

# Homoeopathic Research: Problems and Results on Effectiveness - including Data from the Program for the Evaluation of Complementary Medicine PEK

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The “Program for the Evaluation of Complementary Medicine” (PEK, 1999–2005) of the Schweizer Bundesamt für Gesundheitswesen (BAG, previously BSV) was set up to provide data on effectiveness, appropriateness and cost-effectiveness (WZW) of complementary medicines with a view to decide whether it should remain part of basic insurance. However, The PEK Project was from the start [1], but especially in its final phase, marked by tremendous deficiencies and flaws which were articulated in comments made by a member of the steering committee [2, 3] as well as the Review Boards [4]: collection of data was interfered with; results were not allowed to be presented; the final report was censored; conclusions, especially those regarding homoeopathic practices are still incomplete, are missing, or were not published at all [5, 6]. This subject will not be discussed here any further. It can only be hoped that “prospective political decisions will be made according to scientific information available and not according to preconceived ideas” [7].

How were the Swiss homoeopathic doctors involved in the PEK? In the “Lancet-study” of the Institute of Social and Preventive Medicine ISPM Bern under Professor Egger [8] participation of homoeopaths was refused, and even access to information [9, 10]. In the HTA report (*Health Technology Assessment*) about homoeopathy [11, 12, 13] homoeopaths were able to participate in certain areas as co-authors. Furthermore, many homoeopaths took part in the PEK-practical study.

**Background:** The “Programm Evaluation Komplementärmedizin PEK” (Program for the evaluation of complementary medicine) of the Swiss government was set up to provide data on effectiveness, appropriateness and cost-effectiveness of complementary medicine. Towards its end, the project suffered from various shortcomings. In the field of homoeopathy, research literature and the practice of Swiss doctors were examined.

**Problems:** The biggest obstacles for the acceptance of homoeopathy are high potencies beyond the molecular limit and the unknown mode of action. From its beginning, homoeopathy was based on empirical research yet conventional research is currently demanded to decide whether it works. Homoeopathy is an individual method and cannot be forced into standardised research patterns. Nearly all homeopathic trials disregard these basic rules and are lacking in practical relevance and external validity.

**Results and Conclusion:** Despite these problems, among experimental studies the basophil degranulation tests and animal intoxication studies demonstrate the best evidence. The Health Technology Assessment (HTA) of the PEK examined clinical studies: 20 of 22 Systematic Reviews showed positive results for homoeopathy, among them all the large rigorous meta-analyses. This result is supported by other large surveys not evaluated in the HTA. In the domain of “Upper Respiratory Tract Infections/ Allergies” 24 of 29 studies were positive. In their “Lancet-study” Egger and the Institute of Social and Preventive Medicine ISPM Berne found positive results in both groups, 110 homoeopathic and 110 matched conventional studies (funnel plot analysis). Only after a doubtful restriction and extrapolation from 8 homoeopathic and 6 conventional studies, did the result become negative for homoeopathy. The “Lancet-study” is neither representative nor transparent and the study selection is inadequate. Further shortcomings are discussed here. A more appropriate approach to the assessment of homoeopathic effectiveness are large outcome studies with long-term observation under real practice conditions. They show a substantial practical effectiveness and utility of homoeopathy. The article provides an outlook and proposals for future research and evaluation of homoeopathy.

**Key words:** Homoeopathic research, problems, clinical results, PEK studies, future research.

## Difficulties concerning Research on Homoeopathy

The greatest problem for the acceptance of homoeopathy are the high potencies beyond the molecular limit and its unknown mode of action. Is it just hocus-pocus or can the medication really work? According to the criteria of conventional pharmacology, they cannot possibly work. But homoeopathy showed quick results when used during epidemics, in the treatment of millions of sick people or in acute and chronic diseases of animals and babies. Hocus-pocus? Research will show.

From the start homoeopathy was based on empirical research, but in the face of the endangered paradigm, this did not interest anybody outside homoeopathy, therefore the call for conventional clinical research. However, homoeopathy is based on a purely individual choice of medication. There is no specific medication for a particular diagnosis. Almost all studies on homoeopathy disregard the basic principle and ground rules of homoeopathy, they are not practice orientated and usually without any relevance to homoeopathic practices. This means that external validity is low and the danger of false negative results is great. In other words: homoeopathy is being forced into an unsuitable research format and external validity is sacrificed for internal validity (external validity = validity regarding actual practical treatment; inner validity = inner, methodic-statistical validity of a study). Particularly dicey and usually inappropriate is the “gold standard” of clinical studies, the random controlled study (RCT), which falsifies homoeopathic practice and is similarly inadequate in other more complex questioning.

## Results and Discussions

Since the end of the 1980s there has been no comprehensive literature overview of homoeopathic research [14, 15]. Right from the start, within the framework of the PEK, homoeopathic doctors demanded an extensive review of literature [1]. This was promised, but within the framework of the HTA unfortunately only minimally complied with.

To a large extent only models and hypotheses are available on the active principle. In basic research there are indeed indications – from NMR/ Nuclear-Magnetic-Resonance and UV-spectrography – of dynamic changes of

solvents by homoeopathic potencies, however, this evidence is not strong enough and cannot be reproduced [16, 17].

In spite of these said problems, numerous studies have succeeded exemplarily in proving the experimental effect and clinical efficacy of homoeopathy. In these experimental studies efficacy was most often and most successfully proven and reproduced with the basophil degranulation (BDT) tests used in allergology [18] as well as animal intoxication studies. (Protection and detoxification of the test animal by potencies of the respective poison; Meta analysis of more than 105 studies [19]). Many of these studies came from pharmacological faculties at French universities and were more or less ignored for decades by those assessing homoeopathy. A large number of the studies, using these two methods, were positive. However, the BDT trials of Benveniste [20] – which were published in *Nature* – engendered heated controversies. Other experimental approaches also showed positive results, for instance the interference in the metamorphosis of amphibians with potentized Thyroxin ([21] i.a.). The sum of positive evidence in experimental studies is remarkable.

In the clinical assessment of homoeopathy one should not ignore the “soft” evidence: historical evidence, case reports and the 200 years practical experience with millions of sick people. According to Mathie [22] proof of efficacy is particularly strong amongst clinical studies in 9 diagnoses, however, in others it was less conclusive. In the HTA-Report “Homöopathie” of the PEK [11, 12, 13] only the area of Upper Respiratory Tract Infections/Allergies (URTI/A) were investigated: 24 out of 29 evaluated studies show positive results (significance or trend) in favour of homoeopathy and prove its effectiveness. 23 out of 29 studies are controlled. Here the difficulty and complexity in the search for homoeopathic literature is evident. In spite of extensive search strategies above and beyond indexed publications, more than 20 further URTI/A studies [e.g. in 23] were subsequently found. Their clearly positive evidence supports the conclusion.

In the overview studies of the HTA, 20 out of 22 Systematic Reviews (SR) show a positive result, above all the large rigorous conventional reviews by Kleijnen et al [24], Boissel [25], Linde et al. [26] and Cucherat

[27]. Further comprehensive meta-analyses and overviews with an abundance of positive evidence were in fact used as data source – they were not evaluated in the HTA: they also verify the clinical effectiveness of homoeopathy [e.g. 22, 23, 28 i.a.]. In the “Lancet-study” [8] Prof. Egger and the Institute of Social and Preventive Medicine ISPM Bern come to other conclusions. This is not the place to discuss the untenable procedure of these authors, which for one and a half years caused the media headlines “Homoeopathy equals Placebo” to circulate, thereby violating the confidentiality clause and internal PEK agreements. All this, even before the homoeopaths taking part in the PEK study were eventually able to see the study in January 2005 and comment on it [9]. The study compares 110 homoeopathic with 110 matched conventional studies. And what does the study show? It is not representative and not valid. The authors are therefore not in a position to make any statement on homoeopathy.

1. They do not measure real practical homoeopathy but confuse it with distorted homoeopathy for study purposes. In practice no patient would be treated as in one of the 110 studies!
2. On the other hand a large majority of the studies show a similarly positive result as conventional medicine.
3. The negative result is solely obtained through a doubtful restriction of 8(!) larger, randomly selected, mostly non-practice-orientated homoeopathy studies, compared to 6(!) conventional studies, as well as a rather doubtful statistical extrapolation. The Lancet publication does not mention on which 8 studies the negative result is based. Only after several months do they appear on its web site, however, no reason is given for their choice.
4. Many other details of the ISPM study are faulty and not tenable: The analysis and the graphic statistics are completely non-transparent, information and assessments for individual studies are totally missing. The work is tendentious: references to the low external validity of the investigated RTC studies and to the danger of false negative results are missing, as well as references to diametrically opposed results of other larger surveys. The criterion of study size is overweighted and the study selection is inadequate. The meta analysis and graphic statistic (Funnel Plot) is unsuitable for heterogeneous studies as

in the case of homoeopathy. One cannot lump it all together. The choice of studies is incomplete and faulty: 60 studies are rejected without any explanation. In the Kleijnen et al. [24] and Wein [23] studies alone, there are altogether some 250 RTC studies of which about three quarters are positive. Accordingly the authors have in no way covered the controlled homoeopathy studies as fully as they believe. In this way they are contradicting their own criteria [29] and those of the “Cochrane Collaboration”. By reducing it to 8 studies they devalue their own Funnel Plot Method and are possibly creating their own “selection bias”. In spite of a majority of positive RTC studies a negative result is achieved in this way.

The statement “homoeopathy equals placebo” is scientifically untenable. The letter to the editor written to the SVHA, like many others, was rejected by Lancet but was published as “open letter” in many other places [30]. Numerous critical responses appeared elsewhere [e.g. in 31, 32]. In its editorial Lancet has declared “the end of homoeopathy” – or is it rather the end of bio-medical reliability?

How are the results of the homoeopathy studies to be evaluated? The question is reminiscent of the problem of the glass that is half full or half empty. From a strictly homoeopathic viewpoint one could to a large extent ignore these studies – but the studies do exist. Almost all studies are non-practice orientated because model and external validity is missing and in contrast to conventional studies, for the most part meaningless and uninteresting in practical work. In addition, homoeopathy to a large extent lacks money, research infrastructure and a financially strong pharmacological industry. In view of these facts the large number of positive verifications of its effectiveness is amazing and remarkable. In the light of this one could say: the glass is at least half full. In contrast, again and again different models were used in the homoeopathy studies, relatively few were reproduced and the totality of studies is small – compared to those of conventional medicine – which is not surprising, given the small practical relevance. In the light of this, the glass is half empty. However, even from a critical viewpoint the following should hold: “Absence of evidence is not evidence of absence” [33] – especially in the case where there is inadequate basic

research.

What would be better? By far the most studies available today are forcing homoeopathy into an unsuitable and restrictive research format. The homoeopathic mode of action is unknown: On the strength of observations during treatments, homoeopathy, unlike conventional medicine, does not have a specific effect on diseases, instead it probably has an unspecific effect on regulation and self-healing as well as individually specific action in the respective patient. Because of this, effectiveness is probably best measured in real context instead of its pharmacological workings *per se*. The investigative method of choice best suited to the principle of individualization and methodology of homoeopathy is the individual case study – for study purposes on a large enough number of patients and over longer time periods. During recent years more practice orientated studies were increasingly carried out, which may demonstrate the clinical effectiveness of homoeopathy with regards to acute and chronic diseases in its natural practice environment. Large epidemiological Outcome-Studies with long-term observation are particularly valuable [e.g. 34, 35, 36, 37, 38], which under real-life practice conditions prove the excellent and substantive effect of homoeopathy; amongst these was a study on almost 4000 patients with chronic diseases [36]. The results of the PEK practice studies are in the same vein [5, 6]. Some of these studies also include control groups under conventional treatment. Homoeopathy therefore illustrates the paradoxical phenomena of good clinical effectiveness and practical usefulness in spite of less convincing results in conventional efficacy studies (effectiveness paradox [39]).

### Future Research of Homoeopathy

Some hypotheses (see also [15]):

A. Starting point and addressee: The historical material about rapid successes during epidemics [28] and its proven reliability over a period of 200 years has not been adequately researched, however, the “soft facts” speak for homoeopathy. In practice homoeopathy shows stable (long-term) effectiveness in acute bacterial infections as well as in chronic and recurring diseases, as opposed to placebos. This can be reproduced

intraindividually with the right medication but not when the wrong medication is chosen. Homoeopathy has few side-effects, is cheap and shows up positive in Outcomes-Studies, as well as in most experimental and clinical studies, even though they have low external validity. The question arises, what is actually still missing to achieve WZW verification. Public Health Authorities, economists, patients, homoeopaths, general practitioners, clinical pharmacologists or faculties of medicine would all have a different answer to this question. Therefore the research outline would be totally different according to the addressee, the reason and the objective. At all events, it is essential and of the utmost importance to clearly point out the problematic and significance of the research method and its conclusions in each study publication.

- B. Suitable and stable research infrastructure at universities or other qualified institutions as well as extensive world-wide collection and overhaul of existing research results (including literature not indexed yet) is a basic requirement for future research.
- C. Future research must clearly distinguish between research aimed at directly assisting in the advancement of homoeopathy and research that aims to further its scientific and political acceptance (justification studies). In this case, research has to consider both the conventional and the homoeopathic criteria in equal measure.
- D. Improvement in the quality of homoeopathic treatment rests primarily on its system inherent research (testing of medication, symptom and progress analysis, increase of clinical experience and know-how, etc.) Included here should be the investigation into its mode of action, its scientific and humanistic foundations, the method of production and quality, as well as some epidemiological questions (see G). The important questions of health and disease and its integrative treatment apply to both homoeopathy and conventional medicine.
- E. To prove the effectiveness of homoeopathy individual case studies (intraindividual examination) with individual choice of medication is best – on sufficient patients and in the case of chronic diseases over a long enough period of time.

First and foremost, broadband observational studies (outcomes studies) are best for reliable data collection; data regarding practice, effectiveness, expediency and cost of homeopathic treatment, all this carried out under real life practice conditions, minimally influenced by unsuitable methods of research. They should adequately consider the validity criteria of the EBM (Evidence Based Medicine) as well as homeopathy and if possible should encompass comparisons with control groups. An option would be the collective comparison between the homeopathic and conventional treatment of a group over a longer period of time as recommended by supporters of homeopathy in the PEK.

- F. Randomized controlled trials (RCT) with individual prescription should only be carried out according to a detailed study plan and pilot phase. In homeopathy, especially in the case of chronic illnesses, they are extremely complex, difficult and ethically questionable. Our point of view is that it makes little sense to randomly add 2 or 3 additional indication studies to the already existing 1000 or more experimental and clinical studies, without precise questioning. In any case, exceptions require careful planning. Possibly this would best be done in the case of acute illnesses (less complexity) or special cases (e.g. hyperactive children [40]).
- G. RCT studies without individual medicine selection are contrary to the basic principle of homeopathy, and usually have low external validity. They only make sense if specific and noteworthy evidence of effectiveness can be confirmed by an experimental model. Even here good planning is essential. The reproduction of promising studies would be especially meaningful and feasible in an appropriate setting, as, for instance in the case of traumatology and allergic illnesses. The common denominator of such studies are clearly defined situations with a possible limitation of the individualization principle (standardized therapies may cover most of the cases). Some questions regarding limited individuality could also be of homeopathic and epidemiological interest: for instance in traumatology, insect bites and allergies, in immunology (nosodes), poisoning (animal intoxication

models) and so-called unilateral diseases.

- H. In experimental trials (“*in vitro*”, animal, plants), similar points apply as in G. First and foremost would be the establishment of a few stable and reproducible trial systems, which in spite of their low external validity might provide definite evidence of efficacy.
- I. Fundamental research: This would encompass questions about the principle of efficacy, physicochemical (and humanistic?) fundamentals and medication problems; questions that would be of interest to homeopathy yet somewhat difficult to research.

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