advice sought before starting, in particular thinking carefully about measurement scales (subjective data not expressed in numbers but crossing a box), and assuming all respondents lack prior experience in such recording. The question of timescales is a sensitive one therefore it would be better to include only new patients. If the aim is to look at the daily practice, a large demographic data is needed. The question about why the patients chosen homeopathy must be addressed. A comparison group is not a common requirement in such studies, but to avoid editorial comments on this question, it would be explained in the discussion part. The aims of the study must be kept clearly in mind. Example: analysis of effectiveness versus conventional medicine (CM); cost-effectiveness versus CM. It would be recommended to use inclusion criteria (such as state of health) and sub-groups (as example acute cases). The study of patient's satisfaction is not the same as looking at treatment efficiency. Efficiency can best be checked through Quality of Life studies, in this case at least 2 successive questionnaires are needed with a greater risk of drop out.

▪ Dr Kivellos Spiros (Athens) introduced a severity scale that aims to embody the laws 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 injuries). The homeopathic prognosis can be estimated using such a scale and group classification has been elaborated.

• **Conclusions from this colloquium:**

- ✚ There is evidence that highly dilute homeopathic dilutions have biological activity.
- ✚ The presence of a “footprint” of the original substance can be detected in the high diluted homeopathic preparations.
- ✚ Explaining the observed phenomenon a new paradigm for medical sciences exists.
- ✚ Veterinary studies confirm the clinical efficacy of homeopathy.
- ✚ Human studies reveal clinically significant improvement in 70% of patients (more in children); the homeopathic effects cannot be attributed only to a placebo effect and for some indications the efficacy of homeopathy has reached a high level of statistical significance.
- ✚ Future studies are needed that investigate the preventive effects of homeopathy in children and chronic diseases. Funding of research into homeopathy must be considered as vital.

Finally, the participants wrote the following **press release**:

At the invitation of the European Committee for Homeopathy, which represents 33 homeopathic doctors' associations in 24 European countries, joining the XVIII symposium of GIRI, ten internationally renowned university professors in the field of research met in Brussels for a 3 day meeting starting on Friday November 12th 2004.

The results of the research discussed by these university professors are all in accord with one another – namely, that there is clear evidence for the effectiveness of homeopathic medications. There is sufficient reason for further research.

The professors expressed their amazement at the lack of response from the health authorities to these convincing results.

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