decreased general health combined with significant bacteriuria.

*Results:* Five of seven patients opted for homeopathic treatment. The bacterial strains detected in urinalysis were E. coli, proteus mirabilis and Klebsiella pneumonia, respectively. Morphologic and functional reasons for recurrent UTI were excluded by sonography, cystoscopy and urodynamics. After treatment, with a median follow-up of 15 months, 3 of these patients remained free of UTI, whereas UTI frequency was reduced in the other 2 patients. In three patients, standard prophylactic treatment could be reduced. No side effects were encountered.

*Conclusion:* Our initial experience with homeopathic prevention of UTI is encouraging. Keys for a fruitful cooperation are well-qualified partners, mutual respect and the motivation to cooperate closely. For an evidence-based evaluation of this concept, prospective studies are required.

# Homeopathy in the public health system: the experience in Lucca Hospital (1998-2011)

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The Homeopathic Clinic in Lucca, funded by the Region of Tuscany, was originally set up in 1998 as part of a pilot project designed to evaluate the possibility of including complementary medicine (CM) into the public health care system.

The following are the main activities in the field of clinics, research and education carried out in these years.

*Outcome:* The data have been updated with those collected from September 1998 to December 2010: 2,592 patients visited for a total of 6,812 consecutive visits. The results were assessed using the Glasgow Homeopathic Hospital Outcome Score (GHHOS).

*Paediatric patients:* An observational longitudinal study was carried out on 551 paediatric patients below or equal to the age of 14 years (mean age 5.9 years), that is 25.7% of 2,141 patients consecutively examined from 1998 to 2008.

*Adverse effects:* In order to assess the possible risk arising from the use of homeopathy a prospective study was carried out to investigate the adverse drug reactions related to homeopathic medicines. Out of 335 homeopathic consecutive follow-up visits, nine adverse reactions were reported (2.68%).

*Clinical risk management:* A training course for the health professionals of Tuscan public centres of CM, including homeopathy, was conducted. The aim was to develop a plan for the management of clinical risk starting from the analysis of the activities in the clinics of CM, and a systematic approach aiming at identifying and preventing risks.

*Homeopathic aggravation:* To evaluate the type, intensity and frequency of homeopathic aggravation, in particular with Quintamillesimal dilutions (LM or Q), and its prognostic value, a retrospective study was realized on the basis of clinical data. The study examines 1,108 patients consecutively visited, and 441 cases with follow-up. Sixty-three of them (14%) reported a homeopathic aggravation.

*Compliance:* In order to understand why the patients did not return for follow-up consultations (drop-out) a telephone survey was carried out on each patient visited from 6/1,2002 to 5/31, 2003, who did not return for a follow-up visit. 37 patients out of 73 referred to the effectiveness of the treatment and the improvement in their state of health as the reason why they did not return.

*Long term outcome of atopic patients:* To study the outcome of atopic diseases (AD) in paediatric patients homeopathically treated and the clinical evolution of 213 (38.6%) with atopic diseases out of 551 children consecutively examined from 1998 to 2008. After 5 years from the first visit, all the children were contacted for long-term evaluation of the disease.

*Anti-cancer treatment:* An outpatient Clinic of integrative medicine applied to oncology was set up in October 2010. In the preliminary stage of activities, 97 patients were visited, with various types of cancer.

*Cost-benefit evaluation:* A study of the Homeopathic Clinic of Lucca demonstrated cost/effectiveness of homeopathy in respiratory diseases. Cost variation for the specific chemical/therapeutic subgroup recorded a decrease in the first and second year of $-46.29\%$ ($p < 0.01$, $n = 105$) and $-47.45\%$ ($n = 72$) respectively.

All these data demonstrate the validity of the integration carried out in Tuscany and the need to strengthen and consolidate the activities of complementary medicine in public healthcare structures.

# Will this medicine work for me? Towards a scientific answer

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Which answer would you prefer: 1. "This medicine works better than a placebo", or: 2. "I estimate the chance that this medicine will work in your case to be 60%"?

These two answers reflect a two and a half century lasting dispute between two statistical methods, 'classical' (frequentist) and Bayesian. The first is regarded to be more scientific, the latter played a major part in solving many of history's most important problems, like deciphering coded messages in WO II and predicting disasters. Nowadays many computer programs incorporate Bayes' theorem to handle experiential knowledge.

Because RCT evidence does not allows other conclusions, the patient can only expect a yes-or-no statement

about efficacy of conventional medicines. But this answer might still be false in his particular case. Other factors, like correct diagnosis, genetic susceptibility and comorbidity, also determine if the medicine works. The diagnostic process preceding the prescription is Bayesian and renders the probability of a specific diagnosis.

Bayesian philosophy is about learning from past experience, e.g. about characteristics of patients responding well to specific medicines. Like a medical diagnosis, the choice of a homeopathic medicine is a Bayesian process. Different personal characteristics add up, stepwise increasing the chance that a specific homeopathic medicine will work.

Hitherto homeopathic doctors have been using Bayesian statistics implicitly: characteristic symptoms pointing towards a specific medicine occur more frequently in patients responding well to that medicine than in patients responding to other medicines. It is a small step to make this rule explicit in various types of research and data collection. All we need to know is the prevalence of a symptom in the population responding well to a specific symptom and in the remainder of the population. The ratio between these two is called the Likelihood Ratio (LR).

The research we need is accepted in conventional diagnosis research. Like all kinds of research we will have to deal with possible bias; like our reference standard: what is a good result? Symptoms should be defined more accurately, etcetera. These problems have been neglected in the past. We must realise that this research is meant to improve homeopathy, not to prove it. However, improved homeopathy will render better proof.

Several methods for Bayesian assessment of symptoms are demonstrated. The most valid and time-consuming method is prospective research of a small set of symptoms, but even with this method we can achieve a tremendous scientific improvement of homeopathy within a limited amount of time. Within ten years we could know LRs of characteristic symptoms for our most frequently prescribed homeopathic medicines. Applying the formula that goes with Bayesian theory we will be able to tell the patient: "Based on the symptoms you gave me I expect the chance that medicine A works for you to be x%".

*Keywords:* Clinical research, research methodology

# Protocol for prevention and treatment of dengue fever and its complications

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*Background*: Dengue virus (DENV) currently infects 50-100 million people/year, causing about 500,000 cases of severe complications (dengue haemorrhagic fever; dengue shock syndrome) and 20-25,000 deaths. From USD 1.35 billions/year Brazil spends in dengue, USD one billion is allocated to the vector control programme. All attempts at control of the mosquito vector have systematically failed, and there is no specific treatment or vaccine currently available. Homeopathy has a long record of success in the treatment of epidemic diseases. Although recent experiences pointed to the possible efficacy of homeopathic prophylaxis and treatment in dengue, with low cost, satisfactory acceptance by the targeted population, and lack of adverse events, clinical trials reported controversial results.

*Aim*: To assess the effectiveness of homeopathic intervention in the prevention and treatment of dengue fever.

*Study design*: Multicentre study including Brazilian counties with high incidence and prevalence of DENV infection, and where primary healthcare staff include homeopathic doctors. *Stage 1*: Training of multi-professional staff and preparation of infrastructure. *Stage 2*: Selection of the epidemic medication by an expert panel based on the signs and symptoms exhibited by 20 confirmed cases. *Stage 3—Prophylaxis*: will include all 18-60 year-old individuals spontaneously visiting the participating centres; sample size: 500/group to detect minimum difference of .132 with $\alpha$=.05, power=.8, 1:1 randomisation. *Stage 4—Treatment*: will include 18-60 year-old individuals with notified dengue, presenting with muscle pain and headache until disease day 3, and available for blood sample collection at the beginning and end of the study; sample size: 120/group; $\alpha$=.05, power=.8; estimated effect=20%, 1:1 randomisation. Exclusion criteria: mental disorders, pregnancy. Exit criteria: disease complications. In *Stages 3 and 4*, the epidemic medication will be randomly administered to 50% of the exposed population; the other 50% will be given a placebo. *Stage 3*: 1 single dose of dilution 30cH. *Stage 4*: medication/placebo in dilution 30cH every 4 h for 2 days and every 8 h for 5 days. Both staff and volunteers will be blinded as to the treatment given. Variables: clinical; laboratory (CBC; NS1 antigen; IgM/IgG).

*Outcomes*: *Stage 3*: reduction of the number of dengue cases in the exposed population according to the study records and reports by governmental sanitary surveillance agencies. *Stage 4*: reduction of the intensity and duration of muscle pain and headache; use of analgesics (type and amount); number of days off work/other activities; end of fever; changes in risk grade (A to D).