

Editor: Dr Raj K. Manchanda, Secretary for Research, LMHI & Director General, Central Council for Research in Homoeopathy (India)

SCIENTIFIC FRAMEWORK OF HOMEOPATHY

Evidence Based Homeopathy

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Contributors

Facilitation, Guidance & Content appraisal

Dr. Raj K. Manchanda

Secretary for Research, LMHI &

Director General, Central Council for Research in Homoeopathy (CCRH)

Dr. Michel Van Wassenhoven

Former Secretary for Research, LMHI &

President, Belgian Homeopathic Medicines Registration Commission AFMPS

Content planning & writing

Dr. Debadatta Nayak

Research Officer (Homoeopathy)/Scientist-1, CCRH

Dr. Harleen Kaur

Senior Research Fellow (Homoeopathy), CCRH

Review

Dr. Renzo Galassi

President, LMHI

Dr. Thomas Peinbauer

President, European Committee for Homeopathy

Dr. (Prof.) Chaturbhujaya Nayak

Former Director General, CCRH &

Director, Bakson Homoeopathic Medical College & Hospital, Greater Noida, India

Dr. Lex Rutten

Officier in de orde van Oranje Nassau (2002).

Erepenning van de Vereniging van Homeopathische Artsen in Nederland in 1992

Arie Vrijland onderscheiding in 1992

Dr. Altunay Agaoglu

Treasurer, LMHI &

President, Classical Homeopathy Association &

LMHI National Vice President, Turkey

Dr. Anna Pla

Coordinator, Research Subcommittee, ECH

Contributors

Dr. Wanlop Tanakietti, Dr. Leopold Drexler, Dr. Guenter Lang, Dr. Katona Edit

Foreword

As we write to introduce you to this valuable document of Scientific Framework of Homeopathy, we primarily have two things in mind.

One, in wake of the evidence building in favour of Homeopathy at clinical, biological, molecular and even nano-molecular level, a document that provides a critical overview of each of these aspects based on the major works in the respective fields, could come in handy for many arguments and counter arguments we might have to deal with as a homeopath or researcher in homeopathy. This overview, in each chapter, is followed by a list of most peer-reviewed works in that category. The subjects range from homeopathic pathogenetic trials, clinical verification and homeopathy in epidemic diseases to clinical research, basic research, and even the disciplines like veterinary homeopathy and homeopathy in agricultural science. We are hopeful also that my colleagues will be able to find in this document their ready reference guide for basic information related to

Homeopathy framework, like situation and education of Homeopathy in world, how it is perceived as a model for healthcare delivery and the knowledge and attitude of the users of Homeopathy.

Secondly, we hope, after going through this document, more colleagues, be it at institutional level or independent, will feel inspired to contribute to the evidence basis of Homeopathy in their own way. It is not only at organisational levels that good researches happen. Research is a by-product of a series of dedicated observations and analyses, most of which is possible sitting at your treatment chambers, and adding to your clinical acumen a dash of basic methodology of research.

LMHI is dedicated to offer every possible service to the homeopathic profession. One of the ways is keeping you abreast with research in Homeopathy through this piece of work.

Thomas Peinbauer
ECH
President



Renzo Galassi
President
LMHI

Preface

The first and foremost aim of this book, a joint production of Liga Medicorum Homoeopathica Internationalis, European Committee for Homeopathy (Belgium) and Central Council for Research in Homoeopathy (India), is to secure the position of homeopathy in today's world. Various chapters inside throw light on the current situation of homeopathy and its research in various fields. The arguments that surface in relation to homeopathy from the critics have also been tackled citing logical and scientific reasoning from various learned scientists whose works have brought scientific recognition to homeopathy. Additionally, the book will serve as a ready reckoner for the legal and educational framework of homeopathy.

For homeopathy to make further inroads in the future of medicine, extensive research is the order of the day. Of late, the advances in homoeopathic research have yielded encouraging results. A repertoire of homeopathic researches that heralds the 21st century for the science is presented in this book. These researches range from basic and fundamental to epidemiological and clinical. There is a dire need to understand the priority areas of research in homeopathy to build upon concrete evidence data for firm footing of the science in the medical world and to make homeopathy more visible on the globe.

LMHI takes regular initiatives to offer through its conventions and publications a platform where the diligent researches in various parts of the world can be converged, shared and discussed. Sharing of clinical experiences is equally important, for the service

rendered by a homeopath who is proving Sir Hahnemann right through every cure established on the human/plant/animal kingdom, is no less than that offered by a scientist working ardently in his laboratory with the same aim. This book, therefore, caters to both.

The scientific framework of homeopathy is a brainchild of my dear colleague and former Secretary for Research Dr. Michel Van Wassenhoven. The credit is due to him for bringing out the earlier editions of this vital document completely on his own. In the past year though, there have been numerous developments and achievements in homeopathic research. As Secretary for Research of LMHI, I feel privileged to present to you the revised edition of this publication, which is fortified with more information and evidence basis.

As we present this book to our fellow beings within homeopathy and outside, we hope that the cloud looming over the science element of homeopathy is melting away a little more; the world is getting to know about the prowess of Homeopathy a little more; and the gap between Homeopathy and its ultimate beneficiaries – all the beings that have life – is being bridged a little more too.



Raj K. Manchanda
Secretary for Research, LMHI &
Director General, Central Council for
Research in Homoeopathy,
Ministry of AYUSH, Government of India

Executive Summary

This piece of work intends to provide you with the information related to homeopathy in its varied aspects, ranging from its educational and legal framework to recent advances in terms of scientific establishment of homeopathy. The book begins with an overview of the current place of homeopathy in healthcare, with references from recent surveys. The declarations by WHO in support of the traditional and complementary medicine (T&CM) are presented next. This includes the recent most declaration in Delhi, especially for South-east Asian region where T&CM is practised extensively.

A chapter on synoptic view of the users of homeopathy worldwide has special focus on the indicators like knowledge and attitude of the users towards homeopathy, which clearly reveals a need to improve the public access to this system. The chapter on educational framework lays out the status of the education of T&CM and throws light on the fact whether Homeopathy is taught as an independent degree or diploma course, or an additional one in T&CM curriculum. The level of education for Homeopathy, that is, graduation or above, is also mentioned wherever relevant.

Keeping in mind the growing concern over the ethical and safety issues of homeopathic medicines, this book features a separate chapter entailing the key issues that revolve around safety issues in broadly harmless homeopathic medicines. The ethical aspects explain how and why homeopathy is ethically required in today's times, as also the ethical responsibilities of homeopathy as a system.

Another highlight of the book is a chapter on basic research, with some literal mulling over the physicochemical and pharmacodynamic mysteries

behind Homeopathy. An overview of the latest in clinical research pointing out where are we headed in this area is yet another stimulating feature of the book.

The chapter on homeopathic pathogenetic trials and clinical verification provides a collection of the hallmark researches in the two fields.

The role of homeopathy in veterinary and agricultural streams is important, and its use equally beneficial to the ecological system and the science. More points regarding this are discussed inside in the related chapters. The chapter on homeopathy in epidemics is also updated.

An inventory of homeopathic researches is presented under respective chapters in the book, mostly highlighting their aims, findings and conclusions. However, the work of such huge stature cannot be converged into one tome, nor is this the intention of this publication in first place. Therefore, the readers are welcome to add to this inventory the researches that have escaped our notice, largely due to its publication in non-peer reviewed journals or in a language other than English. Comments or conclusion at the end of each chapter touch upon the thought-provoking points of the researches and suggest the way ahead.

The references used in the book are mentioned as footnotes for the ease of reading, while some definitions used in the chapters are given in the end.

A careful perusal of this book would provide the readers an overview about the status of homeopathy as well as orient them towards future action points required at varied ends in order to further elevate the level of homeopathy as a scientific system.

Chapter: I

Homeopathy in Healthcare

Homeopathy originated in disregard to the crude practices of the orthodox medicine back in the eighteenth century. Hahnemann saw leeching, bloodletting and other forms of crude practices intended to alleviate people's suffering, only adding to the misery and pain. An accomplished clinician himself, he discontinued this form of practice and resorted to his skills as chemist and translator to earn his means. However, the plight of the patients could not let 'clinician' in him rest. That was when a chapter on the therapeutic ability of Cinchona bark to cure malaria in the Cullen's *Materia Medica*, a book that Hahnemann was translating, turned a new leaf in the history of medical science. Homeopathy was eventually born as a scientific system of medicine, based solely on the concepts and methods derived from scientific experiments. In fact, historically, it turns out that Homeopathy was the most likely source for later placebo-controlled crossover and parallel group experiments. The first ever blind trial using placebo dates back to the 19th-century homeopathic therapeutic trials and provings. Single-blind placebo controls, still used today by both contemporary and CAM systems, was first put to biomedical use by Homeopathy.¹

Coming of age, Homeopathy has undergone many Randomised Controlled Trials (RCTs). A review of the 188 peer-reviewed RCT papers published in homeopathy from 1950-2013 revealed that 82 (44%) of these studies yielded positive findings; 10 (5%) were negative; 89 (47%) were non-conclusive; while 7 (4%) contained non-extractable data. The majority (153; 81%) of the 188 papers reported placebo-controlled studies, whilst the remaining 35 (19%) reported studies with a non-placebo comparator (e.g. usual medical care). Only 63 RCTs (34%) of the 188 papers studied individualised homeopathy (46 of those 63 were placebo-controlled); each of the other 125 papers (66%) studied non-individualised homeopathy (i.e. selected a single homeopathic medicine for investigation).²

¹ Dean ME. A homeopathic origin for placebo controls: 'an invaluable gift of God'. *Altern Ther Health Med*. 2000 Mar; 6(2):58-66.

² Faculty of Homeopathy; Research; Randomised controlled trials in homeopathy; URL: <http://www.facultyofhomeopathy.org/research/randomised-controlled-trials-in-homeopathy/>; Accessed on 23rd June 2014

Global status

WHO considers homeopathy as one of the most commonly used forms of Traditional & Complementary Medicine (T&CM).³ According to a WHO document, there is a need to harness the potential contribution of all sorts of T&CM to health, wellness and people-centred health care and to promote safe and effective use of T&CM by regulating, researching and integrating T&CM products, practitioners and practice into health systems, where appropriate. Many states have made great efforts to advance T&CM, and established or developed national and regional policies and regulations to promote the safe and effective use of T&CM. The global distribution of homeopathy is encouraging, especially because it appears to be spreading further.⁴ There is a realisation of the fact that people will continue to use homeopathy and benefit from it, as homeopathy is a good medicine.⁵

Recognition and use by practitioners

In many countries all over the world homeopathy has gained official status. It has been officially recognized by the government as a system of medicine or medical specialty in Central and South America (Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, Mexico), Asia (India, Pakistan, Sri Lanka) and Europe (Belgium, Bulgaria, Hungary, Lithuania, Portugal, Romania, Russia, United Kingdom). In some of these countries, namely Brazil, India, Mexico, Pakistan, Sri Lanka and the United Kingdom, homeopathy has been integrated into the national health care systems. In India, Pakistan and Sri Lanka, the legal standing of homeopathy is equivalent to that of conventional western (allopathic) medicine, many practitioners are certified in both homeopathy and allopathic medicine, and the primary care provider for many patients is a homeopathic doctor.⁶

³ WHO; Safety issues in the preparation of homeopathic medicines 2009; URL: www.who.int/medicines/areas/traditional/Homeopathy.pdf

⁴ Kayne S; Global perspectives; Charlton M., *Classical Homeopathy* 2003; pp 47-61

⁵ Specne D., *Good Medicine: Homeopathy*; *BMJ* 2012;345:e6184

⁶ Ulrich D. Fischer; Memorandum submitted by the

In Europe, the extent to which the countries have established a statutory regulation of homeopathy and how such regulation is performed varies widely. Homeopathic medicine as a distinct system of medicine is recognised by law in Belgium (1999), Bulgaria (2005), Germany (1998), Hungary (1997), Latvia (1997), Portugal (2003), Romania (1981), Slovenia (2007) and the United Kingdom (1950). The laws in Bulgaria, Hungary, Latvia, Romania and Slovenia explicitly allow the practice of homeopathic medicine to medical doctors only. In Belgium and Portugal the law does not exclude non-medical practitioners, but has not yet been implemented. In Slovenia, although the law permits medical doctors to practise homeopathic medicine, the medical association withdraws doctors' licenses if they actually practise it.⁷

In the European Union there are approximately 40,000 physicians who have taken a training course in homeopathy. Many more doctors in Europe prescribe homeopathic medicines without any homeopathic training: approximately 25–40% of the GPs from time to time, 6–8% of them on a more regular basis. In Germany doctors can obtain, after passing an examination, an additional qualification "Homoöpathischer Arzt" recognised by the Bundesärztekammer. A similar situation exists in Austria where the additional qualification "Homoöpathie" is recognized by the Österreichische Ärztekammer. In 1997 the French Medical Association (Ordre National des Médecins) recognised homeopathy as an existing therapeutic medical method and stated that homeopathic education should be installed at Universities. Further, a subspecialty under the term of "certificate of capacity in homeopathy" has been in place in Switzerland since 1998 in collaboration with the Swiss Medical Association FMH, for doctors holding a title of a current specialty such as General Medicine, Internal Medicine or Paediatrics.⁸

Despite the growing appreciation of homeopathy, the American Institute of homeopathy (AIH) has fewer than 500 members. This number is reported to be misleading

AIH membership is much rarer than the use of homeopathy among American physicians. In a national survey asking the physicians whether they had used homeopathy or would use it, 5.9% reported they did and another 29.4% reported they would use homeopathy, which amounts to a total of 33.8%. The figures by specialty were 26.3% for paediatrics, 29.4% for internal medicine, and 41.2% for family and general practice. Although growing rapidly, the use of homeopathy remains a minority, as do the CAM therapies. However, the rarity of medical homeopathy in America does not accurately reflect the presence of homeopathy in the world's medical community.⁹

In India alone, as in 2011, there were 2,24,279 registered homeopathic practitioners (185.8 practitioners per million population), trained and educated in hundreds of homeopathic medical colleges, recognized and supported by the Indian Government.¹⁰

In other parts of the world too, the practice of homeopathy is known. In Nigeria, the homeopathic practice is known to be existing for 40 years. In Malaysia, an organisation called the Registered Medical Practitioners Association established in 1985 has about 500 members. Singapore recognises homeopathy, but there is no legislative framework so far. Approximately 150 homeopaths practise in Australia, while Cuba too has well-organised homeopathic presence with a total of about 922 homeopaths. In Russia and Costa Rica too, homeopathy is available unofficially.¹¹

Besides, there are a few thousand veterinary surgeons in the world who provide homeopathic treatment to pets, food-producing and other animals. The International Association for Veterinary Homeopathy (IAVH) established minimum training standards and the requirements for teaching programmes, examinations and continuing education. In most EU Member States there are special homeopathic training programmes for veterinarians as well as for dentists and pharmacists.¹²

Liga Medicorum Homeopathical Internationalis (LMHI) (HO 31); Evidence Check 2: Homeopathy; House of Commons: Science and Technology Committee; Fourth Report of Session 2009–10; Ev 160-2; URL: http://www.homeowatch.org/policy/evidence_check.pdf

⁷European Committee for Homeopathy; Regulatory status; URL: <http://www.homeopathyeurope.org/regulatory-status>; Accessed on June 23, 2014

⁸Ulrich D. Fischer; Memorandum submitted by the Liga Medicorum Homeopathical Internationalis (LMHI) (HO 31); Evidence Check 2: Homeopathy; House of Commons: Science and Technology Committee; Fourth Report of Session 2009–10; Ev 160-2; URL:

http://www.homeowatch.org/policy/evidence_check.pdf

⁹Carlston M.; Homeopathy today; Carlston M., Classical Homeopathy 2003; pp 33-45

¹⁰Dept. of AYUSH, Homeopathy: Science of Gentle Healing; 2013; Govt. of India; URL: <http://www.ccrhindia.org/Dossier/content/cover.html>; Accessed on: June 23, 2014

¹¹Kayne S; Global perspectives; Charlton M., Classical Homeopathy 2003; pp 47-61

¹²Ulrich D. Fischer; Memorandum submitted by the Liga Medicorum Homeopathical Internationalis (LMHI) (HO 31); Evidence Check 2: Homeopathy; House of Commons: Science and Technology

Cost & Insurance cover

Homeopathic medicines are much less expensive than conventional prescription drugs, because they are generic, non-patented and non-patentable medicinal substances, produced at low costs. On average, homeopathic medicines cost less than Euro 1 per day in acute conditions and a few cents per day (sometimes a fraction of a cent) in chronic conditions.¹³ An analysis of data stretched over a decade in New Delhi, India, revealed that the cost of homeopathic treatment was still one-fourth of the expenditure incurred for allopathic treatment.¹⁴ Given the present set of studies, there is no denying that homeopathy could be an effective and relatively inexpensive addition/alternative to conventional medicine. Further, in a review of 14 studies¹⁵ assessing various aspects of economic evaluations of homeopathy, eight reported on improvement in patients' health after homeopathic treatment combined with some sort of cost savings, while four studies found that homeopathy patients proved more than or at least as much as patients in control groups, at comparable costs.¹⁶

In some areas of the United Kingdom homeopathic

treatment by doctors is covered by the National Health System. In Belgium and Latvia the fees for homeopathic treatment are partially covered by the statutory health insurance. In Austria, Belgium, Bulgaria, Germany, Hungary, Italy, Netherlands, Switzerland and the United Kingdom the cost is covered by private insurance companies. However, in Hungary, there is no possibility of reimbursement by the national health insurance. The costs for homeopathic medicines are covered by the statutory health insurance in Belgium (partially), France (partially), Portugal (only magistral formula) and Switzerland, by additional private insurance companies in Belgium, Germany, Hungary, the Netherlands and the United Kingdom.¹⁷ In Germany, all private insurances reimburse the fees for the consultations with a homeopathic MD, as well as the costs for homeopathic medicines. Homeopathic practitioners are commonly known to report that many patients with health insurance pay out of their pockets for homeopathic services because their insurance does not cover visits to a homeopath.¹⁸

Although India has a large number of public health care facilities, it is estimated that out of pocket expenditure

Committee ; Fourth Report of Session 2009–10; Ev 160-2; URL:

http://www.homeowatch.org/policy/evidence_check.pdf

¹³Ulrich D. Fischer; Memorandum submitted by the Liga Medicorum Homoeopathical Internationalis (LMHI) (HO 31); Evidence Check 2: Homeopathy; House of Commons: Science and Technology Committee ; Fourth Report of Session 2009–10; Ev 160-2; URL:

http://www.homeowatch.org/policy/evidence_check.pdf

¹⁴Manchanda R.K, Verma S.K, Chhatre L.V., Kaur H., Homeopathy in Urban Primary Healthcare Units of the Delhi Government: An Assessment; Medical Pluralism and Homeopathy in India and Germany (1810-2010): A comparison of practices'; 91-104, 2013

¹⁵ As follows:

- Bachinger, A., Rappenhöner, B., Rychlik, R.: Socioeconomic effectiveness of Zeel comp.-therapy compared to patients with hyaluronic acid in patients suffering from osteoarthritis of the knee. [Zursozioökonomischen Effizienz einer Zeel comp.-Therapie im Vergleich zu Hyaluronsäure bei Patienten mit Gonarthrose.] [German] *Z Orthop* **134**(4) (1996)
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¹⁶Viksveen P1, Dymitr Z, Simoens S.; Economic evaluations of homeopathy: A review; *Eur J Health Econ.* 2014 Mar;15(2):157-74

¹⁷<http://www.homeopathyeurope.org/regulatory-status>; Accessed on 23 June 2014

¹⁸Ulrich D. Fischer; Memorandum submitted by the Liga Medicorum Homoeopathical Internationalis (LMHI) (HO 31); Evidence Check 2: Homeopathy; House of Commons: Science and Technology Committee ; Fourth Report of Session 2009–10; Ev 160-2; URL: http://www.homeowatch.org/policy/evidence_check.pdf

on health services is of the tune of 85%, which is among the highest in the world. Even for homœopathy, with the availability of private practitioners, the patients tend to seek treatment in the private sector. Private practice, therefore, is highly popular and co-exists with the public health care facilities in almost all parts of the country.¹⁹

Hospitals

Several hospitals in Europe, in their out-patient departments, currently provide homeopathic treatment by physicians, ie Austria (7), France (2), Germany (5), Spain (2), Italy (some). There are five dedicated public sector homeopathic hospitals in the United Kingdom. In Hungary, however, there is no possibility of homeopathic care in hospitals. While in India, all homeopathic medical colleges have attached hospitals for homeopathic care. Besides, homeopathic wings exist in many multi-specialty hospitals and healthcare units, both private and government.

In India, healthcare services in homœopathy are provided by 215 hospitals and 6812 dispensaries run by state governments and municipal bodies, 35 dispensaries of Central Government Health Scheme, 39 of the labour ministry and 129 of the railway ministry. In the public sector, basic health care through homœopathic treatment is provided to the general public by homœopathic hospitals and dispensaries set up by the government. The network of 6812 homœopathic dispensaries run by the central and state governments and autonomous bodies of the Government including Municipal Councils provide primary health care services. Homœopathic treatment facilities are also provided by public sector undertakings such as Thermal Power Corporations, National Aluminum Corporation, Central Reserve Police Force, Border Security Force, etc. However, a majority of homeopathic practitioners in India operate singly through private clinics, which vary immensely in terms of available facilities and consultation costs and treatment costs. Small clinical

establishments with limited clinical facilities are there, as also, large multi specialty facilities, with inpatient, outpatient departments, laboratories, and para-clinical facilities. Homœopathic treatment is also available in large allopathic hospital establishments largely through the efforts of individual homeopathic practitioners in the private sector and through co-location of facilities in the government sector. Further, homœopathic hospitals in India operate along with educational colleges and independently providing an array of OPD and IPD services including radiological and pathological facilities. The numbers of hospitals in the country are, however, limited. These cater primarily to patients requiring long term care rather than intensive care. As such the uptake in these hospitals is limited.²⁰

Users

Over the past 30–40 years homeopathy has benefited from growing demand both from doctors and from the public in the majority of the European countries. According to a survey by European Commission order three Europeans out of four know about homeopathy and of these about 30% use it for their healthcare. In USA, a study reports of 6.7 million American adults using Homeopathy, which was 3.4% of the adult population.²¹ Another study reported that most homeopathic patients fell in the middle age of 25-44 years, had above-average incomes and were highly educated.²² In India, a secondary data analysis reflected the popularity of homeopathy was increasing among the users, with 58% rise in the patient inflow at the homeopathic primary healthcare units over a decade.²³

Patient outcome

Several studies exist to support the positive effects of Homeopathy in clinics. A review²⁴ of five clinical outcome studies in homeopathy focusing on diverse medical conditions like headache,²⁵ acute otitis media,²⁶ ADHD in children,²⁷ respiratory tract and ear complaints, including

¹⁹Carlston M.; Homeopathy today; Carlston M., Classical Homeopathy 2003; pp 33-45

²⁰Carlston M.; Homeopathy today; Carlston M., Classical Homeopathy 2003; pp 33-45

²¹Eisenberg D, Kessler RC, Foster C et al: Unconventional medicine in the United States, *N Engl J Med* 328:246-252, 1993

²²Goldstein M, Glik D: Use of and satisfaction with homeopathy in a patient population, *Altern Ther Health Med* 4: 60-65, 1998

²³Manchanda R.K, Verma S.K, Chhatre L.V., Kaur H., Homeopathy in Urban Primary Healthcare Units of the Delhi Government: An Assessment; Dinges M.; Medical Pluralism and Homeopathy in India and Germany (1810-2010): A comparison of practices; 91-104, 2013

²⁴Robert T Mathie; Clinical outcomes research: contributions to the evidence base for homeopathy; Homeopathy (2003) 92, 56–57

²⁵Muscari-Tomaoli G, Allegri F, Miali E, et al. Observational study of quality of life in patients with headache, receiving homeopathic treatment. *Br Hom J* 2001; 90: 189–197

²⁶Frei H, Thurneysen A. Homeopathy in acute otitis media in children: treatment effect or spontaneous resolution? *Br Hom J* 2001; 90: 180–182

²⁷Frei H, Thurneysen A. Treatment for hyperactive children: homeopathy and methylphenidate compared in a family setting. *Br Hom J* 2001; 90: 183–188.

allergies²⁸ and male infertility.²⁹ Each of the five studies concluded in favour of the clinical effectiveness of homeopathy.

WHO for CAM (including Homeopathy)

The level of acceptance for the homeopathic science in various parts of the world is varied, as is the knowledge and attitude towards the science. While in some parts, the science exists in an advanced stage and is taught, practised and researched for better validation, in some others it bears complete unfamiliarity. However, with WHO recognising the strengths of Traditional &

Complementary Medicine (T&CM) as a support system to the conventional therapy³⁰, this branch of medicine is being attended to more than ever. As a result, more and more parts of the globe are establishing acts for T&CM, making provisions for its education and integrating T&CM with the orthodox medicine for primary health care (PHC) delivery. Homeopathy, if integrated in the PHC system, can not only be an answer to most day to day illnesses reported in the OPD, but also an economically viable option. WHO's declarations regarding T&CM are given below which reveal WHO recognises the fact that T&CM needs to be formalised globally for better healthcare services

Beijing Declaration

Adopted by the WHO Congress on Traditional Medicine, Beijing, China, 8 November 2008

Participants at the World Health Organization Congress on Traditional Medicine, meeting in Beijing this eighth day of November in the year two thousand and eight:

- Recalling the International Conference on Primary Health Care at Alma Ata thirty years ago and noting that people have the right and duty to participate individually and collectively in the planning and implementation of their health care, which may include access to traditional medicine;
- Recalling World Health Assembly resolutions promoting traditional medicine, including WHA56.31 on Traditional Medicine of May 2003;
- Noting that the term "traditional medicine" covers a wide variety of therapies and practices which may vary greatly from country to country and from region to region, and that traditional medicine may also be referred to as alternative or complementary medicine;
- Recognizing traditional medicine as one of the resources of primary health care services to increase availability and affordability and to contribute to improve health outcomes including those mentioned in the Millennium Development Goals;
- Recognizing that Member States have different domestic legislation, approaches, regulatory responsibilities and

delivery models;

- Noting that progress in the field of traditional medicine has been obtained in a number of Member States through implementation of the WHO Traditional Medicine Strategy 2002-2005;

- Expressing the need for action and cooperation by the international community, governments, and health professionals and workers, to ensure proper use of traditional medicine as an important component contributing to the health of all people, in accordance with national capacity, priorities and relevant legislation;

In accordance with national capacities, priorities, relevant legislation and circumstances hereby make the following Declaration:

At the sixty-second World Health Assembly

22 May 2009 (WHA62.13 - Agenda item 12.4):

Having considered the report on primary health care, including health system strengthening (Document A62/8); Recalling resolutions WHA22.54, WHA29.72, WHA30.49, WHA31.33, WHA40.33, WHA41.19, WHA42.43, WHA54.11, WHA56.31 and WHA61.21; Recalling the Declaration on Alma-Ata which states, inter alia, that "The people

²⁸Riley D, Fischer M, Singh B, et al. Homeopathy and conventional medicine: an outcomes study comparing effectiveness in a primary care setting. *J Altern Complement Med* 2001; 7: 149–159.

²⁹Gerhard I, Wallis E. Individualized homeopathic therapy for male infertility. *Homeopathy* 2002; 91: 133–144.

³⁰WHO; WHO Traditional Medicine Strategy 2014-2023; (2013); URL: http://apps.who.int/iris/bitstream/10665/92455/1/9789241506090_eng.pdf?ua=1

have the right and duty to participate individually and collectively in the planning and implementation of their health care” and “Primary health care relies, at local and referral levels, on health workers, including physicians, nurses, midwives, auxiliaries and community workers as applicable, as well as traditional practitioners as needed, suitably trained socially and technically to work as a health team and to respond to the expressed health needs of the community”;

Noting that the term “traditional medicine” covers a wide variety of therapies and practices which may vary from country to country and from region to region; Recognizing “traditional medicine” as one of the resources of primary health care services that could contribute to improved health outcomes, including those in the Millennium Development Goals;

Recognizing that Member States have different domestic legislation, approaches, regulatory responsibilities and delivery models related to primary health care;

Noting the progress that many governments have made to include “traditional medicine” into their national health care;

Noting that progress in the field of “traditional medicine” has been achieved by a number of Member States through implementation of the WHO traditional medicine strategy 2002-2005 (Document WHO/EDM/TRM/2002);

Expressing the need for action and cooperation by the international community, governments and health professionals and workers, to ensure proper use of “traditional medicine” as an important component contributing to the health of all people, in accordance with national capacity, priorities and relevant legislation;

Noting that the WHO Congress on “Traditional Medicine” took place from 7 to 9 November 2008, in Beijing, China, and adopted the Beijing Declaration on “Traditional Medicine”;

Noting that African Traditional Medicine Day is commemorated annually on 31 August in order to raise awareness and the profile of “traditional medicine” in the African region, as well as to promote its integration into national health systems,

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| 1. | URGES Member States, in accordance with national capacities, priorities, relevant legislation and circumstance: |
| I. | to consider adopting and implementing the Beijing Declaration on Traditional Medicine in accordance with national capacities, priorities, relevant |

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| | legislation and ci rcu msta nces; |
| II. | to respect, preserve and widely communicate, as appropriate, the knowledge of traditional medicine, treatments and practices, appropriately based on the circumstances in each country, and on evidence of safety, efficacy and quality; |
| III. | to formulate national policies, regulations and standards, as part of comprehensive national health systems, to promote appropriate, safe and effective use of traditional medicine; |
| IV. | to consider, where appropriate, including traditional medicine into their national health systems based on national capacities, priorities, relevant legislation and circumstances, and on evidence of safety, efficacy and qual ity; |
| V. | to further develop traditional medicine based on research and innovation, giving due consideration to the specific actions related to traditional medicine in the implementation of the Global strategy and plan of action on public health, innovation and intellectual property; |
| VI. | to consider, where appropriate, establishing systems for the qualification, accreditation or licensing of traditional medicine practitioners and to assist traditional medicine practitioners to upgrade their knowledge and skill in collaboration with relevant health providers, on the basis of traditions and customs of indigenous peoples and communities; |
| VII. | to consider strengthening communication between conventional and traditional medicine providers and, where appropriate, establishing appropriate training programmes with content related to traditional medicine for health professionals, medical students and relevant researchers; |
| VIII. | to cooperate with other in sharing knowledge and practices of traditional medicine and exchanging training programmes on traditional medicine, consistent with national legislation and relevant international obl igations; |

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| 2 | REQUESTS the Director-General: |
| I. | to provide support to Member States, as appropriate and upon request, in implementing the |

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| | Beijing Declaration on Traditional Medicine; |
| II. | to update the WHO traditional medicine strategy 2002-2005, based on countries' progress and current challenges in the field of traditional medicine; |
| III. | to give due consideration to the specific actions related to traditional medicine in the implementation of the Global strategy and plan of action on public health, innovation and intellectual property and the WHO global strategy for prevention and control of non communicable diseases; |
| IV. | to continue providing policy guidance to countries on how to integrate traditional medicine into health systems, especially to promote, where appropriate, the use of traditional/indigenous medicine for primary health care, including disease prevention and health promotion, in line with evidence of safety, efficacy and quality taking into account the traditions and customs of |

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| | indigenous peoples and communities; |
| V. | to continue providing technical guidance to support countries in ensuring the safety, efficacy and quality of traditional medicine; considering the participation of peoples and communities and taking into account their traditions and customs; |
| VI. | to strengthen cooperation with WHO collaborating centres, research institutions and non governmental organizations in order to share evidence-based information taking into account the traditions and customs of indigenous peoples and communities; and to support training programmes for national capacity building in the field of traditional medicine. Eighth plenary meeting, 22 May 2009 A62/VR/8 |

DELHI DECLARATION

12-14 February 2013, New Delhi

A. We, the Health Ministers of South-East Asian countries, representing the Governments of Bangladesh, Bhutan, India, Nepal, Minister of Indigenous Medicine Sri Lanka, and Vice Minister of Health, Timor-Leste, and the representatives of DPR Korea, Indonesia, Myanmar, Maldives and Thailand, met in New Delhi during the "International Conference on Traditional Medicine for South-East Asian Countries", and we –

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| 1. | recalled the importance given at the International Conference on Primary Health Care at Alma Ata in 1978 for inclusion of access to Traditional Medicine in the planning and implementation of health care; |
| 2. | noted the progress of Traditional Medicine in the countries of South East Asia Region, specifically after the World Health Organization (WHO) brought out the strategy for Traditional Medicine 2002-2005; |
| 3. | considered the importance of various resolutions of the World Health Assembly (WHA) and of the South East Asia Regional Committee for promoting Traditional Medicine and Medicinal |

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| | Plants, specifically WHA 56.31, WHA62.13 and SEA/RC56/R6; |
| 4. | appreciated the diversity and richness of Traditional Medical Systems, their courses of study, status of research & development, regulatory frameworks and medicinal flora in the South-East Asian countries; |
| 5. | recognized that Traditional Medicine and Traditional Medicine Practitioners have substantial potential to contribute for improving health outcomes in various countries of the world; |
| 6. | acknowledged the fact that traditional medicine is culturally acceptable, generally available, affordable and widely used in various countries for the treatment of diseases; |
| 7. | noted the fact that for millions of people often living in rural areas in different countries, traditional medicine is a significant source of health care; |
| 8. | recognized the potential of traditional medicine in providing primary health care, and |
| 9. | expressed the need for sharing of experience and knowledge for securing reliance on Traditional Medicine for public health benefits. |

B. DECLARATION

In the light of the above, we hereby agree for cooperation, collaboration and mutual support amongst the South-East Asian Countries in all spheres of Traditional Medicine in accordance with national priorities, legislations and circumstances, and specifically agree to make collaborative efforts aiming at the following:

- I. to promote National policies, strategies and interventions for equitable development and appropriate use of traditional medicine in the health care delivery system;
- II. to develop institutionalized mechanism for exchange of information, expertise and knowledge with active cooperation with WHO on traditional medicine through workshops, symposia, visit of experts, exchange of literature etc.;
- III. to pursue harmonized approach for the education, practice, research, documentation and regulation of traditional medicine and involvement of traditional medicine practitioners in health services;
- IV. to explore the possibility of promoting mutual recognition of educational qualifications awarded by recognized Universities, pharmacopoeias, monographs and relevant databases of traditional medicine;
- V. to encourage development of common reference documents of traditional medicine for South East Asian countries;
- VI. to develop regional cooperation for training and capacity building of traditional medicine experts;

VII. to encourage sustainable development and resource augmentation of medicinal plants in the South East Asian regional countries;

VIII. to establish regional centers as required for capacity building and networking in the areas of traditional medicine and medicinal plants and

IX. to exchange views, experiences and experts for integration of traditional medicine into national health systems in accordance with national policies and regulations.

Conclusion

Given that Homeopathy has the potential to improve individual health at lesser cost and by safer means, its proper integration into national health systems will enable consumers to have a wider choice. Though integration of Homeopathy and conventional medicine may be of the greatest relevance to population living with chronic disease or in health promotion, in certain circumstances it may contribute to the treatment of acute disease. There exists a problem of harmonization between the conventional and non-conventional therapies, including Homeopathy. However, appropriate integration is possible, as also addressed by Dr Margaret Chan, Director-General of WHO, who stated in a T&CM convention in February 2013 that: "The two systems of traditional and Western medicine need not clash. Within the context of primary health care, they can blend together in a beneficial harmony, using the best features of each system, and compensating for certain weaknesses in each. This is not something that will happen all by itself. Deliberate policy decisions have to be made. But it can be done successfully".³¹

³¹ WHO; <http://www.who.int/medicines/areas/traditional/congress/congressopening/en/>; Accessed on

CHAPTER: II

Users of Homeopathy

The users of Homeopathy are a significant part of evolution of Homeopathy worldwide. As Homeopathy spread in different parts of world, its users grew. However, there is a need to contemplate on the reasons that make a patient choose Homeopathy over conventional medicine.

During the time of Hahnemann, the reason that can be traced was the crude treatment methods prevalent then and more personal time in case-taking, which indirectly meant being taken seriously. Within the period 1843-1960, the recognition of the fact that Homeopathy was a 'harmless' therapy encouraged self-medication, which became a major reason for the increase in its users. The trend of prescribing within the family and relatives caught up. The homeopathic pharmacies played a major role in training the laymen about Homeopathy through manuals, guides and pamphlets. However, as health awareness grew in the second part of nineteenth century, the need for trained homeopathic practitioners increased. Such was the demand from the homeopathic users that sometimes a doctor in a locality was moved to familiarise himself with homeopathy, and, in the process, overcame his initial prejudices. Organised patient groups and societies in Germany in the early twentieth century lobbied repeatedly for chairs of Homeopathy in universities and ensured the cost of homeopathic medicines remained low. In places like London, Munich and some parts of USA, homeopathic hospitals existed, which, owing to their well-developed infrastructure, only well-to-do patients visited. The attempts of single committed doctors or those of the patients' groups to develop smaller homeopathic hospitals proved to be

short-lived, with most of these centers turning into orthodox hospitals towards the end of twentieth century. This was basically due to the changing attitudes of the doctors who preferred a more attractive scientific medicine. However, the public demand for Homeopathy continued to increase and as a result, the homeopathic market grew even after 120 years of Hahnemann's death³².

With the advances in the late twentieth century, the orthodox medicine saw a greater optimism by the patients, where the tangible progress made by the system seemed to be capable of conquering all epidemics. On the flipside though, it was gradually observed that the medical practices were incurring much cost, spending less time per patient and shedding the 'holistic' element of treatment. This, in turn, was seen as a compromise in the patient autonomy, a subject that has gained more importance ever since.³³ Even today, one reason why patients opt for homeopathic treatment is because they feel they enjoy more respect as individuals in this therapy.^{34,35}

To understand the new age users of homeopathy, it is important to visualise the scenario globally. While some factors that drive a patient to a homeopath remain fairly consistent worldwide, others vary as per the geographic or ethnic considerations. Anywhere in the world, however, in selecting a treatment, it is likely that a patient wants to know what chance s/he has of getting better after consulting a practitioner.³⁶ There is a chance that a patient, before selecting a therapy which s/he has not tested before, would either follow a recommendation by a friend or a relative^{37,38,39}, or, as is

³²Dinges M., Patients in the History of homeopathy, European association for the History of Medicine and Health Publications' 2002; pp. 2-16

³³ Dinges M., Patients in the History of homeopathy, European association for the History of Medicine and Health Publications' 2002; pp. 2-16

³⁴Stewart W. M., David R., Graham C.M.W., The importance of empathy in the enablement of patients attending the Glasgow Homoeopathic Hospital; British Journal of General Practice; November 2002, 52, 901-05

³⁵ Lert et al; Characteristics of patients consulting their regular primary care physician according to their prescribing preferences for homeopathy and complementary medicine; Homeopathy (2014) 103, 51-57

³⁵Sharples FMC., Haselen R.V., Fisher P., NHS patients' perspective on complementary medicine: a survey; Complementary therapies in Medicine (2003; 11, 243-48

³⁶Steinsbekk A., and Ludtke R., Patients' assessments of the effectiveness of homeopathic care in Norway: A prospective observational multicentre outcome study; Homeopathy (2005) 94, 10-16

³⁷ Steinsbekk A., and Ludtke R., Patients' assessments of the effectiveness of homeopathic care in Norway: A prospective observational multicentre outcome study; Homeopathy (2005) 94, 10-16

³⁸ Framework of the practice: Belgium as an example; Scientific framework of homeopathy: Evidence Based Homeopathy 2013; Revised edition after 67th LMHI Congress, September 2012 (Nara, Japan); pp 22-26

³⁹ Wassenhoven M.V., Pediatric homeopathy: A prospective observational survey based on parent proxy reports of their children's health-related Quality of Life in six European countries and Brazil; Homeopathy (2014)..., 1-7 (in print)

true for more sophisticated individuals, would gather more information about the therapy.⁴⁰ While the former is reported as a trend in countries like Norway⁴¹ and India⁴², the latter is catching on in various parts of the world. It is seen that the education level of patients who see a homeopath is usually high, with evidence reported from U.K.^{43,44,45}, France⁴⁶, Germany⁴⁷, Austria,⁴⁸ Brazil^{49,50}, USA⁵¹ and Switzerland.⁵² The spread of Homeopathy in Europe is reflected in Fig. 1 and Table 1. On assessment of the age profile of the users of Homeopathy, the consistent trend reported across all nations including U.K.^{53,54}, Norway⁵⁵, Germany⁵⁶, Switzerland⁵⁷, India⁵⁸, U.S.A.⁵⁹, Belgium⁶⁰ and France⁶¹, is that most users belong to the middle age group ranging 35-55 years. Also, it has recently been reported that the patients who see a homeopath have a healthier lifestyle and a positive attitude towards CAM.⁶² This, coupled with a decent education level, reflects that an average homeopathic user of today is capable of making an informed choice, and his or her choice of using Homeopathy can be no different.

⁴⁰Jennifer F.H., Dip S.A. and Nancy L.; Doctor-Patient Communication: A Review; *The Ochsner Journal*; 10:38–43, 2010

⁴¹Steinsbekk A., and Ludtke R., Patients' assessments of the effectiveness of homeopathic care in Norway: A prospective observational multicentre outcome study; *Homeopathy* (2005) 94, 10-16

⁴²Manchanda R. K. and Kaur H.; Medical pluralism: past, present, future; *Medical Pluralism in Health Care – Experience from New Delhi* (2013); by Robert Jütte; pp 189-94

⁴³Stewart W. M., David R., Graham C.M.W., The importance of empathy in the enablement of patients attending the Glasgow Homeopathic Hospital; *British Journal of General Practice*; November 2002, 52, 901-05

⁴⁴Spence D. and Thompson E.A.; Homeopathic treatment for chronic disease: A 6-year, university-hospital outpatient observational study; *The Journal of Alternative and Complementary Medicine*; 11(5); 2005; pp 793-98

⁴⁵Robinson T., Responses to homeopathic treatment in National Service general practice; *Homeopathy* (2006) 95; 9-14

⁴⁶Lert et al; Characteristics of patients consulting their regular primary care physician according to their prescribing preferences for homeopathy and complementary medicine; *Homeopathy* (2014) 103, 51-57

⁴⁷Arndt B., Thomas O., Christa R., and Peter F.M., Adaptive coping strategies and attitudes toward health and healing in German Homeopathy and Acupuncture users; *Explore July/August 2010* 6(4), pp 237-245

⁴⁸Dinges M., The next decade for Homeopathy: Any lessons from the last decade?; *Proceedings of 66th Liga Medicorum Homeopathica Internationalis Congress 2011*

⁴⁹Wassenhoven M.V., Pediatric homeopathy: A prospective observational survey based on parent proxy reports of their children's health-related Quality of Life in six European countries and Brazil; *Homeopathy* (2014)...., 1-7 (in print)

⁵⁰Dinges M., The next decade for Homeopathy: Any lessons from the last decade?; *Proceedings of 66th Liga Medicorum Homeopathica Internationalis Congress 2011*

⁵¹Dinges M., The next decade for Homeopathy: Any lessons from the last decade?; *Proceedings of 66th Liga Medicorum Homeopathica Internationalis*

Congress 2011

⁵²Pedro M. et al; Prevalence and characteristics of homeopathy users in a representative sample of the Lausanne population: CoLaus study; *Pharmacoepidemiology and Drug Safety* 2008; 17: 209-13

⁵³Stewart W. M., David R., Graham C.M.W., The importance of empathy in the enablement of patients attending the Glasgow Homeopathic Hospital; *British Journal of General Practice*; November 2002, 52, 901-05

⁵⁴Spence D. and Thompson E.A.; Homeopathic treatment for chronic disease: A 6-year, university-hospital outpatient observational study; *The Journal of Alternative and Complementary Medicine*; 11(5); 2005; pp 793-98

⁵⁵Steinsbekk A., and Ludtke R., Patients' assessments of the effectiveness of homeopathic care in Norway: A prospective observational multicentre outcome study; *Homeopathy* (2005) 94, 10-16

⁵⁶Arndt B., Thomas O., Christa R., and Peter F.M., Adaptive coping strategies and attitudes toward health and healing in German Homeopathy and Acupuncture users; *Explore July/August 2010* 6(4), pp 237-245

⁵⁷Pedro M. et al; Prevalence and characteristics of homeopathy users in a representative sample of the Lausanne population: CoLaus study; *Pharmacoepidemiology and Drug Safety* 2008; 17: 209-13

⁵⁸Manchanda R.K, Verma S.K, Chhatre L.V., Kaur H., Homeopathy in Urban Primary Healthcare Units of the Delhi Government: An Assessment; *Dinges M.; Medical Pluralism and Homeopathy in India and Germany (1810-2010): A comparison of practices*; 91-104, 2013

⁵⁹Jennifer J., Patient characteristics and practice patterns of physicians using homeopathy; *Arch Fam Med/ Vol. 7. Nov/Dec 1998*; 537-40

⁶⁰Framework of the practice: Belgium as an example; *Scientific framework of homeopathy: Evidence Based Homeopathy 2013*; Revised edition after 67th LMHI Congress, September 2012 (Nara, Japan); pp 22-26

⁶¹Colin P., An epidemiological study of a homeopathic practice; *British Homeopathic Journal* (2000) 89; pp 116-21

⁶²Lert et al; Characteristics of patients consulting their regular primary care physician according to their prescribing preferences for homeopathy and complementary medicine; *Homeopathy* (2014) 103, 51-57

Fig. 1 Regulation systems in Europe**Table 1 Regulation in European countries (CAM-CANCER report)**

| | « fully controlled systems » n=19 | « partial controlled systems » n=10 | |
|-------------------------------|--|---|---|
| Countries | Austria, Belgium, Cyprus, Czech Republic, Estonia, France, Germany, Greece, Hungary, Latvia, Lithuania, Luxembourg, Italy, Poland, Portugal Spain, Slovenia, Slovakia, Switzerland | Denmark, Finland, Iceland, Liechtenstein, Ireland, Malta, The Netherlands, Norway, Sweden, UK | |
| who is allowed to treat? | Statutorily regulated individuals. | Statutorily regulated individuals. | Everybody |
| Authorized MedicalActivities: | “risky” medical procedures treating serious diseases safe medical procedures preventive/prophylaxis | “risky” medical procedures treating serious diseases safe medical procedures preventive/prophylaxis | safe medical procedures preventive/prophylaxis |

Female preponderance in the demographic profile is another consistent finding in most

studies.^{63,64,65,66,67,68,69,70,71,72,73,74,75} It has also been seen that these females usually have higher education.⁷⁶ One study⁷⁷ relates this to the fact that young and middle age women first seek homeopathic care in their reproductive ages, and then, being the health watchers of their families, take it further to their children, also leading to higher children inflow at homeopathic clinics. This perhaps explains why another prominent age group of homeopathic users is below 15.⁶³⁻⁷⁵ A recent study verifies the fact that children usually are accompanied with female parent.⁷⁸ This speaks of Homeopathy commonly perceived as a gentle and effective therapy by mothers for their children. Yet, the study by Wassenhoven reveals statistically that the parents usually are not comfortable informing their paediatrician about seeking homeopathic treatment for their children. Around half of parents whose children were undergoing a parallel treatment did not tell their paediatrician about it. Only for 38.3% of patients, both the paediatrician and the homeopath were fully aware of the treatment the patient was taking and for some of these, the paediatrician was

⁶³Dinges M., The next decade for Homeopathy: Any lessons from the last decade?; Proceedings of

⁶⁶thLiga Medicorum Homoeopathica Internationalis Congress 2011

⁶⁴Stewart W. M., David R., Graham C.M.W., The importance of empathy in the enablement of patients attending the Glasgow Homeopathic Hospital; British Journal of General Practice; November 2002, 52, 901-05

⁶⁵Steinsbekk A., and Ludtke R., Patients' assessments of the effectiveness of homeopathic care in Norway: A prospective observational multicentre outcome study; Homeopathy (2005) 94, 10-16

⁶⁶Wassenhoven M.V., Pediatric homeopathy: A prospective observational survey based on parent proxy reports of their children's health-related Quality of Life in six European countries and Brazil; Homeopathy (2014)..., 1-7 (in print)

⁶⁷Manchanda R.K, Verma S.K, Chhatre L.V., Kaur H., Homeopathy in Urban Primary Healthcare Units of the Delhi Government: An Assessment; Dinges M.; Medical Pluralism and Homeopathy in India and Germany (1810-2010): A comparison of practices'; 91-104, 2013

⁶⁸Spence D. and Thompson E.A.; Homeopathic treatment for chronic disease: A 6-year, university-hospital outpatient observational study; The Journal of Alternative and Complementary Medicine; 11(5); 2005; pp 793-98

⁶⁸Steinsbekk A., and Ludtke R., Patients' assessments of the effectiveness of homeopathic care in Norway: A prospective observational multicentre outcome study; Homeopathy (2005) 94, 10-16

⁶⁹Robinson T., Responses to homeopathic treatment in National Service general practice; Homeopathy (2006) 95; 9-14

⁷⁰Arndt B., Thomas O., Christa R., and Peter F.M., Adaptive coping

strategies and attitudes toward health and healing in German Homeopathy and Acupuncture users; Explore July/August 2010 6(4), pp 237-245

⁷¹Pedro M. et al; Prevalence and characteristics of homeopathy users in a representative sample of the Lausanne population: CoLaus study; Pharmacoepidemiology and Drug Safety 2008; 17: 209-13

⁷²Manchanda R.K, Verma S.K, Chhatre L.V., Kaur H., Homeopathy in Urban Primary Healthcare Units of the Delhi Government: An Assessment; Dinges M.; Medical Pluralism and Homeopathy in India and Germany (1810-2010): A comparison of practices'; 91-104, 2013

⁷³Jennifer F.H., Dip S.A. and Nancy L.; Doctor-Patient Communication: A Review; The Ochsner Journal; 10:38-43, 2010

⁷⁴Colin P., An epidemiological study of a homeopathic practice; British Homeopathic Journal (2000) 89; pp 116-21

⁷⁵Lert et al; Characteristics of patients consulting their regular primary care physician according to their prescribing preferences for homeopathy and complementary medicine; Homeopathy (2014) 103, 51-57

⁷⁶Lert et al; Characteristics of patients consulting their regular primary care physician according to their prescribing preferences for homeopathy and complementary medicine; Homeopathy (2014) 103, 51-57

⁷⁷Robinson T., Responses to homeopathic treatment in National Service general practice; Homeopathy (2006) 95; 9-14

⁷⁸Wassenhoven M.V., Pediatric homeopathy: A prospective observational survey based on parent proxy reports of their children's health-related Quality of Life in six European countries and Brazil; Homeopathy (2014)..., 1-7 (in print)

also the homeopath.⁷⁹

Further, it has been observed that patients who use Homeopathy, especially in U.S.A.⁸⁰ and France⁸¹, belong to rather affluent class and are usually into more refined professions like that of teachers or is the only driving force for the patients, especially those who can afford private insurances^{84,85} and pricier treatment options.

The morbidity profile of the users varies greatly, depending both on the location and the type of set up. While a collective study from four countries of Europe⁸⁶ and separate ones from U.K.⁸⁷, Norway,⁸⁸ Belgium,⁸⁹ France,⁹⁰ USA,⁹¹ Germany⁹² and India⁹³ advocate the positive effects of Homeopathy on many chronic ailments, studies from France, Belgium and Norway also reveal that Homeopathy can be used to treat acute illnesses just as effectively. The users of Homeopathy mark their improvement as above average^{63-75,94} mostly, or more than 50% so to say, within six months.⁹⁵ Among the most reported

industrialists, respectively. Also, the working individuals are more likely to opt for this therapy than the non-working ones.^{82,83} Even though economic viability is an added asset of Homeopathy, it cannot be stated that lesser cost

problems lie infectious diseases (both acute and chronic and especially viral), psychological illnesses⁹⁶ like sleep, anxiety and depressive disorders (SADD), rheumatological illnesses, cardiovascular illnesses, dermatological problems, gynaecological problems, endocrinological problems and respiratory allergic illnesses⁶¹⁻⁷³. At least two studies^{97,98} reflect that a short time of 5-10 minutes duration, especially at primary healthcare centers or hospitals (where the set up and available time are different from the private clinics), was not a deterrent to providing adequate homeopathic consultation in most cases. A study revealed that the allocated time to a homeopathic physician was very similar to those for other chronic disease specialists like

⁷⁹ Wassenhoven M.V., Pediatric homeopathy: A prospective observational survey based on parent proxy reports of their children's health-related Quality of Life in six European countries and Brazil; Homeopathy (2014)..., 1-7 (in print)

⁸⁰ Jennifer F.H., Dip S.A. and Nancy L.; Doctor-Patient Communication: A Review; The Ochsner Journal; 10:38-43, 2010

⁸¹ Colin P., An epidemiological study of a homeopathic practice; British Homeopathic Journal (2000) 89; pp 116-21

⁸² Arndt B., Thomas O., Christa R., and Peter F.M., Adaptive coping strategies and attitudes toward health and healing in German Homeopathy and Acupuncture users; Explore July/August 2010 6(4), pp 237-245

⁸³ Pedro M. et al; Prevalence and characteristics of homeopathy users in a representative sample of the Lausanne population: CoLaus study; Pharmacoepidemiology and Drug Safety 2008; 17: 209-13

⁸⁴ Jennifer F.H., Dip S.A. and Nancy L.; Doctor-Patient Communication: A Review; The Ochsner Journal; 10:38-43, 2010

⁸⁵ Lert et al; Characteristics of patients consulting their regular primary care physician according to their prescribing preferences for homeopathy and complementary medicine; Homeopathy (2014) 103, 51-57

⁸⁶ Riley D., Fischer M., Singh B., Haidvogel M. and Heger M., Homeopathy and conventional medicine: An outcomes study comparing effectiveness in a primary care setting; The Journal of Alternative & Complementary Medicine; 7(2) 2001; pp149-159

⁸⁷ Sharples F.M.C., Haselen R.V., Fisher P., NHS patients' perspective on complementary medicine: a survey; Complementary therapies in Medicine (2003); 11, 243-48

⁸⁸ Steinsbekk A., and Ludtke R., Patients' assessments of the effectiveness of homeopathic care in Norway: A prospective observational multicentre outcome study; Homeopathy (2005) 94, 10-16

⁸⁹ Framework of the practice: Belgium as an example; Scientific framework of homeopathy: Evidence Based Homeopathy 2013; Revised edition after

⁹⁰ Colin P., An epidemiological study of a homeopathic practice; British

Homeopathic Journal (2000) 89; pp 116-21

⁹¹ Jennifer F.H., Dip S.A. and Nancy L.; Doctor-Patient Communication: A Review; The Ochsner Journal; 10:38-43, 2010

⁹² Arndt B., Thomas O., Christa R., and Peter F.M., Adaptive coping strategies and attitudes toward health and healing in German Homeopathy and Acupuncture users; Explore July/August 2010 6(4), pp 237-245

⁹³ Manchanda R.K., Verma S.K., Chhatre L.V., Kaur H., Homeopathy in Urban Primary Healthcare Units of the Delhi Government: An Assessment; Dinges M.; Medical Pluralism and Homeopathy in India and Germany (1810-2010): A comparison of practices'; 91-104, 2013

⁹⁴ Framework of the practice: Belgium as an example; Scientific framework of homeopathy: Evidence Based Homeopathy 2013; Revised edition after 67th LMHI Congress, September 2012 (Nara, Japan); pp 22-26

⁹⁵ Steinsbekk A., and Ludtke R., Patients' assessments of the effectiveness of homeopathic care in Norway: A prospective observational multicentre outcome study; Homeopathy (2005) 94, 10-16

⁹⁶ Grimaldi-Bensouda L, Engel P, Massol J, et al. Who seeks primary care for sleep, anxiety and depressive disorders from physicians prescribing homeopathic and other complementary medicine? Results from the EPI3 population survey. BMJ Open 2012; 2:e001498. doi:10.1136/bmjopen-2012-001498

⁹⁷ Manchanda R.K., Verma S.K., Chhatre L.V., Kaur H., Homeopathy in Urban Primary Healthcare Units of the Delhi Government: An Assessment; Dinges M.; Medical Pluralism and Homeopathy in India and Germany (1810-2010): A comparison of practices'; 91-104, 2013

⁹⁸ Spence D. and Thompson E.A.; Homeopathic treatment for chronic disease: A 6-year, university-hospital outpatient observational study; The Journal of Alternative and Complementary Medicine; 11(5); 2005; pp 793-98

⁹⁸ Steinsbekk A., and Ludtke R., Patients' assessments of the effectiveness of homeopathic care in Norway: A prospective observational multicentre outcome study; Homeopathy (2005) 94, 10-16

rheumatologists, neurologists and was substantially shorter than what was allocated to psychiatrists. Yet another study from India revealed a rather ironical situation where a singly employed homeopathic doctor in a PHC is able to spend on an average only 5.2 minutes per patient due to the patient overload, as opposed to 12.9 minutes available to the conventional doctors, who are more in number in the same center. Nevertheless, the popularity of such clinics is increasing. These examples reflect the viability of Homeopathy as a workable model at the primary healthcare level. Further, such real-world examples counter argue the 'more consultation time' reasoning offered by the sceptics as one of the 'placebo' factors that make Homeopathy work.

Overall, the factors that primarily attract the patients to Homeopathy have been assessed as 'worried about side effects of other treatment methods'^{99,100,101,102,103}, 'no results from conventional medicine or evading its long term treatment'^{104,105}, 'better consultation experiences'¹⁰⁶, 'personal preference or family trend'^{107,108,109,110}, 'lesser cost'^{111,112}, 'overall well being'^{113,114,115,116,117}, 'traditional belief in the immaterial or holistic concept'^{118,119}, 'awareness about the lack of role of antibiotics in viral diseases'¹²⁰ and 'distrust in conventional medicine'.^{121,122}

It can be concluded that Homeopathy is being preferred by its users for reasons that are partly due to increasing realisation by its users of its own virtues

⁹⁹ Wassenhoven M.V., Pediatric homeopathy: A prospective observational survey based on parent proxy reports of their children's health-related Quality of Life in six European countries and Brazil; *Homeopathy* (2014)..., 1-7 (in print)

¹⁰⁰ Dinges M., The next decade for Homeopathy: Any lessons from the last decade?; Proceedings of 66th Liga Medicorum Homeopathical Internationalis Congress 2011

¹⁰¹ Arndt B., Thomas O., Christa R., and Peter F.M., Adaptive coping strategies and attitudes toward health and healing in German Homeopathy and Acupuncture users; *Explore* July/August 2010 6(4), pp 237-245

¹⁰² Sharples F.M.C., Haselen R.V., Fisher P., NHS patients' perspective on complementary medicine: a survey; *Complementary therapies in Medicine* (2003); 11, 243-48

¹⁰³ Lert et al; Characteristics of patients consulting their regular primary care physician according to their prescribing preferences for homeopathy and complementary medicine; *Homeopathy* (2014) 103, 51-57

¹⁰⁴ Framework of the practice: Belgium as an example; *Scientific framework of homeopathy: Evidence Based Homeopathy 2013; Revised edition after 67th LMHI Congress, September 2012 (Nara, Japan)*; pp 22-26

¹⁰⁵ Sharples F.M.C., Haselen R.V., Fisher P., NHS patients' perspective on complementary medicine: a survey; *Complementary therapies in Medicine* (2003); 11, 243-48

¹⁰⁶ Stewart W. M., David R., Graham C.M.W., The importance of empathy in the enablement of patients attending the Glasgow Homeopathic Hospital; *British Journal of General Practice*; November 2002, 52, 901-05

¹⁰⁷ Steinsbekk A., and Ludtke R., Patients' assessments of the effectiveness of homeopathic care in Norway: A prospective observational multicentre outcome study; *Homeopathy* (2005) 94, 10-16

¹⁰⁸ Framework of the practice: Belgium as an example; *Scientific framework of homeopathy: Evidence Based Homeopathy 2013; Revised edition after 67th LMHI Congress, September 2012 (Nara, Japan)*; pp 22-26

¹⁰⁹ Wassenhoven M.V., Pediatric homeopathy: A prospective observational survey based on parent proxy reports of their children's health-related Quality of Life in six European countries and Brazil; *Homeopathy* (2014)..., 1-7 (in print)

¹¹⁰ Sharples F.M.C., Haselen R.V., Fisher P., NHS patients' perspective on complementary medicine: a survey; *Complementary therapies in Medicine* (2003); 11, 243-48

¹¹¹ Manchanda R.K., Verma S.K., Chhatre L.V., Kaur H., Homeopathy in Urban Primary Healthcare Units of the Delhi Government: An Assessment; Dinges M.; *Medical Pluralism and Homeopathy in India and Germany (1810-2010): A comparison of practices*; 91-104, 2013

¹¹² Spence D. and Thompson E.A.; Homeopathic treatment for chronic disease: A 6-year, university-hospital outpatient observational study; *The Journal of Alternative and Complementary Medicine*; 11(5); 2005; pp 793-98

¹¹³ Stewart W. M., David R., Graham C.M.W., The importance of empathy in the enablement of patients attending the Glasgow Homeopathic Hospital; *British Journal of General Practice*; November 2002, 52, 901-05

¹¹⁴ Steinsbekk A., and Ludtke R., Patients' assessments of the effectiveness of homeopathic care in Norway: A prospective observational multicentre outcome study; *Homeopathy* (2005) 94, 10-16

¹¹⁵ Framework of the practice: Belgium as an example; *Scientific framework of homeopathy: Evidence Based Homeopathy 2013; Revised edition after 67th LMHI Congress, September 2012 (Nara, Japan)*; pp 22-26

¹¹⁶ Dinges M., The next decade for Homeopathy: Any lessons from the last decade?; Proceedings of 66th Liga Medicorum Homeopathical Internationalis Congress 2011

¹¹⁷ Lert et al; Characteristics of patients consulting their regular primary care physician according to their prescribing preferences for homeopathy and complementary medicine; *Homeopathy* (2014) 103, 51-57

¹¹⁸ Arndt B., Thomas O., Christa R., and Peter F.M., Adaptive coping strategies and attitudes toward health and healing in German Homeopathy and Acupuncture users; *Explore* July/August 2010 6(4), pp 237-245

¹¹⁹ Lert et al; Characteristics of patients consulting their regular primary care physician according to their prescribing preferences for homeopathy and complementary medicine; *Homeopathy* (2014) 103, 51-57

¹²⁰ Colin P., An epidemiological study of a homeopathic practice; *British Homeopathic Journal* (2000) 89; pp 116-21

¹²¹ Wassenhoven M.V., Pediatric homeopathy: A prospective observational survey based on parent proxy reports of their children's health-related Quality of Life in six European countries and Brazil; *Homeopathy* (2014)..., 1-7 (in print)

¹²² Pedro M. et al; Prevalence and characteristics of homeopathy users in a representative sample of the Lausanne population: CoLaus study; *Pharmacoepidemiology and Drug Safety* 2008; 17: 209-13

like 'holism, harmless therapy and cost-effectiveness', but also partly due to the rising

distrust among the users for the existing practices in the conventional medicine.

CHAPTER: III

EDUCATIONAL FRAMEWORK OF T&CM/ HOMEOPATHY

Education in Homœopathy aims to enable graduates to develop as independent and competent public health providers, to work in a variety of roles ranging from private practice to being an integrated member of a team of healthcare practitioners working in large scale clinical setting. Whereas India has adopted an organized university level education system, at par with corresponding conventional and other Indian medicine systems in the country, most other countries in the world are still to adopt independent educational courses.

The education system in many countries is well regulated and practitioners are trained medical practitioners. International Homœopathic associations such as LMHI, British Homeopathic Association (BHA), European Committee for Homeopathy (ECH) and several others in respective countries facilitate practice, learning, education and research. The standards of education and practice have been defined; e.g., ECH Homœopathic Medical Education Standards and accredited diploma courses are conducted by the LMHI. There is wide variation in educational standards and syllabi in different regions.

Austria:

- Officially recognized diploma as an additional qualification (medical doctor / veterinary doctor qualified in homeopathy). Postgraduate education. Optional introductory course on CAM during basic education at the universities of Vienna, Innsbruck and Graz.
- In 10 hospitals homeopathic care is possible on

consultation.

Belgium:

- Post-graduate diploma delivered by private schools. A National diploma exists delivered by the Homeopathic Faculty, grouping the different schools.
- A compulsory optional introductory course at the University of Leuven (U.C.L.)
- No official possibility for homeopathic care in hospitals but patient's rights include homeopathy as a possible patient choice in collaboration with the family medical doctor.

Bulgaria:

- Postgraduate diploma in private schools recognized by the medical association.
- No possibility of homeopathic care in hospitals.

Czech Republic:

- Postgraduate diploma in private schools.
- No possibility of homeopathic care in hospitals.

Denmark:

- Education in private schools open for everybody (no formal medical education required)
- No possibility of homeopathic care in hospitals.

Finland:

- Education in private schools, open for everybody (no foregoing medical education required)
- No possibility of homeopathic care in hospitals.

France:

- Officially recognized diploma as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). Post-graduate education at the universities in Aix-Marseille, Besançon, Lille, Paris-Bobigny, Bordeaux II, Limoges, Poitiers and Lyon. Private schools also exist. Optional introductory course of CAM during the basis education at some universities
- In 2 hospitals patients can come for a homeopathic consultation: Hôpital St. Jacques en Hôpital St. Luc Paris.

Germany:

- Officially recognized diploma as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). Post-graduate education at the universities of Berlin, Düsseldorf, Hannover, Heidelberg and Freiburg. Private schools also exist
- Compulsory optional introductory course of CAM during the basic education at some universities
- In 1 hospital patients can come for a homeopathic consultation: 'Charité'hospital in Berlin.

Greece:

- Postgraduate diploma in private schools and some universities.
- No possibility of homeopathic care in hospitals.

Hungary:

- No homeopathic education for doctors and pharmacists on universities. Postgraduate diploma in private schools, recognised as a requirement for

the university exam on homeopathy, which needs for official private praxis on homeopathy.

- No possibility for homeopathic care in hospitals.

Ireland:

- Postgraduate diploma in private schools, open for everybody (no foregoing medical education required).
- No possibility for homeopathic care in hospitals.

Italy:

- Officially recognized diploma as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). Post-graduate courses for medical doctors in Bologna, Roma, Siena (also dentists and pharmacists) Universities.
- Postgraduate diploma in private schools for medical doctors, dentists, veterinarians, pharmacists. Postgraduate diploma organized by the Provincial Medical College in Reggio Calabria.
- No possibility for homeopathic care in hospitals at this moment but announced.

Luxembourg:

- Postgraduate diploma in private schools.
- No possibility for homeopathic care in hospitals.

Netherlands:

- Postgraduate diploma in private schools.
- Optional introductory course of CAM during the basis education at some universities
- No possibility for homeopathic care in hospitals.

Norway:

- Education in private schools, open to everybody

(no foregoing medical education required).

Poland:

- Officially recognized diploma as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). Post-graduate education at 8 universities. No possibility for homeopathic care in hospitals.

Portugal:

- Postgraduate diploma in private schools.
- No possibility for homeopathic care in hospitals.

Romania:

- Officially recognized diploma as an additional qualification (medical doctor/veterinary doctor qualified in homeopathy). Post-graduate education at 8 universities. Optional introductory course of CAM during the basis education at some private universities
- No possibility for homeopathic care in hospitals.

Slovenia:

- Postgraduate education at the private school of the Slovenian Homeopathic Society accredited by ECH.
- No possibility for homeopathic care in hospitals.

Spain:

- Officially recognized diploma as an additional qualification (medical doctor/veterinary doctor qualified in homeopathy). Post-graduate education at the universities of Sevilla, Murcia and Barcelona.
- Optional introductory course of CAM during the basis education at some universities
- No possibility for homeopathic care in hospitals.

Sweden:

- Education in private schools open for everybody (no foregoing medical education required).
- No possibility for homeopathic care in hospitals.

Switzerland:

- Postgraduate diploma in private schools. At the university of Bern education in CAM is available.
- Homeopathic care only in private hospitals.

Great-Britain:

- Officially recognized diploma as an additional qualification (medical doctor/veterinary doctor qualified in homeopathy). The official recognized "Faculty of Homeopathy" delivers the diplomas. Postgraduate education in private schools, open for everybody.
- Optional introductory course of CAM during the basis education at some universities
- In 4 hospitals homeopathic consultations are possible: London, Liverpool, Bristol and Glasgow.

Turkey:

- Homeopathy is now regulated within the Traditional and Complementary Medicine regulation which was released at the end of November 2014 in Turkey.
- There are no homeopathic doctors with additional qualification on homeopathy yet.
- Post-graduate courses only in universities with a Traditional and Complementary Medicine Department.
- Officially recognized certificates as an additional qualification (MD, dentists) is given by the Health Ministry only for the courses in the Universities
- Private schools are not recognized

South-east Asian Region (SEAR)

Bangladesh

- Educational Institutes of Traditional medicine offers 04 year diploma courses.
- Five Ayurvedic and ten Unani Institute are recognized by the Bangladesh Board of Unani&Ayurvedic System of Medicine.
- The Government established a Unani and Ayurvedic Degree College at Mirpur in 1989 which offers Bachelor Courses in respective fields.
- The Registrar of the Board serves as the Controller of Examinations.
- 44 homeopathic colleges for DHMS and 03 homeopathic colleges for BHMS degree under Bangladesh Homoeopathic Board.

Bhutan

- Officially recognized formal training of traditional medical doctors (drungtsho) began in 1978 with the establishment of a five-year drungtshoprogramme.
- In 1979, the programme became part of the National Institute of Traditional Medicine (NITM).
- The course now consists of five years of institutional training followed by a six-month internship. In 1998, NITM was upgraded to Institute of Traditional Medicine Services.

Burma

- Burma Homoeopathic Society (BHS) conducts classes and issues certificates.
- A one-year course teaches basic principles of Myanmar TM.
- The University of Traditional Medicine confers a Bachelor's degree after four years of training and a one-year internship.
- TM is included in the curriculum of third year M.B.B.S.

DPR Korea

- Pharmacologists of traditional medicines are trained.
- Koryo medicine is taught at the KM faculties of the medical universities having Koryo pharmacology departments.
- The duration of the course is 07 years

India

- In India, organized education in Homœopathy began in the pre-independence period, beginning in Calcutta with the establishment of first homœopathic college, 'Calcutta Homœopathic Medical College' in 1883. Subsequent to the passing of the Central Council bill in both the houses of the parliament, the then President of India gave his assent to the Homœopathy Central Council Act 1973 on 19th December 1973. As per the provisions of the Act, the Government constituted the Central Council of Homœopathy (CCH) to regulate education and practice of the system.
- Following courses for homœopathic education are available in the country:
 - BHMS Course: The Bachelor of Homœopathic Medicine and Surgery (BHMS) is presently the basic educational qualification in Homœopathy. It is a regular full-time 5 ½ years graduate medical degree (including one year of compulsory internship training). The students are imparted training and teaching in pre-clinical, para-clinical and clinical subjects.
 - Post Graduate Degree Course: In 1989, the Homœopathy (Post Graduate Degree Course), Regulations were notified, through which post graduation was made available in 3 specialty subjects. In 2001, four new specialty subjects were included. Physicians with a basic graduate homœopathic degree can opt for Doctor of Medicine (Homœopathy) with options for specialization in the following subjects: Practice

of Medicine, Pediatrics, Psychiatry, Homœopathic Pharmacy, Organon of Medicine & Homœopathic Philosophy, Materia Medica and Repertory.

- Post-doctoral research programs (Ph. D.) in Homœopathy: This has of late been initiated by some universities.
- There are 260 UG, 67 PG colleges of Ayurveda; 14 UG colleges of Yoga & Naturopathy; 40 UG and 06 PG colleges of Unani; 07 UG and 03 colleges of Siddha and 183 UG and 39 PG colleges of Homeopathy. Education in respective discipline is regulated by the respective councils.

Indonesia

- Homeopathy Diploma Program is granted by the College
- Training courses in traditional medicine by Centre for Traditional Medicine Research and Directorate of Selected Community Health Development, also under the Ministry of Health and Social Welfare.
- A Diploma Programme in Traditional Medicine (three years, part of Study Programme of Medical Faculty), complementary and alternative clinics (eight clinics in government hospitals) and private hospitals, and Model Community Health Care Centre for Complementary and Alternative Services have been established.
- The Indonesian homoeopathic College under the auspices of the Association of Homoeopath Indonesia

Nepal

- Formal education in the ayurvedic system is under the supervision of the Institute of Medicine of Tribhuvan University.
- Ayurveda Campus trains Ayurveda graduates (BAMS, a 5½-year course) in the country.
- Mahendra Sanskrit University provides Ayurveda Certificate level training courses (30 months duration)

- Council of Technical Education and Vocational Training (CTEVT) provides 15 months.
- Nepal Homoeopathic Medical College is the first and only homeopathic college in Nepal, currently offering 4½ years of study and 1 year of internship. This leads to a B.H.M.S. (Bachelor of Homoeopathic Medicine and Surgery) degree.
- Homeopathic Health Assistant (HHA) program is also approved by Council for Technical Education and Vocational Training.

Sri Lanka

- There are two teaching institutes in Sri Lanka.
- National Institute of Traditional Medicine carries out educational and training programmes for traditional and ayurvedic practitioners, school children, and the general public.
- The Department of Ayurveda provide alternative resources for Ayurvedic Medical Officers to obtain postgraduate qualifications through the Institute of Indigenous Medicine at the University of Colombo, Rajagiriya.
- Council is empowered to register and recognize homeopathic medical practitioners; recognize homeopathic teaching institutes, dispensaries, and hospitals; hold examinations and award degrees in homeopathic medicine; and arrange for postgraduate study in homeopathy

Thailand

- The systematic teaching of TTM including bachelor's education is imparted by various Institutes and Universities.
- 02 Years standard program of Certificate of Post Graduated in Homeopathy is offered by Homoeopathic Association of Thailand (HAT).

Summary:

In the world, the use of homeopathy has increased in many countries, which, in turn, is resulting in increased education needs of the science. In many parts of Europe, homeopathy, as other CAM therapies, is already partly regulated. Homeopathy is integrated in 6 of the 22 countries. Medical students get familiar with CAM by an introduction course in 9 of the 22 countries.

A postgraduate diploma in homeopathy is recognized in 18 of the 22 countries. In south-east Asia, the homeopathic status is more evolved with most countries imparting

homeopathic education through government regulatory bodies. However, around the world, India remains the infrastructural leader with as many as 260 and 67 colleges for undergraduation and postgraduation in Homeopathy, respectively. Having said that, there is a need to devise a common path which enables a standardised framework for homeopathic education which is taught and recognised in every part of the world.

CHAPTER: IV

SAFETY ISSUES IN HOMEOPATHY

A general consensus exists on the fact that homeopathic treatment is safe and causes minimal to no adverse effects.¹²³ This, in fact, is one of the unique assets of Homeopathy, which has worked in favour of the science, especially in today's era of adverse drug effects from long term treatment. Nonetheless, the researchers have tried to substantiate this existing truth with scientific data. Safety, as perceived by the medical science, has more meaning than one, with both direct and indirect risks included.¹²⁴ A homeopathic treatment is said to be safe when:

1. It doesn't cause adverse drug effects (ADE) in the patient
2. Inadequate qualification of a practitioner doesn't come in the way of establishing a right diagnosis, which could debar the patient from right treatment or timely reference
3. The medicines are quality-assured, and, therefore, safe

Critics have argued that eventhough homeopathic medicines are ultra-diluted, incidence of ADE have been reported.¹²⁵ Nevertheless, these have largely been non-serious in nature. On the other hand, homeopathic aggravation is not to be confused with adverse drug effects, as it is a homeopathic phenomenon wherein a patient reports of slight worsening of the clinical symptoms, with a general sense of well being, followed by overall relief.¹²⁶ Such an occurrence is interpreted as a positive development in the course of homeopathic treatment. Interestingly, the incidence of homeopathic aggravation have been reported in research papers, which speaks in favour of the plausibility of

homeopathy, with its ultra-diluted medicines stirring a response in an individual. Many homeopaths claim to have observed aggravations in 60–70% of their cases. They emphasize that 'as a practitioner you have to ask the patients about aggravation, if you don't, they will seldom tell you'.¹²⁷ More logical rationale behind this concept is, however, wanting. Anyhow, most homeopathic aggravations, being self-limiting, do not call for any counteraction by the homeopathic physician, and hence are not taken into account as an adverse effect. In some cases, however, the response stirred can be out of proportion, mostly owing to frequent repetition or overdosage, and needs to be settled with an antidote. Such occurrences fall in the category of ADE and accounted as such. Besides, the homeopathic medicines, taken in a combined form with other medicines, don't remain purely homeopathic in nature and the adverse reactions from such medicines can not directly be attributed to the homeopathic medicines used.¹²⁸

What unfortunately remains a matter of concern is that not many clinical researches report of either ADE or homeopathic aggravation, thus barring the true analysis of the safety index of homeopathic treatment.¹²⁹ More researches focussing on this particular aspect would be a step in the right direction. Notwithstanding, so far, most researches and reviews carried out in this context conclude that homeopathic treatment is largely safe.¹²⁷⁻¹²⁹ However, there is a need to enhance understanding about clear cut differentiating points between ADE and homeopathic aggravation.

¹²³Bornhoft G, Matthiessen PF. Homeopathy in healthcare—effectiveness, appropriateness, safety, costs. Berlin: Springer; 2011.

¹²⁴Ernst E. The safety of homeopathy. Editorial. Br Horn J 1995; 84: 193-4.

¹²⁵Posadzki P., Alotaibi A., Ernst E.. Adverse Effects of Homeopathy: A Systematic Review of Published Case Reports and Case Series; Int J Clin Pract. 2012;66(12):1178-1188.

¹²⁶Endrizzi C, Rossi E, Crudeli L and Garibaldi D; Harm in homeopathy: Aggravations, adverse drug events or medication errors?; Homeopathy (2005) 94, 233–240

¹²⁷Trine Stub, Anita Salamsen, Terje Alraek; Is It Possible to

Distinguish Homeopathic Aggravation from Adverse Effects? A Qualitative Study; ForschKomplementmed 2012;19:13–19

¹²⁸Endrizzi C, Rossi E, Crudeli L and Garibaldi D; Harm in homeopathy: Aggravations, adverse drug events or medication errors?; Homeopathy (2005) 94, 233–240

¹²⁹F Dantas and H Rampes; Do homeopathic medicines provoke adverse effects? A systematic review; British Homeopathic Journal (2000) 89, Suppl 1, S35-38

Further, ensuring adequate qualification of homeopathic physicians is another core action area to safeguard the right of the patients to safe treatment. It is important that no profession earns a bad name simply because a doctor wasn't able to diagnose a rather serious case with threatening prognosis leading to dire consequences, also breaching the patient ethics in turn. Lack of knowledge of a physician makes homeopathy, or any other treatment for that matter, indirectly unsafe.¹³⁰ Efforts are in progress to standardise the homeopathic education in the world to ensure patients' safety in this regard. LMHI & ECH have together taken some key initiatives to standardise the education scenario of homeopathy worldwide.¹³¹

Additionally, with the worldwide increase in the use of homeopathic medicines and the rapid expansion of the global market, the safety and the quality of homeopathic medicines has become a major concern for health authorities, pharmaceutical industries and consumers. To assure quality of homeopathic medicines, WHO has prepared a document on safety issues that stresses upon Good Manufacturing Practices (GMP) and mentions all the necessary guidelines required to be followed for manufacturing homeopathic medicines.¹³² It should be the mandate of the drug regulatory body of every country to ensure the WHO guidelines are strictly adhered to by the homeopathic pharmaceutical industries.

CHAPTER : V

ETHICAL ISSUES IN HOMEOPATHY

The Father of Medicine, Hippocrates, has left rich medical and ethical heritage. His collection of treatises *Corpus Hippocraticum*, from 5th and 4th centuries BC, comprise not only general medical prescriptions, descriptions of diseases, diagnoses, dietary recommendations etc., but also his opinion on professional ethics of a physician. The Hippocratic Oath, taken by ancient and medieval doctors, requires high ethical standards from medical doctors. Its principles are important in professional and ethical education of medical doctors even today.¹³³ It is incredible to think that 'ethics' was talked of even 2000 years ago.

However, today ethics is a very large and complex field of study with many branches or subdivisions dealing with all aspects of human behaviour and decision-making. The focus of this chapter is medical ethics, especially concerning Homeopathy.¹³⁴ A wide range of ethical issues that a homeopath is subject to is no different from the ones

considered by the practitioners of the conventional medicine. Principle-based ethics, widely respected and followed in today's times, are divided into four categories, including – respect for autonomy, duty of beneficence, duty of non-maleficence and respect for justice. We shall see in the following text how homeopathic practice is in accordance with these ethics.

Respect for autonomy

Autonomy, or self-rule, requires the practitioner to respect the right of patients to make their own decision, be it with respect to their line of treatment, confidentiality, or anything else. The assumption is that mentally competent adults are able to make rational choices for themselves, based on adequate information. Such ethics, should not, however, come in way of autonomy of others. In respecting this principle, a homeopath, makes sure that the patient is

¹³⁰Ernst E. The safety of homeopathy. *Editorial. Br Horn J* 1995; 84: 193-4.

¹³¹Medical Homeopathic Education Standards for ECH And LMHI Allied Schools; European Committee for Homeopathy, 2001 & *Liga Medicorum Homoeopathica Internationalis*, 2005; Amended Version 2008

¹³²Safety issues in the preparation of homeopathic medicines; WHO Library Cataloguing-in-Publication Data; 2009

¹³³Bujalkova M; Hippocrates and his principles of medical ethics; *Bratisl Lek Listy* 2001; 102 (2): 117-120

¹³⁴World Medical Association; *Medical Ethics Manual*; 2nd edition 2009; pp 9

well informed about his illness and course of treatment and respects his or her autonomy when the patient seeks confidentiality, especially because s/he asks for more personal information from the patient for an analytical case-taking that guides correct prescription.

Duty of beneficence

The principle of beneficence is associated with benefiting patients through curing, helping and healing. For a homeopath, the term has a wider meaning as a homeopath does not only limit to benefiting a patient physically, but also mentally and emotionally. That makes his duty professionally broader demanding wider range of skills and competencies. This aspect also includes assessing the situation correctly and when the treatment ceases to provide benefit or is of limited benefit in comparison to some other line of treatment, it is ethically advisable to refer the patient or offer the treatment as only an adjuvant.

Duty of non-maleficence

The principle of non-maleficence, requires the practitioner to refrain from any behaviour which can cause harm to a patient. Overriding the patient's autonomy, for example, by disregarding their expressed wishes, will constitute harm. Emotional, physical, verbal or sexual abuse would certainly constitute harm. A homeopath, in order to avoid any harm to the patient at emotional level, besides the physical level, is skilled enough to handle a patient's emotions and illnesses with compassion. On another note, since Homeopathy offers one of the most gentle and harmless approaches towards treatment, it is logical to administer this therapy first along with other CAM options, with the technology of conventional medicine being used as a back up when needed.¹³⁵ However, severity of a patient's condition is given due consideration to decide which treatment is used first. For example, in a case of

cancer, where chemotherapy is strongly advised, the drastic side effects resulting from it can be overlooked keeping in mind the likelihood of success.

Respect for justice

The 'respect for justice' imposes a duty on physician to act fairly and justly to all their clients regardless of age, gender, class or race. A homeopath is, therefore, ethically bound to distribute benefits and burdens to all his patients in a fair and even manner. This also includes the legal aspect of justice, by which patients enjoy acknowledgement and compensation should something go wrong. Practitioners, in such a case, are expected to respond in a fair and even-handed manner to any complaints made against them.

On the whole, the homeopathic treatment and researches address all the ethical issues concerning its patients.

However, critics argue that the homeopathic treatment is unethical and its use in public should be stopped on this ground. They emphatically claim that even though Homeopathy is popular among the lay people and a significant number of medical professionals¹³⁶, it is best to discontinue its services as its laws are questionable and medicines not more than a placebo. The argument is stretched so far to say that providing homeopathic therapy to a patient is deceitful and a compromise of patient ethics. What is also argued is that since the evidence for efficacy of homeopathy is unsupportive, any expenditure of the government on promotion or funding of Homeopathy, be it practice or research, or that of the patient on its treatment, is a waste of resources, and hence a breach of medical ethics^{137,138}

The actual situation is, however, different from what critics seem to project. As has been pointed out in many

¹³⁵Stone J., An ethical framework for Complementary & Alternative therapists; Routledge 2002

¹³⁶Smith K.; Against homeopathy – A utilitarian perspective; Bioethics; 2012 Oct; 26(8):398-409

¹³⁷Smith K.; Against homeopathy – A utilitarian perspective; Bioethics; 2012 Oct; 26(8):398-409

¹³⁸Shaw D.; Unethical aspects of homeopathic dentistry; Br Dent J. 2010 Nov 27; 209(10):493-6

rejoinders to such arguments^{139,140,141,142}, Homeopathy can be anything but unethical, considering its 'harmless' and safe treatment. Going by the golden maxim used in medicine and also advocated by Hippocrates in his medical oath, 'Primum non nocere – Above all, do no harm', Homeopathy is one system of medicine that has offered most harmless treatments to mankind¹⁴³. To say that its practitioners are banking upon the element of 'placebo' for healing and deceiving patients in the name of treatment, is making a defamatory statement which is in contradiction to the available facts. One can not simply overlook the fact that there exist not only several clinically recognised effects of Homeopathy, which has led to a following of 200 million worldwide¹⁴⁴, but also that upto the end of 2011, 163 randomised controlled trials (RCTs) comparing homeopathy with placebo or conventional medicine have been published in peer-reviewed journals. In terms of statistically significant results, 78 of these were able to draw firm conclusions: 67 were positive for Homeopathy and 11 were negative¹⁴⁵. On the other hand out of many RCTs published in conventional medicine, an analysis reflects that a major 51% of the treatment belonged to the category of 'unknown effectiveness', while only 11% of it was clearly beneficial.¹⁴⁶ And if one adds to that the iatrogenic effects of the treatment, the figures do not speak very positive of the conventional treatment. In that sense, is it right to say that the conventional treatment is 'unethical' or trying to 'deceive'? It is not true because of the benefits it provides to the patients. In the same argument, it is then apt to say that Homeopathy, with a relatively established effectiveness and safety, cannot be termed as 'unethical' or ruled out of the treatment options in public domain on the basis of the factors like 'harmful' or

'placebo'.

As regards the expenditure on Homeopathy or its research being referred to as the waste of resources, and therefore unethical, it seems, considering the growing amount of evidence in favour of Homeopathy, both in humans and laboratory studies, funding for further research in Homeopathy is most warranted and ethically justifiable. The existing researches indicate that Homeopathy is not only plausible, but constitutes one of the frontiers of medical science, and more specifically of complexity science, biophysics, and nanopharmacology.¹⁴⁷ Further, the expenditure being incurred on Homeopathy by the government or patients for the purpose of treatment, is much lesser than the total portion of the budget that is spent on public or individual healthcare, respectively, as also supported by many analyses.¹⁴⁸ In fact, Homeopathy is one of the most cost-effective treatment options available today. In contrast, many a time, a patient refers to Homeopathy after the conventional treatment has failed to relieve. In that case, will the amount spent on the treatment that failed to respond be called a waste of resources?

In conclusion, it is clearly evident that Homeopathy is an ethical system of medicine which provides safe, cost-effective and holistic treatment to its patients. Also, quite like the practitioners and researchers of other therapies, homeopathic professionals ardently adhere to the ethical issues related to their patients or other subjects while carrying out a treatment or research. However, to make the medical stream more ethical as a whole, it is imperative that various therapies work together in an integrated

¹³⁹Milgrom L1, Chatfield K.; Is homeopathy really 'morally and ethically unacceptable'? A critique of pure scientism; *Bioethics*. 2012 Nov;26(9):501-3

¹⁴⁰Eames S., Darby P.; Homeopathy and its ethical use in dentistry; *Br Dent J*. 2011 Apr 9;210(7):299-301.

¹⁴¹Sebastian I. Homeopathy and extraordinary claims--a response to Smith's utilitarian argument; *Bioethics*. 2012 Nov;26(9):504-5

¹⁴²Bellavite P.; On the plausibility of homeopathic 'similitude'; *Bioethics*; 2012 Nov;26(9):506-7

¹⁴³Bornhoft G, Matthiessen PF. Homeopathy in healthcare—effectiveness, appropriateness, safety, costs. Berlin: Springer; 2011.

¹⁴⁴Bellavite P.; On the plausibility of homeopathic 'similitude'; *Bioethics*; 2012

Nov;26(9):506-7

¹⁴⁵British Homeopathic Association; The research evidence Base for Homeopathy. http://www.british-homeopathic.org/export/sites/bha_site/research/evidencesummary.pdf; Accessed on June 16, 2014

¹⁴⁶Sebastian I. Homeopathy and extraordinary claims--a response to Smith's utilitarian argument; *Bioethics*. 2012 Nov;26(9):504-5

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¹⁴⁸Viksveen P1, Dymitr Z, Simoens S.; Economic evaluations of homeopathy: A review; *Eur J Health Econ*. 2014 Mar;15(2):157-74

fashion, so that the health and cost benefits to the patients are maximised and ill effects minimised. In all such

interactions the well-being of patients should be the primary consideration.¹⁴⁹

CHAPTER: VI

META ANALYSES - SYSTEMATIC REVIEW

The “gold standard”, accepted by everybody to evaluate the efficacy of a remedy is a meta-analysis or a systematic audit of RCTs. It is considered an apt method of review owing to its unique feature of providing hierarchical evidence to a study (Table 2). Since 1991, six comprehensive reviews concerning homeopathy were published.

The conclusion of most comprehensive systematic reviews has been that homeopathy has a positive and specific effect greater than placebo alone. Several randomized and controlled studies (RCT) showed a statistical significance difference between homeopathy and placebo. More research is justified.

Report about all comprehensive systematic reviews on homeopathic trials

Table 2

Level of evidence :

I = the existence of meta-analyses and/or systematic positive « reviews » of the literature. **Ila** = controlled multiplied experiments, randomised, positive results.

Iib = some controlled experiments, randomised, positive results.

Illa = study with multiple cohorts, positive

results. **Iib** = study with some cohorts, positive results. **IV** = opinion of experts (clinical and daily cases)

- Kleijnen & al. 1991 British Medical Journal.¹⁵⁰ 105 studies with interpretable results. Meta-analysis based on validated criteria. 77 % of the studies show positive result for homeopathy. The results are mostly favourable for homeopathy regarding the quality of trials. “There is a legal argument for further evaluation of homeopathy”.
- Boissel et al.¹⁵¹ 1996 Report for the European commission. 15 studies. Inclusion of only very rigorous studies (highest quality). Combined p-values for the 15 studies is significant. (p = 0.0002). “It is evident that homeopathy is more efficient than placebo”.

¹⁴⁹Medical Ethics Manual; World Medical Association; 2nd edition 2009; pp 91

¹⁵⁰Kleijnen J, Knipschild P, ter Riet G. Clinical trials of homeopathy British Medical Journal 1991;302:316-323.

¹⁵¹Boissel JP, Cucherat M, Haugh M, Gauthier E. Critical literature review on the effectiveness of homeopathy: overview of data from homeopathic medicine trials. Homeopathic Medicine Research Group. Report to the European Commission. Brussels 1996, 195-210.

Little evidence for non-published negative results.

Further research is justified.

- Linde et al¹⁵² 1997 *The Lancet*. 89 studies.

“Odds ratio” combined 2.45 (95 % CI, 2.05-2.93) in favour of homeopathy.

“Odds ratio” for the best 26 studies was 1.66.

It is not possible that the clinical effects of homeopathy are due completely to placebo.

- Linde and Melchart¹⁵³ 1998 *Journal of Alternative and Complementary Medicine*. 32 studies, inclusion of studies on individualised homeopathy only.¹⁵⁴

Individualised homeopathy is more efficient than a placebo: the value of the combined coefficient was 1.62 (95 % CI, 1.17-2.23).

Further pragmatic research is justified.

- Cucherat et al¹⁵⁵ 2000 *European Journal of Clinical Pharmacology*. 16 trials representing 17 comparisons with placebo (based on data from the Boissel 1996 study).

Several studies have positive results. More trials have a positive result than would be expected to chance alone.

Publication bias is unlikely.

More clinical trials are needed.

- Shang et al¹⁵⁶ 2005 *Lancet*. 110 trials included, but the final conclusion is based on a selection of 8 trials.

Final conclusion (8 heterogeneous trials) : weak evidence for a specific effect of homeopathic remedies, but strong evidence for specific effects of conventional interventions.

Presented as comparison of homeopathy and carefully matched conventional trials, but data about conclusive trials were missing.

Quality of homeopathy trials is better: 21 (19 %) good quality trials for homeopathy, 9 (8 %) for conventional medicine.

Homeopathy is effective for acute upper respiratory tract infections (odds ratio 0*36 [95 % CI 0*26–0*50]), based on 8 trials without indications for bias.

- Bornhöft G., Matthiesen P. 2011. Report for the Swiss Federal Office of Public Health. This report used the health technology assessment (HTA) method examining not only the efficacy of a particular intervention but also its “real world effectiveness”, its appropriateness, safety and costs. This report is fully in line with the principles of EBM, unlike assessments based only on RCTs.

In this assessment papers were selected also looking at the respect of the homeopathic fundamental rules such as similarity and individualisation of treatments. This report contains a systematic review for upper respiratory tract infections and allergies and concluded that a positive effect is not only apparent in placebo controlled studies, but especially also in the comparison with conventional treatments.¹⁵⁷

Other than these comprehensive systematic reviews, many reviews on specific clinical conditions were also done by various investigators. In conditions like Allergies and upper respiratory tract infections^{158,159}, Childhood

¹⁵² Linde K et al. Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trial. *Lancet* 1997;350:834-43

¹⁵³ Linde K, Melchart D. Randomized controlled trials of individualized homeopathy: a state-of-the art review. *J Alter Complement Med* 1998;4: 371-88.

¹⁵⁴ Boissel JP, Cucherat M, Haugh M, Gauthier E. Critical literature review on the effectiveness of homeopathy: overview of data from homeopathic medicine trials. Homeopathic Medicine Research Group. Report to the European Commission. Brussels 1996, 195-210.

¹⁵⁵ Cucherat, M. et al. Evidence of clinical efficacy of homeopathy. A metaanalysis of clinical trials. *Eur J Clin Pharmacol* 2000;56: 27-33.

¹⁵⁶ Shang A, Huwiler-Muntener K, Nartey L, Juni P, Dorig S, Sterne JA, Pewsner D, Egger M. Are the clinical effects of homeopathy placebo effects? Comparative study of placebo-controlled trials of homeopathy and allopathy. *Lancet* 2005;366(9487):726-32.

¹⁵⁷ Bornhöft G., Matthiesen P. (2011). Homeopathy in Healthcare. Effectiveness, Appropriateness, Safety, Costs: An HTA report on homeopathy as part of the Swiss Complementary Medicine Evaluation Programme. Berlin, Heidelberg, New York: Springer-Verlag, 2011. Summary: *Forschende Komplementärmedizin*, 13 (2006) Suppl.2, 19-29.

¹⁵⁸ Bornhöft G, Wolf U, Ammon K, et al. Effectiveness, safety and cost-effectiveness of homeopathy in general practice – summarized health technology assessment. *Forschende Komplementärmedizin*, 2006; 13 Suppl 2: 19–29.

¹⁵⁹ Bellavite P, Orotolani R, Pontarollo F, et al. Immunology and homeopathy. 4. Clinical studies – Part 1. Evidence-based Complementary and Alternative Medicine: *eCAM*, 2006; 3: 293–301.

diarrhoea¹⁶⁰, Influenza treatment¹⁶¹, Post-operative ileus¹⁶², Rheumatic diseases¹⁶³, Seasonal allergic rhinitis (hay fever)^{164,165,166,167} and Vertigo¹⁶⁸ the outcomes are in favor of Homeopathy. In conditions like Anxiety¹⁶⁹, Cancer side-effects¹⁷⁰, Chronic asthma¹⁷¹, Dementia¹⁷², Depression¹⁷³, Fibromyalgia¹⁷⁴, Headache and migraine treatment¹⁷⁵, HIV/AIDS¹⁷⁶, Induction of labour¹⁷⁷, Insomnia^{178,179}, Osteoarthritis¹⁸⁰ and Psychiatric disorders¹⁸¹ outcomes were inconclusive due to lack of high quality study. And only in 06 reviews (Ailments of childhood and adolescence¹⁸², Attention deficit hyperactivity disorder¹⁸³, Cancer treatment¹⁸⁴, Delayed-onset muscle soreness¹⁸⁵, Headache and migraine prevention¹⁸⁶, Influenza prevention¹⁸⁷) there is little or no evidence of effect of homeopathy.

A recent systematic review on thirty-two eligible RCTs

studied 24 different medical conditions in total. Twelve trials were classed 'uncertain risk of bias', three of which displayed relatively minor uncertainty and were designated reliable evidence; 20 trials were classed 'high risk of bias'. Twenty-two trials had extractable data and were subjected to meta-analysis; OR = 1.53 (95% confidence interval (CI) 1.22 to 1.91). For the three trials with reliable evidence, sensitivity analysis revealed OR = 1.98 (95% CI 1.16 to 3.38). Thirty-two eligible RCTs studied 24 different medical conditions in total. Twelve trials were classed 'uncertain risk of bias', three of which displayed relatively minor uncertainty and were designated reliable evidence; 20 trials were classed 'high risk of bias'. Twenty-two trials had extractable data and were subjected to meta-analysis; OR = 1.53 (95% confidence interval (CI) 1.22 to 1.91). For the three trials with reliable evidence,

¹⁶⁰Jacobs J, Jonas WB, Jimenez-Perez M, Crothers D. Homeopathy for childhood diarrhea: combined results and metaanalysis from three randomized, controlled clinical trials. *Pediatric Infectious Disease Journal*, 2003; 22: 229–234.

¹⁶¹Vickers A, Smith C. Homeopathic Oscillocoquinum for preventing and treating influenza and influenza-like syndromes (Cochrane review). In: *The Cochrane Library*. Chichester, UK: John Wiley & Sons, Ltd. CD001957, 2006.

¹⁶²Barnes J, Resch K-L, Ernst E. Homeopathy for postoperative ileus? A meta-analysis. *Journal of Clinical Gastroenterology*, 1997; 25: 628–633.

¹⁶³Jonas WB, Linde K, Ramirez G. Homeopathy and rheumatic disease. *Rheumatic Disease Clinics of North America*, 2000; 26: 117–123.

¹⁶⁴Wiesenaue M, Lütke R. A meta-analysis of the homeopathic treatment of pollinosis with Galphimia glauca. *Forschende Komplementärmedizin und Klassische Naturheilkunde*, 1996; 3: 230–236.

¹⁶⁵Taylor MA, Reilly D, Llewellyn-Jones RH, et al. Randomised controlled trials of homeopathy versus placebo in perennial allergic rhinitis with overview of four trial series. *British Medical Journal*, 2000; 321: 471–476.

¹⁶⁶Bellavite P, Ortolani R, Pontarollo F, et al. Immunology and homeopathy. 4. Clinical studies – Part 2. Evidence-based Complementary and Alternative Medicine: eCAM, 2006; 3: 397–409.

¹⁶⁷Ernst E. Homeopathic Galphimia glauca for hay fever: A systematic review of randomised clinical trials and a critique of a published meta-analysis. *Focus on Alternative and Complementary Therapies*, 2011; 16: 200–203.

¹⁶⁸Schneider B, Klein P, Weiser M. Treatment of vertigo with a homeopathic complex remedy compared with usual treatments: a meta-analysis of clinical trials. *Arzneimittelforschung*, 2005; 55: 23–29.

¹⁶⁹Pilkington K, Kirkwood G, Rampes H, et al. Homeopathy for anxiety and anxiety disorders: A systematic review of the research. *Homeopathy*, 2006; 95: 151–162.

¹⁷⁰Kassab S, Cummings M, Berkovitz S, et al. Homeopathic medicines for adverse effects of cancer treatments (Cochrane Review). In: *The Cochrane Library*. Chichester, UK: John Wiley & Sons, Ltd. CD004845, 2009.

¹⁷¹McCarney RW, Linde K, Lasserson TJ. Homeopathy for chronic asthma (Cochrane Review). In: *The Cochrane Library*. Chichester, UK: John Wiley & Sons, Ltd. CD000353, 2004.

¹⁷²McCarney R, Warner J, Fisher P, van Haselen R. Homeopathy for dementia (Cochrane Review). In: *The Cochrane Library*. Chichester, UK: John Wiley & Sons, Ltd. CD003803, 2004.

¹⁷³Pilkington K, Kirkwood G, Rampes H, et al. Homeopathy for depression: a systematic review of the research evidence. *Homeopathy*, 2005; 94: 153–163.

¹⁷⁴Perry R, Terry R, Ernst E. A systematic review of homeopathy for the treatment of fibromyalgia. *Clinical Rheumatology*, 2010; 29:457–464.

¹⁷⁵Owen JM, Green BN. Homeopathic treatment of headaches: A systematic review of the literature. *Journal of Chiropractic Medicine*, 2004; 3: 45–52.

¹⁷⁶Ullman D. Controlled clinical trials evaluating the homeopathic treatment of people with human immunodeficiency virus or acquired immune deficiency syndrome. *Journal of Alternative and Complementary Medicine*, 2003; 9: 133–141.

¹⁷⁷Smith CA. Homeopathy for induction of labour (Cochrane Review). In: *The Cochrane Library*. Chichester, UK: John Wiley & Sons, Ltd. CD003399, 2004.

¹⁷⁸Cooper KL, Relton C. Homeopathy for insomnia: A systematic review of research evidence. *Sleep Medicine Reviews* 2010; 14: 329–337.

¹⁷⁹Ernst E. Homeopathy for insomnia and sleep-related disorders: A systematic review of randomised controlled trials. *Focus on Alternative and Complementary Therapies*, 2011; 16: 195–199.

¹⁸⁰Long L, Ernst E. Homeopathic remedies for the treatment of osteoarthritis: a systematic review. *British Homeopathic Journal*, 2001; 90: 37–43.

¹⁸¹Davidson JR, Crawford C, Ives JA, Jonas WB (2011). Homeopathic treatments in psychiatry: a systematic review of randomized placebo-controlled studies. *Journal of Clinical Psychiatry*, 72: 795–805.

¹⁸²Altunç U, Pittler MH, Ernst E. Homeopathy for childhood and adolescence ailments: systematic review of randomized clinical trials. *Mayo Clinic Proceedings*, 2007; 82: 69–75.

¹⁸³Coulter MK, Dean ME. Homeopathy for attention deficit/hyperactivity disorder or hyperkinetic disorder (Cochrane Review). In: *The Cochrane Library*. Chichester, UK: John Wiley & Sons, Ltd. CD005648, 2007.

¹⁸⁴Milazzo S, Russell N, Ernst E. Efficacy of homeopathic therapy in cancer treatment. *European Journal of Cancer*, 2006; 42: 282–289.

¹⁸⁵Ernst E, Barnes J. Are homeopathic remedies effective for delayed-onset muscle soreness? – A systematic review of Placebo-controlled trials. *Perfusion (Nürnberg)*, 1998; 11: 4–8.

¹⁸⁶Ernst E. Homeopathic prophylaxis of headaches and migraine? A systematic review. *Journal of Pain and Symptom Management*, 1999; 18: 353–357.

¹⁸⁷Vickers A, Smith C. Homeopathic Oscillocoquinum for preventing and treating influenza and influenza-like syndromes (Cochrane review). In: *The Cochrane Library*. Chichester, UK: John Wiley & Sons, Ltd. CD001957, 2006.

sensitivity analysis revealed OR = 1.98 (95% CI 1.16 to 3.38). The review considered only peer-reviewed publications and concluded that medicines prescribed in individualised homeopathy may have small, specific treatment effects. These findings are consistent with subgroup data available in a previous 'global' systematic review. However, the low or unclear overall quality of the evidence prompts caution in interpreting the findings. New high-quality RCT research is necessary to enable more decisive interpretation.¹⁸⁸

Comments on meta-analyses

Randomized Controlled Trials (RCTs) for homeopathy were originally meant to prove that homeopathy as a method is not a placebo effect, despite the questioned mechanism of action. For this purpose meta-analyses combined trials for different indications in one analysis. Despite heterogeneity that arises from such combinations, some positive evidence could be demonstrated in a number of meta-analysis. We would like to stress that these analyses disregard the surplus value of homeopathy. Homeopathy is predominantly used by patients with chronic and recurrent complaints and is valued for the fact that it appears to have systemic effects, exceeding single indications as is common in conventional medicine.

Selecting subgroups in a limited number of trials readily leads to false negative results. The Cochrane Handbook for Systematic Reviews states "Reliable conclusions can only be drawn from analyses that are truly pre-specified before inspecting the trials' results".¹⁸⁹The Cochrane Handbook fur-

her recommends, "Meta-analysis should only be considered when a group of trials is sufficiently homogeneous in terms of participants, interventions and outcomes to provide a meaningful summary". Pooling of results of studies on different conditions is also questionable if homeopathy works for some conditions and not for others.¹⁹⁰ Because of the questioned mechanism of action the evidence for homeopathy was scrutinized in a way that is not required for conventional therapies. Linde et al (1997) showed that the positive outcome for homeopathy cannot be explained by publication bias.¹⁹¹Shang et al (2005) showed that quality of homeopathy trials is better compared to conventional trials matched on indication.¹⁹²

The analysis by Shang, et al.(2005)

This analysis did not comply with the QUOROM guidelines that sufficient information should be given to reconstruct the conclusions. The authors did not reveal which trials (8 for homeopathy, 6 for conventional medicine) led to the final conclusion. Neither the summary nor the introduction clearly specified the aim of the study. The meta-analysis does not compare studies of homeopathy versus studies of conventional medicine, but rather specific effects of these two methods in separate analyses.^{193,194,195,196}Therefore, a direct comparison must not be made from this study. Post-publication data revealed that the conclusion was not based on a comparison with matched conventional trials, as suggested by the authors.¹⁹⁷The conclusion was based on 8 studies for 8 different indications; the inefficacy of one of these indications, muscle soreness in marathon

¹⁸⁸Mathie et al; Randomised placebo-controlled trials of individualised homeopathic treatment: systematic review and meta-analysis; *Systematic Reviews* 2014, 3:142; doi:10.1186/2046-4053-3-142; pp 1-27

¹⁸⁹Higgins JPT, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions* 4.2.5 [updated May 2005]. In: *The Cochrane Library*, Issue 3, 2005. Chichester, UK: John Wiley & Sons, Ltd.

¹⁹⁰Jonas WB, Kaptchuk TJ, Linde K. A critical overview of homeopathy. *Ann Intern Med* 2003; 138: 393-399

¹⁹¹Linde K e.a. Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trial. *Lancet* 1997;350:834-43

¹⁹²Shang A, Huwiler-Müntener K, Nartey L, Juni P, Dorig S, Sterne JA, Pewsner D, Egger M. Are the clinical effects of homeopathy placebo effects? Comparative study of placebo-controlled trials of homeopathy and allopathy. *Lancet* 2005;366(9487):726-32.

¹⁹³Rutten ALB, Stolper CF. The 2005 meta-analysis of homeopathy: the importance

of post-publication data. *Homeopathy* 2008;97:169-177

¹⁹⁴Frass M, Schuster E, Muchitsch I, Duncan J, Geir W, Kozel G, KastingerMayr C, Felleitner AE, Reiter C, Endler C, Oberbaum M. Asymmetry in The Lancet meta-analysis. *Homeopathy* 2006;95:52-3

¹⁹⁵Oberbaum M, Singer SR, Frass M. Homeopathic research after the Lancet meta analysis—a moment for introspection. *Complement Ther Med* 2005;13:303-5

¹⁹⁶Frass M, Schuster E, Muchitsch I, Duncan J, Gei W, Kozel G, KastingerMayr C, Felleitner AE, Reiter C, Endler C, Oberbaum M. Bias in the trial and reporting of trials of homeopathy: a fundamental breakdown in peer review and standards? *J Altern Complement Med* 2005;11:780-2

¹⁹⁷Shang A, Jüni P, Sterne JAC, Huwiler-Müntener K, Egger M. Author's reply. *Lancet* 2005;366:2083-2085

runners, was already proven (38). The conclusive subset of 8 trials was based on a post hoc definition for 'larger trials', $n=98$ for homeopathy and 146 for conventional medicine. If 'larger' would have been defined as 'above median sample size', including 14 homeopathy trials, the outcome would be significantly positive. Excluding the indication 'muscle soreness in marathon runners' homeopathy is efficacious in most subsets of larger good quality studies.

Shang, et al., stated that the asymmetry of the funnel plot indicated inefficacy when compared with conventional medicine. This comparison was not rectified because of difference in quality, especially in smaller trials. For trials with sample size <100 homeopathy had 14 good quality trials and conventional medicine 2 ($p=0.003$). Stronger effect in smaller good quality trials is caused by better selection of patients and then asymmetry of the funnel plot is no indication for bias. Funnel plots are thought to detect publication bias, and heterogeneity to detect fundamental differences among studies. New evidence suggests that both of these common beliefs are badly flawed. Using 198 published meta-analyses, Tang and Liu demonstrate that the shape of a funnel plot is largely determined by the arbitrary choice of the method to construct the plot.¹⁹⁸ When a different definition of precision and/or effect measure was used, the conclusion about the shape of the plot was altered in 37 (86 %) of the 43 meta-analyses with an asymmetrical plot suggesting selection bias.

As stated before, Shang, et al., were not clear about the aim of their analysis. The methodology of comparing homeopathy with conventional trials matched on indication was suited for comparison of quality. Comparing of effects of subgroups was not allowed because the matching was lost in forming subgroups. The only valid conclusion of this analysis is that quality of homeopathy trials is better than of conventional trials, for all trials ($p=0.03$), but also for smaller trials with $n<100$ ($p=0.003$).

Another interesting finding from Shang, et al., data was:

"The eight trials of homeopathic remedies in acute infections of the upper respiratory tract that were included in our sample, the pooled effect indicated a substantial beneficial effect (odds ratio 0.36 [95% CI 0.26–0.50]) and there was neither convincing evidence of funnel-plot asymmetry nor evidence that the effect differed between the trial classified as of higher reported quality and the remaining trials". In 1997, Linde stated that, "homeopathy functioned not better than placebo in a specific disease". Thus the original hypothesis that homeopathy as a method is a placebo effect was reformulated towards specific indications. This hypothesis corresponds with systematic conventional research. The advantage is less heterogeneity in the set of analyzed trials, but it disregards the surplus value of homeopathy, see above.¹⁹⁹ Compare this surplus value with psychotherapy and Post Traumatic Stress Disorder (PTSD) with symptoms like palpitations, flashbacks, headache and insomnia. Psychotherapy gets closer to the source of the disease than a combination of beta-blockers, painkillers and tranquillizers. It would make no sense to require RCT evidence that psychotherapy works better than beta-blockers. Likewise the same homeopathic medicine could cure headache, eczema and herpes lips in the same patient. The real problem with homeopathy was the implausibility. It makes no sense to prove that homeopathy is plausible for one indication, but not for another.

Nevertheless, there are a number of medical conditions with proof for homeopathy: this is a solution to the problem of heterogeneity of medical conditions. Seventeen systematic reviews or meta-analyses focused on RCTs of homeopathy in 15 specific areas were performed: anxiety, childhood diarrhea, chronic asthma, delayed-onset, muscle soreness, dementia, depression, headache and migraine, HIV/AIDS, induction of labor, influenza treatment and prevention, osteoarthritis, post-operative ileus, seasonal allergic rhinitis (hay fever) and vertigo.

This critical approach has been explained by Jonas,

¹⁹⁸Tang J, Liu JL. Misleading funnel plot for detection of bias in meta-analysis. *J Clin Epidemiol* 2000; 53:477–484

¹⁹⁹Rutten ALB, Stolper E. «Proof» against homeopathy in facts supports

homeopathy. *Homeopathy* 2006;95:57-61.

Kaptchuk and Linde in 2003.²⁰⁰ The **level 1 of evidence** is reached for childhood diarrhea and seasonal allergic rhinitis. Other meta-analysis showed this same level for allergic rhinitis,²⁰¹ post-operative ileus,²⁰² rheumatoid arthritis²⁰³ and the protection from toxic substances.²⁰⁴

Level IIa of evidence is obtained for asthma,²⁰⁵ fibrositis,²⁰⁶ influenza,²⁰⁷ muscular pain,²⁰⁸ otitis media,²⁰⁹ several pain sensations,²¹⁰ side effects of radiotherapy,²¹¹ strains²¹² and infections of the ear, nose and throat.²¹³

Level IIb of evidence is obtained in the treatment of anxiety,^{214,215} hyperactivity disorders,²¹⁶ irritable bowel,²¹⁷ migraine,²¹⁸ osteoarthritis of the

knee,²¹⁹ premenstrual syndrome,²²⁰ pain associated with unwanted post partum lactation,²²¹ prevention of nausea and vomiting during chemotherapy,²²² septicemia,²²³ post-tonsillectomy analgesia²²⁴ and aphthous ulcers.²²⁵

The practical choice of a treatment for a specific patient is only little helped by the RCT results; they are obtained in "an ideal artificial situation" far from the personal context of the patient. The homeopathic diagnosis is more than a search to a disease; it is an approach including the whole person, with the aim of an individualized and global treatment. The method of evaluation has to be adapted to this reality; today Bayes' statistics authorize such research

²⁰⁰Jonas WB, Kaptchuk TJ, Linde K. A critical overview of homeopathy. *Ann Intern Med* 2003; 138: 393-399

²⁰¹Lüdtke R, Wiesenauer M. A meta-analysis of homeopathic treatment of pollinosis with Galphimia glauca. *Wien Med Wochenschr* 1997; 147: 323-7.

²⁰²Barnes J, Resch K-L, Ernst E. Homeopathy for postoperative ileus? A meta-analysis. *J Clin Gastroenterol* 1997; 25: 628-33.

²⁰³Jonas WB, Linde K, Ramirez G. Homeopathy and rheumatic disease. *Rheum Dis Clin North Am* 2000; 26: 117-23.

²⁰⁴Szeta AL, Rollwagen F, Jonas WB. Raoid induction of protective tolerance to potential terrorist agents: a systematic review of low- and ultra-low dose research. *Homeopathy* 2004;93:173-178.

²⁰⁵Matusiewicz R. The effect of a homeopathic preparation on the clinical condition of patients with corticosteroid-dependent bronchial asthma. *Biomed Ther* 1997;15:70-4. & Reilly D, Taylor MA, Beattie NGM, et al. Is evidence for homeopathy reproducible? *Lancet* 1994;344:1601-6.

²⁰⁶Fisher P. An experimental double-blind clinical trial method in homeopathy. Use of a limited range of remedies to treat fibrositis. *Br Homeopath J* 1986;75:142-7 & Fisher P, Greenwood A, Huskinson EC, et al. Effect of homeopathic treatment on fibrositis (primary fibromyalgia). *Br Med J* 1989;299:365-6 and Bell I et al Improved clinical status in fibromyalgia patients treated with homeopathy versus placebo. *Rheumatology* 2004;43(5):577-582.

²⁰⁷Ferley JP, Zmirou D, Adhemar D, Balduci F. A controlled evaluation of a homeopathic preparation in the treatment of influenza-like syndromes. *Br J Clin Pharmacol* 1989;27:329-35 & Papp R, Schuback G, Beck E, et al. Oscillocoquinum in patients with influenza-like syndromes: a placebocontrolled double-blind evaluation. *Br Homeopath J* 1998 ;87 :69-76.

²⁰⁸Tveiten D, Bruseth S, Borchgrevink CF, Norseth J. Effects of the homeopathic remedy Arnica D30 on marathon runners: a randomized, double-blind study during the 1995 Oslo Marathon. *Complement Ther Med* 1998;6:74-4 & Hariveau E. La recherche clinique a l'institut Boiron. *Homéopathie* 1987; 5: 55-8.

²⁰⁹Harrison H, Fixsen A, Vickers A. A randomized comparison of homeopathic and standard care for the treatment of glue ear in children. *Complement Ther Med* 1999; 7: 132-5 & Jacobs J, Springer DA, Crothers D. Homeopathic treatment of acute otitis media in children: a preliminary randomized placebo-controlled trial. *Pediatr Infect Dis J* 2001; 20: 177-83.

²¹⁰Stam C, Bonnet MS, van Haselen RA. The efficacy and safety of a homeopathic gel in the treatment of acute low back pain: a multicentre, randomised, double-blind comparative clinical trial. *Br Homeopath J* 2001; 90: 21-8 & Ernst E, Saradeth T, Resch KL. Complementary treatment of varicose veins – a randomized, placebo-controlled, double-blind trial. *Phlebology* 1990; 5: 157-63.

²¹¹Balzarini A, Felisi E, Martini A, De Conno F. Efficacy of homeopathic treatment of skin reactions during radiotherapy for breast cancer: a randomised, double-blind clinical trial. *Br Homeopath J* 2000; 89: 8-12 & Kulkarni A, Nagarkar BM, Burde GS. Radiation protection by use of homeopathic medicines. *Hahnemann Homoeopath Sand* 1998; 12: 20-3.

²¹²Böhmer D, Ambrus P. Behandlung von Sportverletzungen mit TraumeelSalbe -

Kontrollierte Doppelblindstudie. *Biol Med* 1992; 21: 260-8 & Zell J, Connert WD, Mau J, Feuerstake C. Treatment of acute sprains of the ankle joint. Double-blind study assessing the effectiveness of a homeopathic ointment preparation. *Fortschr Med* 1988;106:96-100.

²¹³de Lange de Klerk ES, Blommers J, Kuik DJ, et al. Effect of homeopathic medicines on daily burden of symptoms in children with recurrent upper respiratory tract infections. *Br Med J* 1994;309:1329-32 & Weiser M, Clasen BPE. Controlled double-blind study of a homeopathic sinusitis medication. *Biol Ther* 1995;13:4-
²¹⁴McCutcheon LE. Treatment of anxiety with a homeopathic remedy. *J Appl Nutr* 1996;48:2-6.

²¹⁵Frei H, Everts R, von Ammon K, Kaufmann F, Walther D, Hsu Schmitz SF, Collenberg M, Steinlin M, Lim C, Thurneysen A. Randomised controlled trials of homeopathy in hyperactive children: treatment procedure leads to an unconventional study design. *Homeopathy*. 2007;96:35-41.

²¹⁶Lamont J. Homeopathic treatment of attention deficit hyperactivity disorder. A controlled study. *Br Homeopath J* 1997;86:196-200.

²¹⁷Rahlf VW, Mössinger P. Asa foetida in the treatment of the irritable colon: a double-blind trial. *Dtsch Med Wochenschr* 1979;104:140-3.

²¹⁸Brigo B, Serpelloni G. Homeopathic treatment of migraines: a randomized double-blind controlled study of sixty cases (homeopathic remedy versus placebo). *Berlin J Res Homeopath* 1991;1:98-106.

²¹⁹van Haselen RA, Fisher PAG. A randomized controlled trial comparing topical piroxicam gel with a homeopathic gel in osteoarthritis of the knee. *Rheumatology* 2000;39:714-9.

²²⁰Yakir M, Kreidler S, Brzezinski A, et al. Effect of homeopathic treatment in women with premenstrual syndrome: a pilot study. *Br Homeopath J* 2001;90:148-53.

²²¹Berrei A, Parant O, Ferval F, Thene M, Ayoubi JM, Connan L, Belon P. Homeopathic treatment of pain associated with unwanted post partum lactation. *J. Gynecol Biol Reprod* 2001;30:353-357.

²²²Genre D, Tarpin C, Braud AC, Camerlo J, Protiere C, Eisinger F, Viens P. Randomized, double-blind study comparing homeopathy (cocculine) to placebo in prevention of nausea/vomiting among patients receiving adjuvant chemotherapy for breast cancer. *Breast Cancer Research and Treatment* 2003;82:sup 1, 637.

²²³Frass M, Linkesch M, Banyai S, Resch G, Dielacher C, Löbl T, Endler C, Haidvogl M, Muchitsch I, Schuster E. Adjunctive homeopathic treatment in patients with severe sepsis: a randomized, double-blind, placebocontrolled trial in an intensive care unit. *Homeopathy* 2005;94:75-80.

²²⁴Robertson A, Suryanarayanan R, Banerjee A. Homeopathic Arnica Montana for post-tonsillectomy analgesia: a randomized placebo control trial. *Homeopathy*. 2007;96:17-21.

²²⁵Mousavi F, Mojaver Y.N, Asadzadeh M, Mirzazadeh M. Homeopathic treatment of minor aphthous ulcer: a reandomized, placebo-controlled clinical trial. *Homeopathy* 2009;98:137-141.

(see further).

Views concerning conclusions of “The Lancet” publication of Shang-Egger²²⁶

The best and most detailed critic of the Shang, et al., publication is a sensitivity analysis of obtained results and conclusions from the selected clinical trials in the final evaluation.²²⁷ If we consider the 21 trials of good quality, OR became 0.76 with IC 95 % of 0.59-0.99 and $p=0.039$, argument for a homeopathic efficacy significantly higher than the placebo effect. Looking at the sensitivity of this analysis, it appears that OR is significantly different of 1 for all combinations between 14 trials ($n = \text{threshold } 69$) and the whole 21 trials (exception: the combination of 17 trials with $n = \text{threshold } 50$). However, in most of these analyses, the funnel plot reveals a moderate (but non significant) asymmetry.²²⁸ The results of predicted OR values using the technique of meta-regression (normally preferred in case of significant asymmetry) show values near one, indicating a possible absence of significant difference between homeopathy and placebo. In addition, this complementary analysis of the Shang publication reveals an important heterogeneity between the clinical trials (higher than 50 %, criteria making a meta-analyze null and void). In this case it is recommended to use the technique of meta-regression, see above, instead of a meta-analysis for traditional random purpose.²²⁹ This heterogeneity can have multiple reasons. One of these is probably the kind of considered diseases or conditions. A justified reproach can be done to Shang in the fact that he retained in his analysis trials where homeopathy has no demonstrated effect as “muscle soreness”, particularly when one of the trial finally retained by Shang contribute to increase considerably the heterogeneity of the sample. If this “muscle soreness” trial is omitted in the analysis, OR calculated on 7 trials (instead of 8) goes to 0.88/0.80 (even if this is still not significant: IC 0.61-1.05). However, in a

sensitive analysis, the difference became significant if we consider 8 trials (rejecting muscle soreness, incorporating another trial on 80 people (OR = 0.75 IC 0.58-0.96 $p=0.025$) or 6 trials with inclusion criteria of 100 people (OR = 0.73 IC 0.59-0.91 $p=0.005$) instead of the 8 trials selected by Shang (inclusion criteria 98 people). Conversely, the positive results with the 21 trials are mostly related to the presence of two large trials on influenza. If one of these two trials would be rejected, OR is no more significantly different of one. Another consequence of this important heterogeneity is the interpretation that can be done to the funnel plot aimed to exclude small sized trials.²³⁰ Indeed, rather than considering small sized trials as more bias sensitive (and as such eliminated for the final analysis), one alternative could be to consider these small sized trials as more effective because they are performed in condition where the effect of homeopathy is particularly clear and as such an important cohort of people is not needed to demonstrate this effect.²³¹ If this is the case (and this situation cannot be excluded a priori), it is clear that the exclusion of small sized trials as Shang decided, is a major bias in the final conclusion. The sensitive analysis demonstrates clearly that the significance of the observed superiority effect of homeopathy compared to placebo

²²⁶Belgian Royal Medicine Academy: abstract from advice on homeopathy approved on 28 February 2009. www.armb.be

²²⁷Lüdtke R, Rütten ALB. The conclusions on the effectiveness of homeopathy highly depend on the set of analyzed trials. *J Clin Epidemiol* 2008, 61, 197-204.

²²⁸Egger M, Smith GD, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *Br Med J*, 1997, 315, 629-634.

²²⁹Egger M, Smith GD, Phillips AN. Meta analysis : principles and procedures. *Br Med J*, 1997, 315, 1533-1537.

²³⁰Egger M, Smith GD, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *Br Med J*, 1997, 315, 629-634.

²³¹Lüdtke R, Rütten ALB. The conclusions on the effectiveness of homeopathy highly depend on the set of analyzed trials. *J Clin Epidemiol* 2008, 61, 197-204.

depends, in a crucial way, on the number of trials taken into account in the analysis.

All published meta-analyses of controlled clinical trials in homeopathy are, more or less, subjects for critics and are controversial.²³² Admittedly the Shang, et al analysis, published in the Lancet is very critical and cannot, as such, and, with it only, support the proposed final conclusion: “This finding is compatible with the notion that the clinical effects of homeopathy are placebo effects.”²³³ Nevertheless, the sensitive analysis of Lütcke et al.,²³⁴ is clear enough by concluding: “Our results do neither prove that homeopathic medicines are superior to placebo nor do they prove the

For homeopathy, 9 out of 21 publications showed statistically significant positive results, 2 negative, 4 were of high quality (Fig. 1).

Source:

www.ispm.ch/fileadmin/doc_download/1431.Study_characteristics_of_homeopathy_studies_corrected.pdf

For the conventional approaches, 11 out of 21 showed statistically significant positive results, 3 negative, 3 were of high quality (Fig. 2).

Source:

www.ispm.ch/fileadmin/doc_download/1431.Study_characteristics_of_allopathy_studies_corrected.pdf



opposite”.

But there is more, if we compare the matched conventional and homeopathic RCT’s proposed by Shang²³⁵ and considering only the most common reason for using homeopathy (see Chapter III: the upper respiratory tract infections) we can see that the efficacy of homeopathy is at least equal to the conventional treatments’ efficacy.

Fig. 1

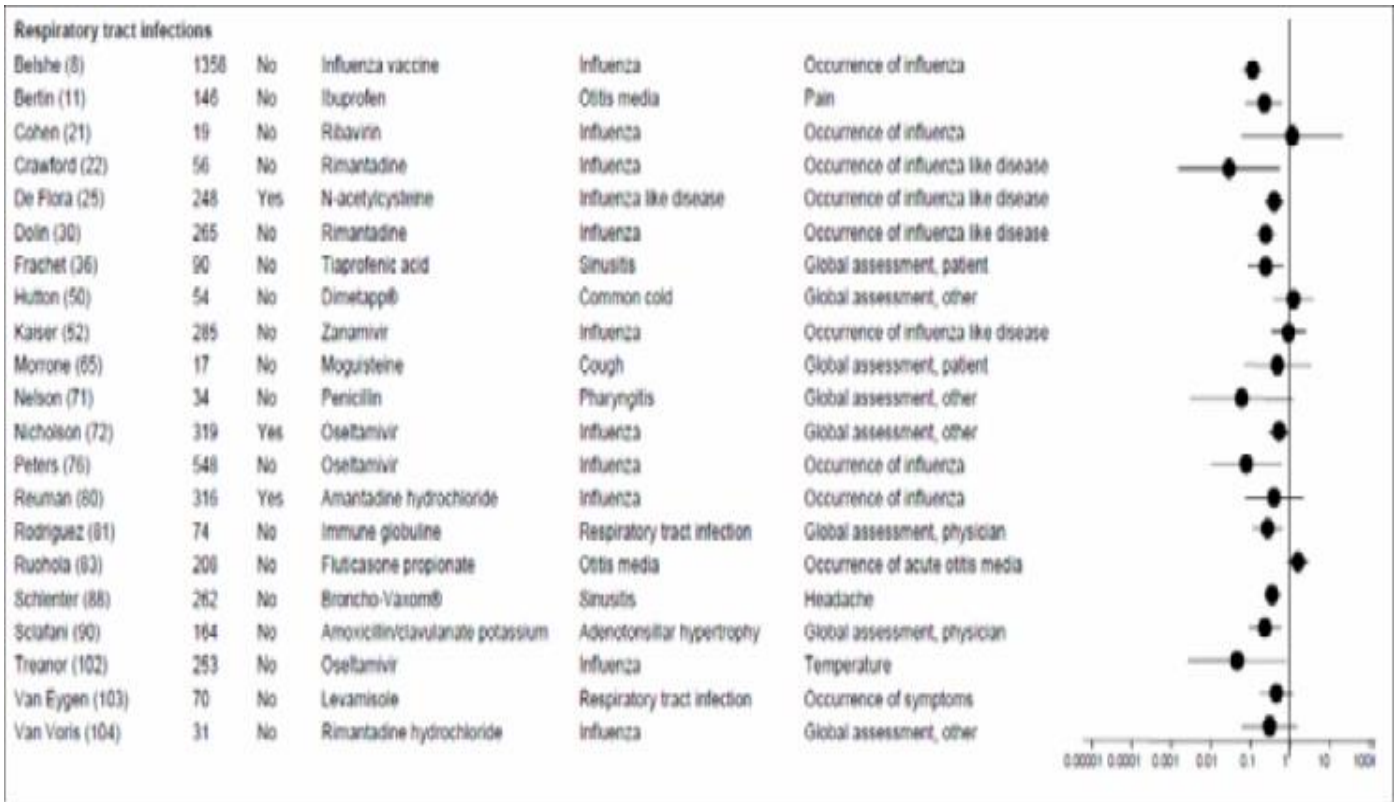
²³²Ernst E. A systematic review of systematic reviews of homeopathy. Br J Clin Pharmacol, 2002, 54, 577-582.

²³³Shang A, Huwiler-Müntener K, Nartey L, et al. Are the clinical effects of homeopathy placebo effects? Comparative study of placebo-controlled trials of homeopathy and allopathy. Lancet 2005, 366, 726-732.

²³⁴Lütcke R, Rutten ALB. The conclusions on the effectiveness of homeopathy highly depend on the set of analyzed trials. J Clin Epidemiol 2008, 61, 197-204.

²³⁵Linde K, Melchart D. Randomized controlled trials of individualized homeopathy: a state-of-the-art review. J Alter Complement Med 1998;4: 371-88.

Fig. 2



Coming to the point, it is relevant to quote the conclusions of R.T. Mathie published in the journal Homeopathy (Vol 92, Issue 2, April 2003, Pages 84-91) after a review of the available literature “The available research evidence emphasizes the need for much more and better-directed research in homeopathy. A fresh agenda of enquiry should consider beyond (but include) the placebo-controlled trial. Each study should adopt research methods and outcome measurements linked to a question addressing the clinical significance of homeopathy's effects.”

Prospective comparison surveys between medical approaches would be promoted (non-inferiority trials) in specific areas described further in this booklet. Randomized placebo-controlled trials are of course a reference for “the best evidence” but respect of the individualized homeopathic treatment and daily practice must always be considered (a very difficult point considering the individual approach in homeopathy).

Conclusion:

As such, we could conclude that more research is certainly needed considering the coherent beam of available results in specific areas described further in this booklet. All levels of evidence are needed.

Chapter: VII

Clinical research

The scope for research in Homeopathy is huge, with several issues either wanting of ample evidence or beyond the domain of existing knowledge. In the recent past, homeopathy has been researched for its viability in medical care through various means – the primary one being clinical research. This chapter shall first look into the available evidence in Homeopathy and then towards the end, discuss why research in homeopathy needs to be approached with different perspective altogether.

Randomised Control Trials

A review of clinical trials in homeopathy reported from 1975 to 2002 found 93 studies comparing homeopathy with placebo or other treatment.²³⁶ Positive effects of homeopathy were found in 50. There is replicated RCT evidence that homeopathy may be effective in childhood diarrhoea, fibromyalgia, influenza (treatment), otitis media, seasonal allergic rhinitis, sinusitis and vertigo. Reviewing 12 systematic reviews of homeopathy for specific medical conditions, reached similar conclusions: homeopathy may be effective for allergies, childhood

diarrhoea, influenza and postoperative ileus, but not for treatment of migraine, delayed-onset muscle soreness or prevention of influenza.²³⁷

There is also some evidence from individual RCTs that homeopathy may be effective in chronic fatigue syndrome, premenstrual syndrome, postpartum bleeding, sepsis, influenza, pain, side-effects of radio-/chemotherapy, sprains, upper respiratory tract infection and stomatitis. Among the single RCTs of homeopathy conducted in clinical areas, including asthma²³⁸, life-threatening sepsis²³⁹ and stomatitis induced by cancer chemotherapy²⁴⁰, chronic fatigue syndrome²⁴¹, premenstrual syndrome²⁴², postpartum bleeding²⁴³ and Arnica for various clinical conditions^{244,245}, most have yielded positive results. In some clinical situations, both RCTs and clinical observational studies have been conducted, providing a fuller picture of the possible role of homeopathy. Such areas include upper respiratory tract and ear infections in children^{246,247,248}, attention deficit hyperactivity disorder^{249,250} and homeopathy for

²³⁶Mathie, R.T., The research evidence base for homeopathy: a fresh assessment of the literature, *Homeopathy* 92 (2003) 84–91

²³⁷Jonas, W.B.; Jimenez-Perez, M.; et al., Homeopathy for childhood diarrhea: combined results and metaanalysis from three randomized, controlled clinical trials, *Pediatr. Infect. Dis. J.* 22 (2003) 229–234

²³⁸White, A.; Slade, P.; Hunt, C.; et al., Individualised homeopathy as an adjunct in the treatment of childhood asthma: a randomised placebo controlled trial, *Thorax* 58 (2003) 317–321.

²³⁹Frass, M.; Linkesch, M.; Banyai, S.; et al., Adjunctive homeopathic treatment in patients with severe sepsis: a randomized, double-blind, placebo-controlled trial in an intensive care unit, *Homeopathy* 94 (2005) 75–80

²⁴⁰Oberbaum, M.; Yaniv, I.; Ben-Gal, Y.; et al., A randomized, controlled clinical trial of the homeopathic medication Traumeel S in the treatment of chemotherapy-induced stomatitis in children undergoing stem cell transplantation, *Cancer* 92 (2001) 684–690

²⁴¹Weatherley-Jones, E.; Nicholl, J.P.; Thomas, K.J.; et al., A randomized, controlled, triple-blind trial of the efficacy of homeopathic treatment for chronic fatigue syndrome, *J. Psychosom. Res.* 56 (2004) 189–197

²⁴²Yakir, M.; Kreitler, S.; Brzezinski, A.; et al., Effects of homeopathic treatment in women with premenstrual syndrome: a pilot study, *British Homeopathic Journal* 90 (2001) 148–153

²⁴³Oberbaum, M.; Galoyan, N.; Lerner-Geva, L.; et al., The effect of the homeopathic remedies Arnica and Bellisperennis on mild postpartum bleeding

– a randomized, double-blind, placebo-controlled study –preliminary results, *Complement. Ther. Med.* 13 (2005) 87–90

²⁴⁴Tveiten, D.; Bruseth, S.; Borchgrevink, C.F.; Norseth, J., Effects of the homeopathic remedy Arnica D30 on marathon runners: a randomized, double-blind study during the 1995 Oslo Marathon, *Complement. Ther. Med.* 6 (1998) 71–74

²⁴⁵Stevinson, C.; Devaraj, V.S.; Fountain-Barber, A.; et al., Homeopathic arnica for prevention of pain and bruising: randomized placebo-controlled trial in hand surgery, *J. R. Soc. Med.* 96 (2003) 60–65

²⁴⁶de Lange de Klerk, E.S.M.; Blommers, J.; Kuik, D.J.; et al., Effects of homeopathic medicines on daily burden of symptoms in children with recurrent upper respiratory tract infections, *Br. Med. J.* 309 (1994) 1329–1332

²⁴⁷Frei, H.; Thurneysen, A., Homeopathy in acute otitis media in children: treatment effect or spontaneous resolution? *Homeopathy* 90 (2001) 180–182

²⁴⁸Jacobs, J.; Springer, D.; Crothers, D., Homeopathic treatment of acute otitis media in children: a preliminary randomized placebo-controlled trial, *Pediatr. Infect. Dis. J.* 20 (2001) 177–183

²⁴⁹Frei, H.; Thurneysen, A., Treatment for hyperactive children: homeopathy and methylphenidate compared in a family setting, *Homeopathy* 90 (2001) 183–188.

²⁵⁰Frei, H.; Everts, R.; von Ammon, K.; et al., Homeopathic treatment of

symptoms related to cancer treatment.^{251,252,253}

Replication of results, a reliable indicator in clinical research, is what remains largely elusive in Homeopathy. The group led by David Reilly has published an impressive series of trials of isopathy^{254,255,256,257} for respiratory allergies, including hayfever, perennial rhinitis and allergy, including a meta-analysis. However, there has been no independent positive replication of these findings still date. Migraine is another area in which there have been replicated studies: a study on 60 patients using classical individualized homeopathy, was reported as showing a highly significant positive result.²⁵⁸ But attempted replications have been much less positive.^{259,260} However, an uncontrolled observational study reported major improvement in quality of life in patients undergoing homeopathic treatment for headache²⁶¹. Another observational study showed large effect sizes ($d = 2.44$) for improvement in headache days over the course of a year and in quality of life.²⁶² Another model with independent replication is Arnica 30x to prevent delayed-onset muscle soreness. The results of two studies in the Oslo marathon have been pooled, and a small but significant effect on muscle soreness, but none on muscle enzymes, was

children with attention deficit hyperactivity disorder: a randomised, double blind, placebo controlled crossover trial, *Eur. J. Pediatr.* 164 (2005) 758–767

²⁵¹Balzarini, A.; Felisi, E.; Martini, A.; et al., Efficacy of homeopathic treatment of skin reactions during radiotherapy for breast cancer: a randomized, double-blind clinical trial, *British Homeopathic Journal* 89 (2000) 8–12

²⁵²Thompson, E.; Reilly, D., The homeopathic approach to the treatment of symptoms of oestrogen withdrawal in breast cancer patients. A prospective observational study, *Homeopathy* 92 (2003) 131–134

²⁵³Jacobs, J.; Herman, P.; Heron, K.; et al., Homeopathy for menopausal symptoms in breast cancer survivors: a preliminary randomized controlled trial, *J. Altern. Complement. Med.* 11 (2005) 21–27

²⁵⁴Reilly, D.T.; Taylor, M.A., Potent placebo or potency? A proposed study model with initial findings using homeopathically prepared pollens in hayfever, *British Homeopathic Journal* 74 (1985) 65–75

²⁵⁵Reilly, D.T.; Taylor, M.A.; McSharry, C.; et al., Is homeopathy a placebo response? Controlled trial of homeopathic potency, with pollen in hayfever as model, *Lancet* ii (1986) 881–885

²⁵⁶Reilly, D.; Taylor, M.A.; Beattie, N.G.M.; et al., Is evidence for homeopathy reproducible? *Lancet* 344 (1994)

²⁵⁷Taylor, M.A.; Reilly, D.; Llewellyn-Jones, R.H.; et al., Randomised controlled trials of homeopathy versus placebo in perennial allergic rhinitis with overview of four trial series, *Br. Med. J.* 321 (2000) 471–476

²⁵⁸Brigo, B.; Serpelloni, G., Homeopathic treatment of migraines – A randomized double-blind controlled study of sixty cases (homeopathic remedy versus placebo), *Berlin Journal of Research in Homeopathy* 1 (1991) 98–106

²⁵⁹Whitmarsh, T.E.; Coleston-Shields, D.M.; Steiner, T.J., Double-blind randomized placebo-controlled study of homeopathic prophylaxis of migraine, *Cephalalgia* 17 (1997) 600–604

²⁶⁰Walach, H.; Häusler, W.; Lowes, T.; et al., Classical homeopathic treatment of chronic headaches, *Cephalalgia* 17 (1997) 119–126

shown.²⁶³ However, a larger-scale study replication, mostly on runners in the London marathon, was negative.²⁶⁴ More recently the results of three linked studies of Arnica 30x in different types of knee surgery have yielded a positive result.²⁶⁵ The models are so divergent, however, that no common quantitative measure can be derived.

Paralytic postoperative ileus has also been studied repeatedly. In a study, patients were treated with Opium and Raphanus 6C; the time to resumption of intestinal transit was the outcome. Initial pilot studies were promising, but a large-scale multicentre study in France did not reproduce the initial results.²⁶⁶ The initial results were so strong, however, that a pooled analysis still yielded significant results.²⁶⁷ Another area with mixed replications is rheumatology. An initial study of individualized homeopathy in rheumatoid arthritis was positive²⁶⁸, but independent studies failed to confirm these results.^{269,270} A trial of a single homeopathic medicine (*Rhustoxicodendron*) in osteoarthritis with little

²⁶¹Muscari-Tomaioli, G.; Allegri, F.; Miali, E.; et al., Observational study of quality of life in patients with headache, receiving homeopathic treatment, *Homeopathy* 90 (2001) 189–197

²⁶²Witt, C.M.; Lüdtke, R.; Willich, S.N., Homeopathic treatment of chronic headache (ICD-9: 784.0) – a prospective observational study with 2 year follow-up, *Forsch. Komplementärmed.* 16 (2009) 227–235

²⁶³Tveiten, D.; Bruset, S., Effect of Arnica D30 in marathon runners. Pooled results from two double-blind placebo controlled studies, *Homeopathy* 92 (2003) 187–189

²⁶⁴Vickers, A.J.; Fisher, P.; Wyllie, S.E.; et al., Homeopathic Arnica 30X is ineffective for muscle soreness after long-distance running: a randomized, double-blind, placebo-controlled trial, *Clin. J. Pain* 14 (1998) 227–231

²⁶⁵Brinkhaus, B.; Wilkens, J.M.; Lüdtke, R.; et al., Homeopathic arnica therapy in patients receiving knee surgery: Results of three randomised double-blind trials, *Complement. Ther. Med.* 14 (2006) 237–246

²⁶⁶GRECHO (Groupe de recherches et d'essais cliniques en homéopathie), Evaluation de deux produits homéopathiques sur la reprise du transit après chirurgie digestive – Un essai contrôlé multicentrique. [Evaluation of the effect of two homeopathic products on the restoration of intestinal peristalsis – A multicentre controlled trial.], *Presse Méd.* 18 (1989) 59–62

²⁶⁷Barnes, J.; Resch, K.L.; Ernst, E., Homeopathy for postoperative ileus? A meta-analysis, *J. Clin. Gastroenterol.* 25 (1997) 628–633

²⁶⁸Gibson, S.; MacNeill, A.D.; et al., Homeopathic therapy in rheumatoid arthritis; evaluation by double-blind clinical therapeutic trial, *Br. J. Clin. Pharmacol.* 9 (1980) 453–459

²⁶⁹Andrade, L.; Ferraz, M.; Atra, E.; et al., A randomized controlled trial to evaluate the effectiveness of homeopathy in rheumatoid arthritis, *Scand. J. Rheumatol.* 20 (1991) 204–208

²⁷⁰Fisher, P.; Scott, D.L., A randomized controlled trial of homeopathy in rheumatoid arthritis, *Rheumatology* 4 (2001) 1052–1055

or no individualization yielded a negative result.²⁷¹ However, a replication, using the same homeopathic medicine but in a different rheumatological condition (fibromyalgia) and incorporating individualization, yielded a positive result.²⁷² Subsequently there have been two further positive results from RCTs of homeopathic treatment of fibromyalgia, but these have used different methods and outcomes: one looked at individualized homeopathy²⁷³ and the other at the entire 'package' of homeopathic care, including consultation and medicine, compared to normal care.²⁷⁴

For anxiety, childhood asthma, insect bites, menopausal symptoms in breast cancer, migraine, muscle soreness, prevention of upper respiratory tract infection, stroke and warts, the current RCT evidence is inconclusive or negative. For other medical conditions the current published evidence is fragmentary. However, it is interesting to note that the evidence overall becomes less positive when filtered for 'internal' trial validity and sample size. It can nevertheless be counter-argued that many of these studies were of poor homeopathic quality, for instance lacking individualization or with unrealistic outcomes.²⁷⁵ Overall, the data from RCTs do not seem to reflect the true picture of the effectiveness of homeopathic treatment. Although a widely respected format for conventional studies, the RCTs most certainly do not encompass the 'homeopathic' features of treatment to yield results which are as encouraging as observational studies which is more patient-oriented. A further probing of this point is done elsewhere in the chapter.

²⁷¹Shipley, M.; Berry, H.; Broster, G.; et al., Controlled trial of homeopathic treatment of osteoarthritis, *Lancet* i (1983) 97–98

²⁷²Fisher, P.; Greenwood, A.; Huskisson, E.C.; et al., Effect of homeopathic treatment on fibrositis (primary fibromyalgia), *Br. Med. J.* 299 (1989) 365–366

²⁷³Bell, I.R.; Lewis, D.A.; Brooks, A.J.; et al., Improved clinical status in fibromyalgia patients treated with individualized homeopathic remedies versus placebo, *Rheumatology* 43 (2004) 577–582

²⁷⁴Relton, C.; Smith, C.; Raw, J.; et al., Healthcare provided by a homeopath as an adjunct to usual care for fibromyalgia (FMS): results of a pilot randomised controlled trial, *Homeopathy* 98 (2009) 77–82

²⁷⁵Fisher P., Mathie R.T., Walach H. and Jonas W.B., *Scientific Research in Homeopathy; Special issues in establishing CAM research quality*; Elsevier Ltd. 2011; pp 169-97

²⁷⁶Davidson, J.; Rampes, H.; Eisen, M.; et al., Psychiatric disorders in primary care patients receiving complementary medical treatments, *Compr. Psychiatry*.

Clinical observational studies

Unfortunately, the clinical areas in which research on homeopathy has been done do not match well with those for which it is used in practice. For instance, homeopathy is commonly used to treat psychiatric problems, including anxiety and depression in France, Germany, the UK and USA,^{276,277,278,279} yet as mentioned above, clinical trial evidence is scant. Reasons for this include model simplicity (for instance, isopathic treatment of allergies has been relatively extensively investigated because it is a simple model), expediency and commercial motives.⁴⁰ In practice homeopathy is frequently used for clinical problems, for instance dermatological or gastrointestinal conditions where there is little or no RCT evidence. A comprehensive observational study at the Bristol Homeopathic Hospital included over 6500 consecutive patients with over 23 000 attendances in a 6-year period.²⁸⁰ At follow-up, 70% of patients reported improved health, 50% major improvement. The best treatment responses were reported in childhood eczema or asthma, and in inflammatory bowel disease, irritable bowel syndrome, menopausal problems and migraine. A study at a public-sector clinic in Italy yielded similar results.²⁸¹ In a prospective, multicentre cohort study in Germany and Switzerland, 73% of 3709 patients with 8-year follow-up contributed data. The most frequent diagnoses were allergic rhinitis and headache in adults, and atopic dermatitis and multiple recurrent infections in children. Disease severity decreased significantly ($P < 0.001$) between baseline, 2 years and 8 years. Younger age, female gender and more severe disease at baseline

39 (1998) 16–20

²⁷⁷Unutzer, J.; Klap, R.; Sturm, R.; et al., Mental disorders and the use of the alternative medicine: results from a national survey, *Am. J. Psychiatry* 157 (2000) 1851–1857

²⁷⁸Trichard, M.; Lamure, E.; Chauferin, G., Study of the practice of homeopathic general practitioners in France, *Homeopathy* 92 (2003) 135–139

²⁷⁹Becker-Witt, C.; Ludtke, R.; Weissshuhn, T.E.R.; et al., Diagnoses and treatment in homeopathic medical practice, *Forsch. Komplementärmed.Klass.Naturheilkd.* 11 (2004) 98–103

²⁸⁰Spence, D.; Thompson, E.A.; Barron, S.J., Homeopathic treatment for chronic disease: a 6-year university hospital based outpatient observational study, *J. Altern. Complement. Med.* 5 (2005) 793–798

²⁸¹Rossi, E.; Endrizzi, C.; Panozzo, M.A.; et al., Homeopathy in the public health system: a seven-year observational study at Lucca Hospital (Italy), *Homeopathy* 98 (2009) 142–148

correlated with better outcomes.²⁸² A 500-patient survey at the Royal London Homoeopathic Hospital showed that many patients were able to reduce or stop conventional medication following homeopathic treatment.²⁸³ The size of the effect varied between diagnoses: for skin complaints, for example, 72% of patients reported being able to stop or reduce their conventional medication; there was no reduction for cancer patients. In both these surveys, many of the patients were suffering from difficult-to-treat 'effectiveness gap' conditions.²⁸⁴

Although these observational studies showed significant and persistent outcomes, it is important to remember that the extent to which the observed effects are due to differential dropout, spontaneous improvement, regression to the mean, lifestyle changes, placebo or context effects is unknown and needs clarification in future explanatory studies. Further, the challenge to reproduce these results at a larger scale, without the involvement of the previous researcher and in another geographic boundary, remains largely unattended. Most studies replicated so far have either included one or more of the previous researchers or similar geographical settings.²⁸⁵ Still, it is evident that observational studies have consistently been yielding more positive results for Homeopathy than the methodological RCTs. The reason why the results of these loosely methodological study design of observational studies are not always able to convert into the strict RCT design, and almost never as strongly, is rather intricate and needs deep analysis. The following part of the chapter discusses this issue at length.

Personalised medicine and prognosis research

Another type of observational study is prognosis research,

²⁸²Witt, C.; Lüdtkke, R.; Mengler, N.; et al., How healthy are chronically ill patients after eight years of homeopathic treatment? Results from a long term observational study, *BMC Public Health* 8 (2008) 413

²⁸³Sharples, F.; Van Haselen, R.; Fisher, P., NHS patients' perspective on complementary medicine, *Complement. Ther. Med* 11 (2003) 243–248

²⁸⁴Fisher, P.; van Haselen, R.; Hardy, K.; et al., Effectiveness Gaps: A new concept for evaluating health service and research needs applied to complementary and alternative medicine, *J. Altern. Complement. Med.* 10 (2004) 627–632

²⁸⁵Walach H., Jonas W.B.; Homeopathy; The Therapies; pp 229–45

²⁸⁶Hingorani AD, Windt DA van der, Riley RD, Abrams K,

studying effect modifiers: variables that influence outcome of treatment. This type of research becomes increasingly important in medicine since the emergence of pharmacogenomics, learning that the medicine should not only fit the indication, but also the person (personalised or stratified medicine).²⁸⁶ This principle of personalised medicine has always been the core of homeopathic philosophy. Prognosis research resembles diagnosis research: several symptoms and personal characteristics increase or decrease the probability that a specific medicine will work, instead of the probability of a specific diagnosis.

As in conventional medicine prognosis research is becoming more important. There have been retrospective observational studies,^{287, 288} and a prospective observational study.²⁸⁹

Place of Randomised Control Trials in Homeopathy

There is a need to understand why Homeopathy, which has managed to survive 200 years unscathed, despite the attacks of sceptics and non-believers, fails to convert its clinically acknowledged results in a systematically staged research model like RCT. Many explanations exist, some pertaining to understanding of the disease concept and factors that contribute in its recovery, some to more complex approach in homeopathic treatment, and still some other to the design of the research models, particularly RCTs. We shall deal with all one by one.

As far as the understanding for disease is concerned, the assumption that disease is merely a pathological change, the recovery of which can be marked by a specific effect of a drug on a diagnostically assessable parameter is a

Moons KGM. Prognosis research strategy (PROGRESS) 4.

Stratified medicine research. *BMJ* 2013;345:e5793

²⁸⁷Wassenhoven M van. Verification of homeopathic symptoms. 2008 B Jain Archibel pub. Assesse, Belgium

²⁸⁸Rutten ALB, Frei H. Frequently occurring polar symptoms assessed by successful cases. *Homeopathy* 2012;101:103-111

²⁸⁹Rutten ALB, Stolper CF. Diagnostic test evaluation by patient-outcome study in homeopathy: balancing of feasibility and validity. *J Eval Clin Practice* 2009;15:1230-1235

result of the Virchow's cellular pathology model of disease. However, this model has long been superseded by the psychosocial model of disease and health.^{290,291} An understanding needs to be developed that disease is a phenomenon of multifaceted causality and can be influenced by a number of possible routes, pharmacological specificity being only one of them. The effects of a therapy that lead to changes in the quantifiable parameter are the specific effects, while those that influence the disease through other routes achievable through more holistic treatment and counselling, are called non-specific effects. All therapies yield non-specific and specific effects, with a variable ratio of the two. Homeopathy, being a holistic medicine, relies on a self-regulation process where only the defence mechanism of an individual is stimulated to act in defence of the disease. It could also be hypothesized that most CAM therapies including Homeopathy, by instilling hope, which could be a conjoined result of prolonged counselling, holistic treatment, freedom from side effects etc., influences psycho-neuro-endocrinological axis,²⁹² or redress a delicate balance of physiological systems.²⁹³ In conventional medicine too, the non-specific effects of a treatment are sometime reported to be more productive.^{294,295,296} Going by this understanding of treatment, the result of a therapy needs to be additive of both the specific and non-specific effects, which is not possible to infer from blinding methods in a control study.

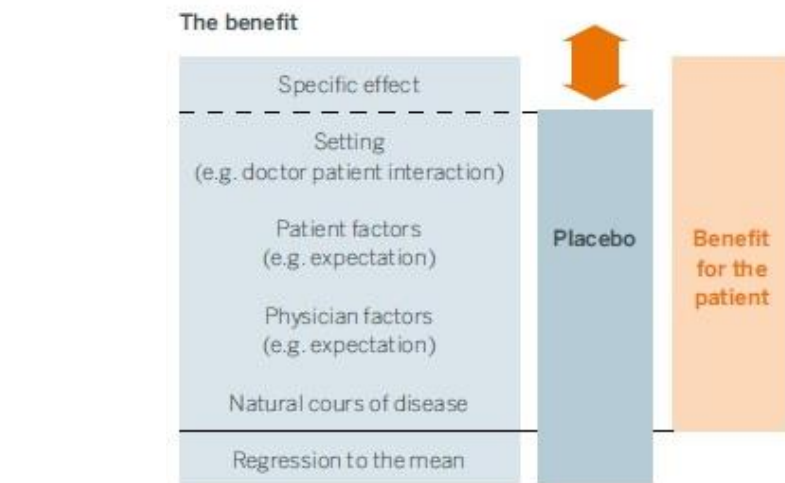
Homeopathic treatment, so to speak, has more to deal within its scope of recovery than mere removal of a specific pathology. Additionally, the points to be focused in a case are rather individualistic and bear reflection of both mental and physical states. It is, therefore, improper to take into account only the specific effects reflected physically by patients of a homogenous group for

²⁹⁰Engel GL 1981 The need for a new medical model: a challenge for biomedicine. In: Capla AL, Engelhardt T, McCartney J (eds) Concepts of health and disease. Addison-Wesley, Reading, MA

²⁹¹Engel GL 1982 Thebiopsychosocial model and medical education. New England Journal of Medicine 306: 802-05

²⁹²Frank JD 1989 Non-specific aspects of treatment: The view of a psychotherapist. In: Shepherd M, Sartorius N (eds) Non-specific aspects of treatment. Huber, Berne, pp 95-114

²⁹³Walach H., Jonas W.B. and Lewith G.: The role of outcomes research in evaluating complementary and alternative medicine; Lewith G., Jonas W.B. and Walach H.; Clinical research in complementary therapies; 1st edition; 2002; pp



interpreting the results of such complex treatment, in which the medication would vary from person to person, even if they belong to same disease classification. Conversely, a set of individuals suffering from different diseases could also be given the same medicine, if other characteristic symptoms indicate so. To say then that Homeopathy, which treats an individual in a relatively complex manner than its conventional counterpart, doesn't work because it fails in RCTs, where only cause-and-effect relationship is studied, is drawing a far-fetched conclusion.

As it is, in the real world

Fig. 1

situation, the validity of various research designs, especially RCTs has been challenged. A successful RCT, with maximum internal validity and highly accurate specific effects, found in a homogenous group of patients, has a limited viability in a real-world situation where the patients are usually co-morbid and with varied levels of severity. Further, the blinding posed by the design is often

29-45

²⁹⁴Moerman DE 1983 General medical effectiveness and human biology: placebo effects in the treatment of ulcer disease. Medical Anthropology Quarterly 14: 3-16

²⁹⁵Kirsch I, Sapirstein G 1998; Listening to Prozac but hearing placebo: a meta-analysis of antidepressant medication. Prevention and Treatment: <http://journals.apa.org/prevention1:2a>

²⁹⁶Walach H, Maidoff C 1999 Is the placebo effect dependent on time? In: Kirsch I (ed) Expectancy, experience, and behaviour. American Psychological Association, Washington DC, pp 321-32

breached, mostly at the doctors' end, who can easily guess the treatment group because of the resulting side effects. Although this impacts the results of the studies, such shortcomings are rarely addressed when evaluating the evidence. Further, with the funding springing from the pharmaceutical industries, the results could be positively biased to suit their needs.²⁹⁷

Therefore, if we want to evaluate Homeopathy, or any other medical science, in a pragmatic manner, the real-world analysis is necessary. RCT may not be the best option to produce the maximal therapeutic response, especially in homeopathy, and may even be ethically questionable considering the lopsided design of this model. It is argued that outcomes studies and non-randomised, quasi-experimental comparisons are the most reliable research designs, if Homeopathy were to be studied for its benefits. The outcomes of such studies will also impact the general public more than the RCTs that are generally considered gold-standard in research but fail to immediately benefit the public at large due to their low external validity (Fig. 1). Blinded, placebo-controlled RCTs must, therefore, be backed with outcome and comparison data, which, in turn, would mean higher investment and more time. On the contrary, the outcomes studies and non-randomised, quasi-experimental comparison studies are not valued scientifically owing to the chance of running into bias and subjective comparability. However, these studies are often more worthwhile from a practical, patient-oriented and political point of view. Also, it goes without saying that no single method is capable of solving all the problems. RCTs and outcome studies can also be executed together, by nesting one within the other or following a RCT with a long-term observational phase.²⁸⁵

It can be concluded that outcomes research is a valuable tool in evaluating homeopathy. It cannot replace controlled and well-established trial methodology but it can and should complement it. It adds the element of practical relevance and external validity to the otherwise detached research efforts of RCTs. Further, it enables gathering data which RCTs are not designed for. Also, the

²⁹⁷ Walach H., Jonas W.B. and Lewith G.: The role of outcomes research in evaluating complementary and alternative medicine; Lewith G., Jonas W.B. and Walach H.; Clinical research in complementary therapies; 1st edition; 2002; pp 29-45

patients who do not wish to be randomised, or have strong preferences and belief systems in Homeopathy can also be a part of this study. The outcomes research also allows one to study the long-term effects of a treatment, which is another important aspect not covered by RCT. As such, the scientific community needs to be more open-minded about unconventional methods for homeopathic research, as these could lead to a different outcome altogether.

Model Validity – A tool to assess homeopathic research

BioMedCentral Medical Research and Methodology systematic reviews of homeopathic publications

This method was carved out to validate a research through not only the scientific quality of a publication but also by giving equal importance to the homeopathic medical approach. To allow this assessment in a systematic way, a group of researchers (ISCHI) elaborated and tested a new method for appraising model validity of randomized controlled trials of homeopathic treatment: multi-rater concordance study.

A paper²⁹⁸ on this describes a method for assessing the model validity of RCTs of homeopathy. To date, only conventional standards for assessing intrinsic bias (internal validity) of trials have been invoked, with little recognition of the special characteristics of homeopathy. They aimed to identify relevant judgmental domains to use in assessing the model validity of homeopathic treatment (MVHT). We define MVHT as the extent to which a homeopathic intervention and the main measure of its outcome, as implemented in a randomized controlled trial (RCT), reflect 'state-of-the-art' homeopathic practice.

To reach this goal they used an iterative process, within an international group of experts. They developed a set of six judgmental domains, with associated descriptive criteria. The domains address:

(I) the rationale for the choice of the particular

²⁹⁸ Mathie. R.T. & all (2012). "Method for appraising model validity of randomized controlled trials of homeopathic treatment: multi-rater concordance study." BMC Medical Research Methodology 2012, 12-49.

- homeopathic intervention;
- (II) the homeopathic principles reflected in the intervention;
- (III) the extent of homeopathic practitioner input;
- (IV) the nature of the main outcome measure;
- (V) the capability of the main outcome measure to detect change;
- (VI) the length of follow-up to the endpoint of the study.

Six papers reporting RCTs of homeopathy of varying design were randomly selected from the literature. A standard form was used to record each assessor's independent response per domain, using the optional verdicts 'Yes', 'Unclear', 'No'. Concordance among the eight verdicts per domain, across all six papers, was evaluated using an appropriated statistical method. (65)

The six judgmental domains enabled MVHT to be assessed with 'fair' to 'almost perfect' concordance in each

case. For the six RCTs examined, the method allowed MVHT to be classified overall as 'acceptable' in three, 'unclear' in two, and 'inadequate' in one.

They concluded that future systematic reviews of RCTs in homeopathy should adopt the MVHT method as part of a complete appraisal of trial validity. This work is ongoing now.

In the Journal Homeopathy (2013);102:3-24, Mathie, R.T. & all published the next step. Looking at randomised controlled trials of homeopathy in humans and characterising the research journal literature available for systematic review, they concluded that from the 489 available records, 226 needs to be rejected as non-journal, minor or repeat publications, or lacking randomisation and/or controls and/or a 'homeopathic' intervention. The 263 accepted journal papers will be the basis for a forthcoming programme of systematic reviews.

Homeopathy in various specialties

Considering homeopathy's individualize patient approach, the scientific framework is much broader than could be expected. Homeopathic physicians are mostly focused on research about individualization, similarity and globality. That does not exclude research on some diagnoses and a lot of indications are reaching a IIIb level of evidence and would be further considered for more research.

Examples without reference are from the 63rd LMHI Congress on Evidence Based Homeopathy (2008); later publications are referenced:

Allergology

- Flitchev S, Nestorov I, Groudev D, Ivanov M. Les possibilités de l'homéopathie dans la prévention et dans le traitement de l'asthme chez des enfants atopiques. Etude prospective incluant 64 enfants.
- Jurj G. Homeopathic treatment of atopic dermatitis in children. Prospective study on 35 patients.
- Kekata M, Villano G, Ben Salah-Mezghanni S, Pellegrini A,

Hayouni A, Mtiraoui A. Asthme allergique et thérapeutique homéopathique. Prospective study on 6 patients. Macri F. Medical audit of paediatric patients with allergic disorders. Comparison study of two groups, 52 patients treated with allopathy, 50 patients treated with homeopathy.

- Marijnen P, Fayard AL. Hypericum perfoliatum et Lucite estivale bénigne: de l'observation vétérinaire à l'indication thérapeutique. Preventive, prospective, multi-centric study on 105 patients.
- Popowski P. Dermatite atopique et recherche clinique en médecine ambulatoire. Retrospective study on 27 patients. Vander Brempt X, Cumps J, Capieaux E. Efficacité clinique de 2LALERG dans le rhume des foins. Double-blind placebo controlled study on 41 patients.
- Gründling C, Schimetta W, Frass M. Real-life effect of classical homeopathy in the treatment of allergies: A multicenter prospective observational study. All clinical symptoms were shown to improve substantially,

in most cases quite markedly ($p < 0.001$). 62 % of patients undergoing conventional medication therapy at baseline were able to discontinue at least one medication, while the remaining patients (38 %) reported a dose reduction in at least one medication. No side effects were reported during treatment. *Wien Klin Wochenschr.* 2012 Jan; 124(1-2):11-7. Epub 2011 Dec 8.

- Bellavite P et al. published a systematic review of clinical research including a special section on respiratory allergies, in general the observed results are reaching a clear evidence level. *Advances in homeopathy and immunology: a review of clinical research.* *Frontiers in Biosciences S3*, 1363-1389, June 1, 2011.
- Van Wassenhoven M. published a paper about Allergic conditions and especially the use of *Arsenicum album* evaluated using the LR approach retrospectively. The effects are mathematically confirmed. *Clinical verification in homeopathy and allergic conditions.* *Homeopathy* (2013) 102,54-58.
- H.F. Shafei et al. published a paper about individualized homeopathy in a group of Egyptian asthmatic children and it improved the severity of asthma in children. *Homeopathy* (2012); 101:224-230.
- Koji Hozama presented a randomized, double blinded, placebo control trial about Japanese Cedar pollinosis using Cedar pollen 30C in 125 patients followed during 3 years. The results suggest that this remedy has an advantage over placebo in reducing anti-allergic medicine consumption of these patients. *Proceedings of 67 LMHI Congress.*
- Ullman Dana and Frass Michael published a review of Homeopathic Research in the Treatment of Respiratory Allergies and concluded from the publications on homeopathic treatment in allergic patients describe significant effects. *Altern Med Rev* 2010;15(1):48-58 or www.thorne.com/altmedrev/.fulltext/15/1/48.pdf

Dentistry

- Camacho C, Lozano S, Melo M, Pedraza C, Vanegas S, Benitez G, Palencia R, Revelo I. Effectiveness of homeopathic medicine *Arnica 7CH* versus *Naproxen*® on post operative extraction of third molar including pain relief (15 patients).
- Clercq JM, Capieaux E, Jenaer M. Micro-immunotherapy applied to *parodontal diseases*. Follow-up of 20 patients. Jussara Diffini SM. Oral health of 6 to 14 year-old children treated with allopathy and homeopathy. Comparison study on 599 children.
- Jussara Diffini S.M. Evaluation and comparison of salivary conditions of children with respiratory problems treated with allopathic and homeopathic medications. Comparison study on 90 patients.
- Tiba H, Contin I, Itagaki C, Wierzchon LM, Fachada AP, Feigelstein GM. Application of the homeopathy in patients of TMD (Temporo Mandibular disorders) and Orofacial Pain. Follow-up of 50 patients.
- Fayard AL. Etude observationnelle sur la prise en charge de la poussée dentaire en France. *Entretiens Internationaux de Monaco* 24/25 April 2010- Assessment of Knowledge and Research in Homeopathy.
- C. Raak et al. published a systematic review and meta-analysis on the use of *Hypericum perforatum* for pain conditions in dental practice. From this review of 21 relevant published papers. All studies included used *Arnica Montana* above *Hypericum*, the results are more influenced by *Arnica* than *Hypericum*. Further RCTs using *Hypericum* alone should be performed. *Homeopathy* (2012);101:201-210.
- Mazzocchi and F. Montanaro published an observational study of the use of *Symphytum 5CH* in

the management of pain and swelling after dental implant surgery. *Homeopathy* (2012);101:211-216.

Dermatology

- Chakraborty D, Chakraborty T, Das S, Sengupta J. A Randomized Double Blind Clinical Trial of A Homeopathic Medicine In The Treatment of Trophic ulcer and Neuropathy in Leprosy. *Indian Journal of Research in Homeopathy*. Vol 3, N°4, October-December 2009;54-65. Follow-up of 160 patients.
- Chandrasekhar Goda & all. Role of homeopathic treatment in scabies infection in advasi children attending resident schools. Prospective, randomized, placebo controlled study on 300 children. *Indian Journal of Research in Homeopathy*. Vol 4 N°2 April-June 2010 p 33-40.
- Jitesh T.K. Knowledge, attitude and practices of homoeopathic doctors in the treatment of psoriasis. Prospective observational survey of 1995 cases. *Proceedings 66th LMH I Congress 2011*.

Gerontology

- Teut M, Lüdtke R, Willich SN, Witt CM. Homeopathic treatment of elderly patients – A prospective observational study with 2 years follow-up of 83 patients. *Proceedings 64th LMHI Congress*.

Gynecology

- Berrebi A, Parant O, Ferval F, Thene M, Ayoubi JM, Connan L, Belon P. Traitement de la douleur de la montée laiteuse, non-souhaitée, par homéopathie dans le post-partum immédiat. *J. Gynecol Obstet Biol Reprod* 2001 ;30 :353-557. Chiche JL. *Actea Racemosa* 30CH dans la dystocie cervicale pendant l'accouchement. Etude sur 24 parturiantes. *Dungler T, Colas A. Sanguinaria Canadensis* 7CH in the

treatment of flushes. Study including 87 patients.

- Honneger F, Lavallee V, Aguerre C, Cresp C, DesmontyMinjon ML, Doussin-Dirks A, Ducos-Klingebiel S, LeblancLebarazer A. Mycoses vaginales récidivantes et traitement homéopathique: un travail prospectif sur 13 patients. *Masson JL, Colas A. Prise en charge homéopathique des bouffées de chaleur chez la femme ménopausée. Prospective, multi-centric study on 438 patients. Homeopathy* 2008 ;97(1) :10-15.
- Roca M. Treatment of Prolactinoma with homeopathy. Follow-up of 16 patients.
- Shangloo GK. Evidence Based Medicine – Homeopathic cure to uterine fibroid and ovarian cyst. Follow-up of 123 patients.
- Shukla P. Evidence Based Study on breast lumps and homeopathic management. Follow-up of 480 patients. *Cardigno P. Homeopathy for the treatment of menstrual irregularities: a case series. Homeopathy*. 2009;98:97-106. Colau JC et al. Efficacy of a non-hormonal treatment, BRN-01, on menopausal hot flashes: a multicenter, randomized, double-blind, placebo-controlled trial including 108 women and showing a significant effect on Hot Flash Related Daily Interference Scale (HFRDIS) compared with placebo. *Drugs R.D.* 2012 Sept 1;12(3):107-19.

Endocrinology

- Grelle L.C.E. Homeopathic treatment of subclinical hypothyroidism. Prospective follow-up of 5 patients.
- Baroli A. Micro-immunotherapy applied to auto immune thyroid pathologies: clinical cases of chronic thyroïditis. Follow-up of two patients.
- Relton C. A 'cohort multiple' pragmatic randomised controlled trial of treatment by a homeopath for women with menopausal hot flushes who cannot

take hormone replacement therapy. Observational cohort of 856 women. Proceedings of 66th LMHI Congress. 2011.

- Rajkumar Manchanda presented a randomized survey of autoimmune thyroiditis in 194 children followed during 18 months showing statistically significant decrease of TSH levels and antibodies titres for the homeopathic treated group. Proceedings of 67th LMHI Congress.

Infectiology

- Arjoun H, Démonceaux A, Monastiri K. Les bronchiolites du nourrisson et l'homéopathie. Etude comparative allopathie-homéopathie sur 40 cas.
- Bahloul H, Musial E, Mahfoudh A. Traitement homéopathique de la varicelle de l'enfant. Etude comparative de l'évolution de 16 enfants et la littérature.
- Derbel, Belkadhi M, Villamo G, Mtiraoui A. Rhinopharyngites à répétition chez l'enfant, prise en charge en homéopathie. Etude prospective de 25 cas.
- Fayard AL. Traitement de l'irritation oculaire par un collyre homéopathique associant Euphrasia, Calendula et
- Magnesia Carbonica (Homeoptic®). Placebo controlled study on 31 patients.
- Rusev DS, Petrova G. Sulfur iodatum – Subsidiary homeopathic medicine on infectious diseases of children. Follow-up of 24 children with long lasting fever of unknown origine.
- Nyapati SR, Punyamurty HM, Jani D. Non-surgical intervention in nasal sinus polyp and treatment by homeopathy. A retrospective and comparative study. Proceeding 65th LMHI Congress.
- Witt CM, Lüdtker R, Willich SN. Homeopathic treatment of patients with chronic sinusitis: A prospective observational study with 8 years follow-up. BMC Ear Nose Throat Disorder. 2009;9(1):7.
- Chaturbhuja Nayak & all. A multicentric open clinical trial to evaluate the usefulness of 13 predefined homeopathic medicines in the management of acute rhinitis in children. (638 children) Indian Journal of Research in Homeopathy Vol 4, N°2, April-June 2010 p 23-32.
- Bordet MF. Intérêt de la thérapeutique homéopathique chez les patients traités par interféron Ribavirine pour une hépatite C. Entretiens Internationaux de Monaco 24/25 April 2010-Assessment of Knowledge and Research in Homeopathy.
- Rérole F., Vincent S. Study of the limitation of the adverse effects of quinine by the concomitant administration of China rubra 7C when treating malaria in pregnant women in Cotonou (Benin). Entretiens Internationaux de Monaco 24/25 April 2010-Assessment of Knowledge and Research in Homeopathy.
- Taylor JA, Jacobs J. Homeopathic ear drops as an adjunct to standard therapy in children with acute otitis media. Homeopathy (2011) 100, 109-115.
- Bellavite P et al. published a systematic review of clinical research including a special section on infections of upper airways and ear-nose-throat ailments, in general the observed results are reaching a clear evidence level. Advances in homeopathy and immunology: a review of clinical research. Frontiers in Biosciences S3, 1363-1389, June 1, 2011.
- Mazzoli S et al. Published a prospective comparative survey with a follow-up of 4 months on high risk Human Papillomavirus in genital infections of both male and woman. In the treated group 50 % negative testing was obtained at the end of the survey for only 7 % in the untreated group. Int J of High Dil Res (2012); Vol 11 n°40:134-135.

Nephrology

- Singh A. Renal failure: can dialysis be stopped?

Proceeding 65th LMHI Congress.

- Siddiqui VA & all. To explore the utility of *Lycopodium clavatum* in urinary calculi. Indian Journal of Research in Homeopathy. July-September 2010;Vol 4 n°3:34-43. Kamal L, Singh M, Singh V, Kumar R. Chronic kidney disease: an evidence based clinical study to assess the efficacy of homeopathic drugs in its management. Followup of 301 patients. Proceedings 66th LMHI Congress 2011.

Neurology

- Adler UC, Paiva NMP, Cesar AT, Adler MS, Molina A, Padula AE, Calil HM. Individualized homeopathic medicines versus fluoxetine for the acute treatment of adults with depression: double-blind randomized non inferiority trial on 59 patients.
- Bolognani F, Mendes F, Kede J, Mendes P. Homeopathy and muscular dystrophy (Duchene, Becker, Limb Girdle, Steiner). Study on 242 patients.
- Bolognani F, Mendes M, Mendes A, Kede J, Maia A. Relation between *plumbum metallicum* and Progressive Spinal Amiotrophy in Brasil. Study on 44 patients.
- Bolognani F, Mendes D, Martins S, Maia A, Serpa C, Damasceno A, Fonseca G, Teixeira M, Durao F. Attention Deficit Hyperactivity Disorder in relation with *Zincum metallicum*. Study on 33 patients.
- Damaceno AMG. Bolognani F, Xavier MF, Mendes AP, Serpa C. Homeopathic therapy on a study of Infantile Cerebral Palsy. 9 years follow-up of 275 patients.
- Fonseca GR, Bolognani F, Durao F, Souza K, Acioly M, Bagarollo M. Study of homeopathic medication effects on cognitive and motor performance in autistic children. Follow-up of 7 children with a comparison group of 23 children.
- Kivellos S, Papatriantafyllou J, Papilas K, Karagerogiou K, Vithoulkas G. Practicing classical homeopathy in a headache clinic of a major public hospital in Athens, Greece. Four years experience treating migraine patients. Follow-up of 36 patients.
- Maia AP, Bolognani F, Mendes F, Fonseca G. The effect of homeopathic treatment in controlling aggressiveness in patients with cerebral palsy. 9 years follow-up in 57 patients. Martins S, Bolognani F, Maia AP, Fraga CS, Mendes M. Choreo Athetosis condition and homeopathy. Follow-up of 75 patients.
- Mateescu RA. Attention Deficit Hyperactivity Disorder in children and homeopathic treatment. Follow-up of 15 children.
- Mendes MFX, Carillo Jr R, Gosik MS, Bolognani FA. Parkinson's disease and homeopathic therapy (*serotoninum*). Follow-up of 4 patients.
- Naghiu NR. Homeopathic treatment and family input in treatment of autism. Prospective study on 118 patients. Serpa C, Bolognani F, Martins S, Mendes F, Maia AP, Fonseca G. Influence of homeopathic drug on cognition of patients with cerebral palsy. Follow-up of 275 patients. Teixeira MIM, Bolognani F. Spastic condition and Homeopathy. Retrospective study on 54 patients.
- Roberfroid M, Cumps J, Henry MF, Jenaer M. Micro-immunothérapie et traitement de la sclérose en plaque: résultats d'une évaluation clinique de 59 patients.
- Naudé DF, Couchman IMS, Maharaj A. Chronic primary insomnia: Efficacy of homeopathic *simillimum*. Randomized, double-blind, placebo-controlled study on 30 patients. Homeopathy. 2010 ;99 :63-68.
- Bell IR and al. Measurable effects of homeopathic medicines in Insomnia. Double-blind, placebo-controlled study on 54 patients. Sleep Medicine doi. 10.1016/j.sleep.2010.03.013
- Gupta N and all. Homoeopathic medicinal treatment of autism. Prospective open survey. Indian Journal of Research in Homeopathy. October-December 2010;Vol 4 n°4:19-28.
- Balan S. Migraine – An Experience Survey. Retrospective survey of 3245 patients. Proceedings 66th LMHI

Congress 2011.

- Helène Renoux presented 2 pediatric clinical cases; one of autism and the other on the contrary pathological psychical fusion using a same indicated remedy *Olibanum sacrum*. Proceedings of 67th LMHI Congress.
- Ronko Itamura presented a serie of 31 depression cases using a three-step indication of recovery and concluded that the homeopathic treatment is a very useful strategy in addition to/or instead of conventional treatment for depression. Proceedings of 67th LMHI Congress.

Oncology

- Pevenage S. Expériences pratiques vétérinaires en oncologie en utilisant 2LC1 en association avec les traitements conventionnels. Follow-up de 15 cas.
- Schlappack O. Homeopathic treatment of radiation-induced itching in breast cancer patients. A prospective observational study. *Homeopathy*. 2004; 93:210-215.
- Bagot JL. L'homéopathie dans les soins de support en cancérologie. Entretiens Internationaux de Monaco 24/25 April 2010- Assessment of Knowledge and Research in Homeopathy.

Pediatrics

- Kruse S, Abendroth K, Schetzek S, Dorcsi-Ulrich M. Complementary homeopathic therapy in the neonatological intensive care unit as observed in 25 patients presenting intracerebral hemorrhage third degree. Proceedings 64th LMHI Congress.
- Kruse S, Abendroth K, Schetzek S, Dorcsi-Ulrich M. Complementary homeopathy in pediatric oncology. Proceedings 64th LMHI Congress.
- Patel M, Pawaskar N, Mundra P, Tamboli P, Kothare G. An approach to acute diarrhoeal disorders through sector and constitutional homoeopathic treatment in tribal children attending Balwadis. RCT. *Indian Journal*

of Research in Homeopathy. Vol 4, n°4 October-December: 36-48.

- Kusse FC, Sevat MHL. Kindergeneeskunde en homeopathie. Overview of publications. *Tijdschr. Kindergeneeskd.* 2011;79(nr 6):168-173.

Pharmacology

- Goyens M. Rules of Good Practice in Pharmacy. Hendrickx J. Internal Quality Standards and Methods for Homeopathic Medicinal Preparations in Pharmacies. Mouyart MA. A list of first safe dilutions, a tool for all. Sollie P. Availability and accessibility of raw materials and stocks. Problems in the daily pharmaceutical practice.

Prostate

- Gupta G, Singh JP, Tandon S, Singh S, Nayak C, Singh H, Raveendar Ch, Nair KRJ, Oberai P. Evidence based clinical study to assess the usefulness of homeopathic medicines in patients with Benign Prostatic Hyperplasia. *Indian Journal of Research in Homeopathy*. 2010. Vol 4, n°4 October-December: 49-56.
- Confirmed by Praveen Oberai et al in a multicentric prospective observational study on 231 patients. *Indian Journal of Research in Homeopathy*. Vol 6, N°3; JumySpetember 2012:16-25.

Rheumatology

- Relton C, Smith C, Raw J, Walters C, Adebajo AO, Thomas KJ, Young TA. Healthcare provided by a homeopath as an adjunct to usual care for Fibromyalgia (FMS): results of a pilot RCT. *Homeopathy*. 2009; 98:77-82.
- Witt CM, Lüdtke R, Baur R, Willich SN. Homeopathic treatment of patients with chronic low back pain: A prospective observational study with 2 years' follow-up. *Clinical Journal of Pain*. 2009; 25:334-339.

Traumatology – Toxicology

- Khuda-Bukhsh A.R. Can homeopathy ameliorate sufferings of arsenic victims? A simplistic approach in management of a menacing rural health problem in India (contaminated ground water). Placebo-controlled double-blind study on 225 patients.
- Dobrev K. La place de l'homéopathie dans la préparation préanesthésique et dans la période postopératoire précoce dans département d'anesthésiologie et de soins intensifs de l'Hôpital Universitaire de Stara Zagora en Bulgarie.
- Jansen JP, Bol JGB, Andringa HH. Use of homeopathy in the treatment of post-traumatic stress disorder. Review of results in three homeopathic practices in Groningen. Retrospective study of 23 patients.
- This list is not exhaustive. A lot of cases series are regularly published in all areas of medicine. Topics are various and are linked to the main questions in medicine.

Tables for clinical research and cost-effectiveness studies

In the tables below, the data is assessed in columns:

- Condition/Study = Name of principal author, topic, number in the complete reference list;
- N = number of patients included in the survey;
- Design QoL = description of the design of the survey, used questionnaire;
- Test group = treated group under study;
- Control group = used comparison group if any;
- Results = major results of the survey

| Condition/Study | N | Design Economic Survey | Test group | Control group | Results |
|---|-----|--|--|---|---|
| Becker-Witt et al 2003 ²⁹⁹ Different chronic conditions | 493 | Prospective, comparative cohort study | Homeopathy and patients could opt for concomitant conventional therapy | Patients could opt for conventional therapy | Patients seeking homeopathic treatment had a better outcome overall compared with patients on conventional treatment. |
| Chauffer in 2000 (104) | | Compilation of nationally available data (secondary sources) | Homeopathy | - | Homeopathic medication prices per unit lower than allopathic ones (number of prescriptions unknown, though). Fewer reimbursements for homeopathic doctors, only 1 % of reimbursement of French national health insurance system |
| Frei et al 2001 ³⁰⁰ Acute otitis media | 230 | Prospective, uncontrolled interventional study | Homeopathy | - | 72% resolved within 12 hours, 28 % were given antibiotics. Conventional treatment was 14 % more expensive (109 SFR vs. 94,6 SFR) |
| Frenkel et al 2002 ³⁰¹ Atopic and allergic disorders | 48 | Prospective, uncontrolled interventional study | Homeopathy primarily in addition to conventional treatment | - | Before intervention on average 3.1 different conventional drugs/patient after 1.6 (p=0.001). Before intervention 31 used |

²⁹⁹Becker-Witt et al. Effectiveness and costs of Homeopathy compared to conventional medicine – a prospective multicenter cohort study. London: The Royal Homeopathic Hospital, 2003.

³⁰⁰Frei H, Thurneysen A. Homeopathy in acute otitis media in children: treatment effect or spontaneous resolution? Br Homeopath J 2001 Oct ;90 (4):180 -2 90(4):180-182.

³⁰¹Frenkel M, Hermoni D. Effects of homeopathic intervention on medication consumption in atopic and allergic disorders. Altern Ther Health Med 2002 Jan -Feb ;8 (1):76 -9 8(1):76-79.

| | | | | | |
|--|-------------------------------|---|---|-------------------------|---|
| | | | | | conventional drugs (costs on average \$40) after intervention 35 (costs on average \$16). |
| Güthlin et al 2003 302 Different chronic conditions | 750 | Prospective, uncontrolled observational study | Homeopathy | - | Significant changes in quality of life, less sick leave. |
| Haselen et al 1999 303 Rheumatoid arthritis | 89 (random sample out of 427) | Retrospective study | Homeopathy (n=89) Acupuncture (n=4) | - | 32% of patients reduced conventional drugs. Total costs to treat 89 patients were 7129 GBP (including medication, staff time and diagnostic procedures - 29 % of the costs for consultation, 22% for conventional drugs) |
| Jain 2003 304 Reduced costs by homeopathic drug prescription | 109 | Prospective uncontrolled observational study | Homeopathy | - | Savings by homeopathic treatment calculated by deducting costs for homeopathic medication from conventional medication (hypothetical) for same diagnosis and same duration amounted to 60.40 Pound Sterling. |
| Kooreman et al. 2012 (111) All conditions | 151.952 | Retrospective Health Insurance Dataset comparison | Alternative medicine including homeopathy | Conventional | Reduction of 7 % of costs for GP-CAM due to lower hospitalisations and lower pharmaceutical costs; lower mortality rate. |
| Rossi et al. 2009 305 Respiratory Diseases | 105 | Retrospective observational study | Homeopathy | Conventional | Reducing conventional remedies use, 42,4 % costs saved even 71,1 % in chronic asthma. |
| Schafer et al. 2002 306 Hay fever, asthma, atopic eczema, food hypersensitivity | | Population-based nested case control study | Alternative Medicine | No alternative medicine | 26. % used CAM, patients were significantly younger and better educated. CAM mostly provided by MDs, median costs for single and entire treatment of 4 and 205 euro. CAM User scored efficacy of conventional therapy lower than non user (p<0,001) |
| Sevar. 2005 307 | 455 | Prospective cohort | Homeopathy | - | Conventional Drug cost saving of £ |

³⁰²Güthlin C, Walach H. Prospektive Dokumentationsstudie in der niedergelassenen Praxis- ein Erprobungsverfahren zur Akupunktur und Homöopathie. *EHK* 2001;186-194.

³⁰³van Haselen RA, Graves N, Dahiya S. The costs of treating rheumatoid arthritis patients with complementary medicine: exploring the issue. *Complement Ther Med* 1999; 7(4):217-221.

³⁰⁴Jain A. Does homeopathy reduce the cost of conventional drug prescribing? A study of comparative prescribing costs in general practice. *Homeopathy* 2003 Apr;92(2):71-6

³⁰⁵Rosi E, Crudeli L, Endrizzi C, Garibaldi D. Cost-benefit evaluation of homeopathic vs conventional therapy in respiratory diseases. *Homeopathy*. 2009;98:2-10.

³⁰⁶Schafer T, Riehle A, Wichmann HE, Ring J. Alternative medicine in allergies - prevalence, patterns of use, and costs. *Allergy* 2002; 57(8):694-700.

³⁰⁷Sevar R. Audit of outcome in 455 consecutive patients treated with homeopathic medicines. *Homeopathy* 2005;94:215-221.

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| All conditions | | study. | | | 39,90/patient/year. |
| Taieb et al. 2003308 Chronic allergic rhinitis. | 300 | Prospective, comparative cohort study | Homeopathy (HM) | Conventional treatment (CM) | At 3 months SF-12 score on physical dimension HM 51,8; CM 47,9 (p<0.05). Lowering of cost of care for patients from 45,74 € for CM to 27 € for HM. Lowering of cost of care for the social security system with 50 % for patients using HM. |
| Trichard et al 2003309 Anxiety disorders | 394 | Prospective, comparative cohort study | Homeopathy | Conventional treatment | The homeopathic drug strategy produced equivalent results but less overall costs reimbursed by the national health system |
| Trichard et al 2003 310 Acute Rhinopharyngitis | 499 | Prospective, comparative cohort study | Homeopathy | Conventional Therapy (antibiotics) | Comparable overall cost between both treatment strategies but less sick leave in the homeopathic group |
| Trichard et al. 2003 311 | 5549 | Cross-sectional descriptive survey | Homeopathy | - | Only costs for medication included – average overall cost 6.78 € of which 3.78 € were reimbursed |
| Wassenhoven et al 2004312 All conditions | 782 | Observational unselected study and comparison with nationally available data (secondary sources) | Homeopathy | - | Following homeopathic treatment there were significant reductions in consultations with other specialists and generalists, and in the cost of treatment. € 370 compared with € 287 The largest cost savings were made by patients with the worst ratings of their physical condition prior to seeking homeopathic treatment. |
| Witt et al 313 Atopic eczema | 135 | Prospect., comparative cohort study | Homeopathy | Conventional treatment | Comparable efficacy but fewer costs for the homeopathic group. |

³⁰⁸Taieb C, Myon E. Chronic allergic rhinitis, usefulness of the homeopathic treatment. *International Society of Pharmacoeconomics & Outcomes Research. 8th Annual International Meeting* May 18-21,2003.

³⁰⁹Trichard M, Chaufferin G. Cost-effectiveness study of treatment of anxiety disorders by homeopathic general practitioners. *Improving the success of homeopathy*, 2003.

³¹⁰Trichard M, Chaufferin G. Effectiveness, Quality of Life, and Cost of Caring for Children in France with Recurrent Acute Rhinopharyngitis Managed by Homeopathic or Non-Homeopathic General Practitioners. *Dis Manage Health Outcomes* 2004;12(6):419-427.

³¹¹Trichard M, Lamure E, Chaufferin G. Study of the practice of homeopathic general practitioners in France. *Homeopathy* ed. 2003, Vol92/3;135-139.

³¹²van Wassenhoven M, Ives G. An observational study of patients receiving homeopathic treatment. *Homeopathy* 2004 January,93:3-11.

³¹³Witt C. Effectiveness of homeopathy, an example of systematic research in children with atopic eczema. *Proceedings of 63rd LMHI Congress*. May 20-24, 2008.

| No. | Study | N | Design | Intervention | Control | Results |
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| 1. | Zanasi A, Mazzolini M, Tursi F, Morselli-Labate AM, Paccapelo A, Lecchi M. Homeopathic medicine for acute cough in upper respiratory tract infections and acute bronchitis. <i>Pulmonary Pharmacology and Therapeutics</i> , Volume 27, Issue 1, 2014, Pages 102-108. | 40 | A randomized, double-blind, placebo-controlled trial | A homeopathic syrup | Placebo | In each group cough scores decreased over time, however, after 4 and 7 days of treatment, cough severity was significantly lower in the homeopathic group than in the placebo one ($p < 0.001$ and $p = 0.023$, respectively). In both groups its viscosity significantly decreased after 4 days of treatment ($p < 0.001$); however, viscosity was significantly lower in the homeopathic group ($p = 0.018$). Instead, the subjective evaluation did not significantly differ between the two groups ($p = 0.059$). |
| 2. | Jong MC, Ermuth U, Augustin M. Plant-based ointments versus usual care in the management of chronic skin diseases: A comparative analysis on outcome and safety. <i>Complement Ther Med</i> . 2013;21:453-9 | 112 | Prospective mono-centric comparative analysis | Homoeopathic topical ointments containing mahonia or cardiospermum | Usual care creams containing calcipotriene and corticosteroids | After two years, the main outcome of responders to treatment was 52.3% (95%-CI: 36.1-64.9) in the ointment and 41.2% (95%-CI: 20.4-42.2) in the UC group. Change in SF-12 was not significantly different between both groups; PO: 5.4 (95%-CI: 3.4-7.3) versus UC: 3.2 (95%-CI: 1.5-4.9). The adjusted EQ-5D was found to be significantly different between the two groups after two years, in favour of the ointment group; PO: 0.113 (95%-CI: 0.052-0.174) and UC: -0.008 (95%-CI: -0.055-0.038). Other secondary outcome parameters such as patient satisfaction and number of adverse drug reactions were comparable. |
| 3. | Wassenhoven MV. Clinical verification in homeopathy and allergic conditions. <i>Homeopathy</i> | 3538 | Cohort | Individualized homeopathy | -- | For preventive treatments in hay fever patients, Arsenicum album was the most effective homeopathic medicine followed by Nux vomica, Pulsatilla pratensis, Gelsemium, Sarsaparilla, Silicea and Natrum muriaticum. For asthma |

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| | 2013;102:54-8 | | | | | patients, Arsenicum iodatum appeared most effective, followed by Lachesis, Calcarea arsenicosa, Carbo vegetabilis and Silicea. For eczema and urticaria, Mezereum was most effective, followed by Lycopodium, Sepia, Arsenicum iodatum, Calcarea carbonica and Psorinum. |
| 4. | Nayak C, Oberai P, Varanasi R, Baig H, Raveender Ch, Reddy GRC, et al. A prospective multi-centric open clinical trial of homeopathy in diabetic distal symmetric polyneuropathy. Homeopathy 2013;102:130-8 | 336 (247 analyzed) | Prospective multi-centric clinical observational study | Individualized homeopathy | -- | A statistically significant improvement in DDSPPS total score ($p = 0.0001$) was found at 12 months from baseline. Most objective measures did not show significant improvement. Lycopodium clavatum ($n = 132$), Phosphorus ($n = 27$) and Sulphur ($n = 26$) were the medicines most frequently prescribed. |
| 5. | Wadhvani GG. Homeopathic drug therapy homeopathy in chikungunya fever and post-chikungunya chronic arthritis: an observational study. Homeopathy 2013;102:193-8 | 126 | Prospective observational study | Individualized homeopathy | -- | Complete recovery was seen in 84.5% cases in a mean time of 6.8 days. 90% cases of PCCA recovered completely in a mean time of 32.5 days. |
| 6. | Coppola L, Montanaro F. Effect of a homeopathic-complex medicine on state and trait anxiety and sleep disorders: a retrospective | 71 | Open-label, retrospective, observational study | Homeopathic-complex medicine Datif-PC® | -- | Compared to baseline, the average State-Trait Anxiety Inventory (STAI)-state score at visit 2 decreased by more than 6 points, while the STAI-trait score decreased by more than 3 points. This was statistically significant ($p < 0.0001$) for both subscales. These findings were stable in subgroup analyses (gender, age and anxiety level). The |

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| | observational study. Homeopathy 2013;102:254-61 | | | | | average number of hours slept per night increased significantly at visit 2 compared to baseline (from 5.1 ± 1.1 to 5.56 ± 0.9 h, $p < 0.0001$). A marked decrease in the average number of night-time awakenings was also observed at the second visit (-42%, $p < 0.0001$) |
| 7. | Oberoi P, Balachandran I, Nair KRJ, Sharma A, Singh VP, Singh V, Nayak C. Homoeopathic management in depressive episodes: a prospective, unicentric, non-comparative, open-label observational study. Ind J Res Hom. 2013;7(3):116-25 | 83 | Prospective, non-comparative, openlabel, observational study | Individualized homeopathy | -- | A statistically significant ($P = 0.0001$, $P < 0.05$) difference in the meanscores of HDRS, using the paired t-test, was observed. The mean scores at baselineand at end were 17.98 ± 4.9 and 5.8 ± 5.9 , respectively. Statistically significantdifferences were also observed in the BDI and CGI scales. The most frequently usedmedicines were: Natrum muriaticum ($n = 18$), Arsenicum album ($n = 12$), Pulsatillanigricans ($n = 11$), Lycopodium clavatum ($n = 7$)and Phosphorus ($n = 6$). |
| 8. | Danno K, Colas A, Masson JL, Bordet MF. Homeopathic treatment of migraine in children: results of a prospective, multicenter, observational study. J Alt Complement Med. 2013;19(2):119-23. | 168 | Observationa l, prospective, open, nonrandomiz ed, noncompara tive, multicenter study | Individualized homeopathy | -- | The frequency, severity, and duration of migraine attacks decreased significantly during the 3-monthfollow-up period (all $p < 0.001$). Preventive treatment during this time consisted of homeopathic medicines in98% of cases (mean = 2.6 medicines/patient). Children spent significantly less time off school during follow-upthan before inclusion (2.0 versus 5.5 days, respectively; $p < 0.001$). The most common preventive medicines usedwere Ignatia amara (25%; mainly 9C), Lycopodium clavatum (22%), Natrum muriaticum (21%), Gelsemium (20%), andPulsatilla (12%; mainly 15C). Homeopathy alone was used for the treatment of migraine attacks in 38% of cases.The most commonly used medicines were Belladonna (32%; |

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| | | | | | | mainly 9C), Ignatia amara (11%; mainly 15C), Iris versicolor (10%; mainly 9C), Kalium phosphoricum (10%; mainly 9C), and Gelsemium (9%; mainly 15C and 30C). |
| 9. | Roll S, Reinhold T, Pach D, Brinkhaus B, Icke K, Staab D, et al. Comparative effectiveness of homeopathic vs. conventional therapy in usual care of atopic eczema in children: long-term medical and economic outcomes. PLoS ONE 2013;8(1):e54973. | 135 | Prospective multi-centre comparative observational non-randomized rater-blinded study | Individualized homeopathy | Standard conventional care | The adjusted mean SCORAD showed no significant differences between the groups at 36 months (13.7 95% CI [7.9-19.5] vs. 14.9 [10.4–19.4], p = 0.741). The SCORAD response rates at 36 months were similar in both groups (33% response: homeopathic 63.9% vs. conventional 64.5%, p = 0.94; 50% response: 52.0% vs. 52.3%, p = 0.974). Total costs were higher in the homeopathic versus the conventional group (months 31–36 200.54 Euro [132.33–268.76] vs. 68.86 Euro [9.13–128.58], p = 0.005) |
| 10. | Koley M, Saha S, Ghosh S, Mukherjee R, Kundu B, Mondal R, et al. Evaluation of patient satisfaction in a government homeopathic hospital in West Bengal, India. Int J High Dilution Res. 2013;12(43):52-61 | 390 | Institutional, cross-sectional, observational study | -- | -- | Patients' satisfaction appeared to be high. |
| 11. | Elio R, Marco P, Paola B, Marialessandra P, Mariella DS, Monia P, Monica DF. Homeopathy in the public health system: Outcome data from the | 1129 | Data collection survey | Different forms of homeopathy | -- | The most common presentations were for symptoms concerning respiratory (29.4%), digestive tract (17%) and dermatological(14.7%) diseases. A total of 47% of patients reported major improvement or even resolution of their clinical picture (GHHOS +3+4); an extremely low percentage of treatment with no results (10%); and a negligible |

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| | Homoeopathic Clinic of the Campo di Marte Hospital, Lucca, Italy (1998–2010). European J Integr Med. 2013 (article in press) | | | | | percentage of worsening (0.5%). The younger the age the more successful the therapy outcome ($p < 0.001$) and longer treatment appeared to give better results ($p < 0.001$) |
| 12. | Farrer S, Baitson ES, Gedah L, Norman C, Darby P, Mathie RT. Homeopathic prescribing for chronic and acute periodontal conditions in 3 dental practices in the UK. Homeopathy 2013; 102:242-7 | 51 | Data collection survey | Individualized homeopathy | -- | At least one follow-up (FU) appointment was reported for each of 46 patients (22 chronic [6 with IDS, 16 without IDS]; 24 acute [10 with IDS, 14 without IDS]). In chronic cases, strongly positive outcomes (score of +2 or +3) were reported by 2 (33.3%) of 6 IDS patients and by 1 (6.3%) of 16 non-IDS patients. In acute cases, strongly positive outcomes were reported by 7 (70%) of 10 IDS patients and by 8 (57.2%) of 14 non-IDS patients (no statistically significant difference between sub-groups). The FU conditions most frequently treated with homeopathy were chronic periodontitis (19 patients) and acute periodontal abscess (11 patients). |
| 13 | TREATMENT OF SYMPTOMATIC LEIOMYOMA OF UTERUS: AN OPEN OBSERVATIONAL PILOT STUDY | 45 | Homeopathic Links, Volume 27, Issue 1, Spring 2014, Pages 50-55. | Ghosh S, Mundle M, Chakraborty B, Saha S, Koley M, Hossain SI. | -- | The most frequently consulted alternative therapists for uterine fibroids (leiomyomas) are the homeopaths; however, there is a paucity of research evidence. Based on a study involving 45 recruited patients with symptomatic uterine fibroids, the authors conclude that individualized homeopathy can be regarded as effective in this condition; however, randomised controlled trials are worth investigating. Source: http://www.thieme-connect.com/products/ejournals/abstract/10.1055/s-0033-1350967 |

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| 14 | HOMEOPATHY FOR INFERTILITY TREATMENT: A CASE SERIES | | Clinical and Experimental Obstetrics and Gynecology, Volume 41, Issue 2, 2014, Pages 158-159. | Kalampokas T, Botis S, Kedikgianni-Antoniou A, Papamethodiou D, Kivellos S, Papadimitriou V, Salvanos G, Paparistidis N, Gavaris I, Sofoudis C, Kalampokas E, Farmakides G, Vithoulkas G. | Homeopathy has been used in the past for treating a broad aspect of diseases. In gynecology, its use remains limited. Taking under consideration its clinical aspects, the authors attempted to use it for treating female sub fertility problems. With this study, the authors present five cases of female infertility treated successfully with the use of homeopathic treatment in a large obstetrics-gynecology Hospital in Athens. http://www.ncbi.nlm.nih.gov/pubmed/24779242 |
| 15 | INTEGRATIVE HEALTH CARE METHOD BASED ON COMBINED COMPLEMENTARY MEDICAL PRACTICES: REHABILITATIVE ACUPUNCTURE, HOMEOPATHY AND CHIROPRACTIC | 64 | African Journal of Traditional, Complementary and Alternative Medicine, Volume 11, Issue 1, 2013, Pages 180-186. | Rodríguez-van Lier ME, Simón LM, Gómez RE, Escalante IP. | 64 patients rotated by the 3 areas taking an average of 30 meetings with rehabilitative acupuncture, 12 with homeopathy and 10 with chiropractic in January 2012 - 2013. We included the environmental aspects, biological, emotional, and behavioural to identify, recognize and integrate the form of manifestation of the disease. Later, it was ordered in a coherent way the etiologic factors, precipitating factors and identified the vulnerability of the patients as well as the structural alterations, classifying them in immediate, mediate and late. The changes in each meeting were submitted clinical attitudinal, behavioural, clinical and organic. The model of care was multifaceted and interdisciplinary with a therapeutic approach of individualization and a holistic view to carry out a comprehensive diagnosis and provide quality health care to the population. |

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| | | | | | http://www.ncbi.nlm.nih.gov/pubmed/24653575 |
| 16 | CLINICAL EVALUATION OF VISCUM ALBUM MOTHER TINCTURE AS AN ANTIHYPERTENSIVE: A PILOT STUDY | | Journal of Evidence Based Complementary and Alternative Medicine, Volume 19, Issue 1, 2014, Pages 31-35. | Poruthukaren KJ, Palatty PL, Baliga MS, Suresh S. | <p>Viscum album, an infrequently used antihypertensive in homeopathy, is evaluated by 1-group pretest-posttest model in primary hypertension. The drug was administered for 12 weeks at a dosage of 10 drops 3 times a day. Using paired t test, a significant drop in blood pressure ($P < .0001$) and serum triglyceride ($P < .0001$) was observed in the treatment group. This dual effect of <i>Viscum album</i> shows promise in optimizing therapy for primary hypertension.</p> <p>http://www.ncbi.nlm.nih.gov/pubmed/24647376; http://chp.sagepub.com/content/19/1/31.full.pdf+html</p> |
| 17 | COMMON FACTOR MECHANISMS IN CLINICAL PRACTICE AND THEIR RELATIONSHIP WITH OUTCOME | | Clinical Psychology and Psychotherapy, 2014. doi: 10.1002/cpp.1894. | Gaitan-Sierra C, Hyland ME. | <p>This study investigates three common factor mechanisms that could affect outcome in clinical practice: response expectancy, the affective expectation model and motivational concordance. Clients attending a gestalt therapy clinic (30 clients), a sophrology (therapeutic technique) clinic (33 clients) and a homeopathy clinic (31 clients) completed measures of expectancy and the Positive Affect and Negative Affect Schedule (PANAS) before their first session. After 1 month, they completed PANAS and measures of intrinsic motivation, perceived effort and empowerment. Expectancy was not associated with better outcome and was no different between treatments. Although some of the 54 clients who endorsed highest expectations showed substantial improvement, others did not: 19 had no change or deteriorated in positive effect, and</p> |

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| | | | | | <p>18 had the same result for negative effect. Intrinsic motivation independently predicted changes in negative affect ($\beta = -0.23$). Intrinsic motivation ($\beta = 0.24$), effort ($\beta = 0.23$) and empowerment ($\beta = 0.20$) independently predicted positive affect change. Expectancy ($\beta = -0.17$) negatively affected changes in positive affect. Clients found gestalt and sophrology to be more intrinsically motivating, empowering and effortful compared with homeopathy. Greater improvement in mood was found for sophrology and gestalt than for homeopathy clients. These findings are inconsistent with response expectancy as a common factor mechanism in clinical practice. The results support motivational concordance (outcome influenced by the intrinsic enjoyment of the therapy) and the affective expectation model (high expectations can lead for some clients to worse outcome). When expectancy correlates with outcome in some other studies, this may be due to confound between expectancy and intrinsic enjoyment. Common factors play an important role in outcome. Intrinsic enjoyment of a therapeutic treatment is associated with better outcome. Active engagement with a therapeutic treatment improves outcome. Unrealistic expectations about a therapeutic treatment can have a negative impact on outcome.</p> <p>Source:http://www.ncbi.nlm.nih.gov/pubmed/24634051</p> |
| 18 | MEDICINE PRESCRIPTION PRACTICES | OF | Journal of Integrative Medicine, Volume 12, | Saha S, Koley M, Arya JS, Choubey G, Ghosh S, | The authors aimed to determine the practice and attitudes of prescription by homeopathic undergraduate students. A cross-sectional study was |

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| | HOMEOPATHIC UNDERGRADUATE STUDENTS IN WEST BENGAL, INDIA | | Issue 1, 2014, Pages 7-12. | Ganguly S, Ghosh A, Saha S, Mundle M. | <p>carried out involving all the students from four government homeopathic schools of West Bengal, India using self-administered questionnaires. Chi-square tests and logistic univariate regression analyses were performed to identify associations and differences. A total of 328 forms were completed. Of these, 264 (80.5%) homeopathic undergraduate students admitted of prescribing medicines independently. The most common reasons for this were 'urgency of the problem' (35.2%), 'previous experience with same kind of illness' (31.8%), and 'the problem too trivial to go to a doctor' (25.8%). About 63.4% of the students thought that it was alright to independently diagnose an illness while 51.2% thought that it was alright for them to prescribe medicines to others. Common conditions encountered were fever, indigestion, and injury. Students who prescribed medicines were more likely to belong to Calcutta Homeopathic Medical College and Hospital (OR 5.8; 95% CI 2.247-14.972). Prescription by students gradually increased with academic years of homeopathic schools. Prescription of medicines by homeopathic undergraduate students is quite rampant and corrective measures are warranted.</p> <p>Source:http://www.ncbi.nlm.nih.gov/pubmed/24461590; http://www.jcimjournal.com/articles/publishArticles/pdf/S2095-4964(14)60004-2.pdf</p> |
| 19 | CHARACTERISTICS OF PATIENTS CONSULTING THEIR REGULAR | | Homeopathy , Volume 103, Issue 1, 2014, Pages | Lert F, Grimaldi-Bensouda L, Rouillon F, Massol J, | The objective of this study was to describe and compare patients visiting physicians in general practice (GPs) who prescribe only conventional |

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| | <p>PRIMARY CARE PHYSICIAN ACCORDING TO THEIR PRESCRIBING PREFERENCES FOR HOMEOPATHY AND COMPLEMENTARY MEDICINE</p> | | 51-57. | <p>Guillemot D, Avouac B, Duru G, Magnier AM, Rossignol M, Abenheim L, Begaud B; EPI3-LASER Group.</p> | <p>medicines (GP-CM), regularly prescribe homeopathy within a mixed practice (GP-Mx), or are certified homeopathic GPs (GP-Ho). The EPI3-LASER study was a nationwide observational survey of a representative sample of GPs and their patients from across France. Physicians recorded their diagnoses and prescriptions on participating patients who completed a self-questionnaire on socio-demographics, lifestyle, SF-12 questionnaire and the complementary and alternative medicine beliefs inventory (CAMBI). A total of 6379 patients (participation rate 73.1%) recruited from 804 GP practices participated in this survey. Patients attending a GP-Ho were slightly more often female with higher education than in the GP-CM group and had markedly healthier lifestyle. They did not differ greatly in their co-morbidities or quality of life but exhibited large differences in their beliefs in holistic medicine and natural treatments, and in their attitude toward participating to their own care. Similar but less striking observations were made in patients of the GP-Mx group. Patients seeking care with a homeopathic GP did not differ greatly in their socio-demographic characteristics but more so by their healthier lifestyle and positive attitude toward CAM.</p> <p>Source:http://www.ncbi.nlm.nih.gov/pubmed/24439455</p> |
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| 20 | USE OF COMPLEMENTARY ALTERNATIVE MEDICINE IN PEDIATRIC OTOLARYNGOLOGY PATIENTS: A SURVEY | | International Journal of Pediatric Otorhinolaryngology, Volume 78, Issue 2, 2014, Pages 248-252. | Gruber M, Ben-Arye E, Kerem N, Cohen-Kerem R. | <p>The authors investigated the pattern of CAM use among children and adolescents attending a pediatric otolaryngology clinic in a cross-sectional survey, using anonymous questionnaires filled-in by the parents accompanying young patients. Parents were asked about their general attitude toward CAM and whether they had ever consulted or considered a consultation with a CAM therapist. Subsequently, CAM users were asked to provide details on CAM modalities used and on their overall satisfaction with CAM therapy. Of 308 questionnaires administered, 294 parents responded (95% response rate). 32% reported considering CAM, or previous or current CAM use. Homeopathy was reported to be used by 36% parents. CAM users assessed success rate as being: successful (37%), unsuccessful (24%) or undetermined (39%). In most cases parents stated that the primary physician was aware of CAM use by the child (74%). The otolaryngologist awareness of parents' preference and interest may contribute to decision making regarding pediatric patients' management.</p> <p>Source:http://www.ncbi.nlm.nih.gov/pubmed/24332665</p> |
| 21 | DIFFERENCES IN USE OF COMPLEMENTARY AND ALTERNATIVE MEDICINE BETWEEN CHILDREN AND ADOLESCENTS WITH CANCER IN GERMANY: | | Pediatric Blood Cancer, Volume 61, Issue 3, 2014, Pages 488-492 | Gottschling S, Meyer S, Längler A, Scharifi G, Ebinger F, Gronwald B. | Use of complementary and alternative medicine (CAM) in children with cancer is increasing, however, data concerning differences between children and adolescents focusing on prevalence, reasons for use/non-use, costs, adverse effects, and socio-demographic factors are lacking. A population-based survey over a 1 year period with 497 participants was |

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| | A POPULATION BASED SURVEY | | | | <p>conducted. Of the 457 respondents (92%) 322 were children and 135 adolescents with malignancies. 31% reported CAM use from the time when being diagnosed, compared to an overall lifetime prevalence rate of 41% before cancer diagnosis. Homeopathy and Bach flower remedies were among the most frequently used CAM therapies. The main reasons for use were to reduce therapy-related side effects, to strengthen the immune system, to achieve physical stabilization and to increase healing chances. Socio-demographic factors associated with CAM use were higher parental education and higher family income. A majority of CAM users (97%) would recommend CAM use. Most users (78%) informed a physician about CAM use. Side effects were rarely reported (5%), minor and self-limiting. Clinical care and the physician-patient relation would profit from an enhanced understanding of CAM and a greater candidness towards the parental needs.</p> <p>Source:http://www.ncbi.nlm.nih.gov/pubmed/24038864</p> |
| 22 | USE AND PERCEIVED BENEFITS OF COMPLEMENTARY THERAPIES BY CANCER PATIENTS RECEIVING CONVENTIONAL TREATMENT IN ITALY | | Journal of Pain Symptoms Management , Volume 47, Issue 1, 2014, Pages 26-34. | Bonacchi A, Fazzi L, Toccafondi A, Cantore M, Mambrini A, Muraca MG, Banchelli G, Panella M, Focardi F, Calosi R, Di Costanzo F, Rosselli M, Miccinesi G. | <p>This study aimed to investigate the demographic and psychological characteristics of Italian cancer patients who use complementary therapies (CTs) and the perceived benefit of users. 803 patients from six Italian oncology departments were interviewed about CT use and completed two questionnaires to explore psychological distress and the resilience trait called sense of coherence (SOC). Patients included in the study had different primary tumor sites and were in different phases of the disease and care process. At the time of measurement, 37.9% of patients were</p> |

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| | | | | | <p>using one or more types of CTs. Homeopathy was one of the most frequently (6.4%) used CTs. The Italian context is characterized by a high percentage of patients who informed their physicians about CT use (66.3%) and who experienced benefits (89.6%); 75.2% of the patients had used CTs in the past. Multivariate analysis revealed that young, female patients, who previously used CAM in the past, appear more likely to use at least one type of CT in the present. Predictors of the use of CTs varied according to the type of CT. Among psychological factors, SOC was positively associated with both past and present CT use. Overall prevalence of CTs among Italian cancer patients is high and is in accordance with the European average. In addition to clinical and socio-demographic factors, the resilience trait SOC also was associated with CT use.</p> <p>Source:http://www.ncbi.nlm.nih.gov/pubmed/23916679</p> |
| 23 | CAM USE IN PEDIATRIC NEUROLOGY: AN EXPLORATION OF CONCURRENT USE WITH CONVENTIONAL MEDICINE. | | PLoS One, Volume 9, Issue 4, 2014, Page e94078. | Galicia-Connolly E, Adams D, Bateman J, Dagenais S, Clifford T, Baydala L, King WJ, Vohra S. | <p>A survey instrument was developed to inquire about use of CAM products and therapies, including reasons for use, perceived helpfulness, and concurrent use with conventional medicine, and administered to patients or their parents/guardians at the Stollery Children's Hospital in Edmonton and the Children's Hospital of Eastern Ontario (CHEO) in Ottawa, Canada. Overall CAM use at the Stollery was 78%, compared to 48% at CHEO. Homeopathy was identified as one of the commonest CAM used products (24%) and practice (16%). Many patients used CAM products at the same time as conventional medicine but just over half (57%) discussed this</p> |

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| | | | | | <p>concurrent use with their physician. CAM use is common in pediatric neurology patients and most respondents felt that it was helpful, with few or no harms associated. However, this use is often undisclosed, increasing possibility of interactions with conventional drugs.</p> <p>Source:http://www.ncbi.nlm.nih.gov/pubmed/24736474</p> <p>http://www.plosone.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pone.0094078&representation=PDF</p> |
| 24 | <p>ADDITIVE HOMEOPATHY IN CANCER PATIENTS: RETROSPECTIVE SURVIVAL DATA FROM A HOMEOPATHIC OUTPATIENT UNIT AT THE MEDICAL UNIVERSITY OF VIENNA.</p> | <p>Complementary Therapies in Medicine, Volume 22, Issue 2, 2014, Pages 320-332.</p> | <p>Gaertner K, Müllner M, Friehs H, Schuster E, Marosi C, Muchitsch I, Frass M, Kaye AD.</p> | <p>Data from cancer patients who had undergone homeopathic treatment complementary to conventional anti-cancer treatment at the Outpatient Unit for Homeopathy in Malignant Diseases, Medical University Vienna, Department of Medicine I, Vienna, Austria, were collected, described and a retrospective subgroup-analysis with regard to survival time was performed. In four years, a total of 538 patients visited OPD, 62.8% were women, nearly 20% had breast cancer. 53.7% had undergone at least three homeopathic consultations and 18.7% fulfilled inclusion criteria for survival analysis. The surveyed neoplasms were glioblastoma, lung, cholangiocellular and pancreatic carcinomas, metastasized sarcoma, and renal cell carcinoma. Median overall survival was compared to expert expectations of survival outcomes by specific cancer type and was prolonged across observed cancer entities (p<0.001).</p> <p>Source:http://www.ncbi.nlm.nih.gov/pubmed/24736474</p> | |

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| 25 | SURVEY OF GERMAN NON-MEDICAL PRACTITIONERS REGARDING COMPLEMENTARY AND ALTERNATIVE MEDICINE IN ONCOLOGY | | Oncol Res Treat. Volume 37, Issue 1-2, 2014, Pages 49-53. | Koehl B, Muenstedt K, Micke O, Muecke R, Buentzel J, Stoll C, Prott FJ, Dennert G, Senf B, Huebner J. | | <p>A survey was conducted by using an online questionnaire on the 1,500 members of the non-medical practitioner (NMP) associations, of which 299 took part. The treatments were found to be heterogeneous. Homeopathy was used by 45% of the NMPs; 10% believed it to be a treatment directly against cancer. Many therapies provided by NMPs were biologically based and therefore might interfere with conventional cancer therapy. Thus, patients were at risk of interactions, especially as most NMPs did not adjust their therapies to those of the oncologist. Moreover, risks might arise from these CAM methods as NMPs partly believed them to be useful anticancer treatments. This might lead to the delay or even omission of effective therapies.</p> <p>Source:http://www.ncbi.nlm.nih.gov/pubmed/24613909</p> |
| 26 | WHAT IS IT ABOUT HOMEOPATHY THAT PATIENTS VALUE? AND WHAT CAN FAMILY MEDICINE LEARN FROM THIS? | | Quality in Primary Care. Volume 22, Issue 1, 2014, Pages 17-24. | Schmacke N, Müller V, Stamer M. | | <p>The survey in Germany was conducted on 21 women and 5 men suffering from chronic conditions by using questionnaire-based, semi-structured expert interviews about their views on the medical care provided by homeopathic medical practitioners. The 'fit' between therapist and patient proved to be particularly important. Both the initial homeopathic consultation and the process of searching for the appropriate medication were seen by patients as confidence-inspiring confirmations of the validity of homeopathic therapy which they considered desirable in this personalised form. The possible</p> |

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| | | | | | <p>adoption by family medicine of elements of homeopathy may be seen as controversial, but this study again indicates the vital importance of successful communication to ensure a sustainable doctor-patient relationship.</p> <p>Source:http://www.ncbi.nlm.nih.gov/pubmed/24589147</p> |
| 27 | <p>COMPLEMENTARY AND ALTERNATIVE MEDICINE IN THE GERMAN OUTPATIENT SETTING: EXTENT, STRUCTURE AND REASONS FOR PROVISION</p> | | <p>Das Gesundheitswesen, 2014</p> | <p>Thanner M, Nagel E, Loss J.</p> | <p>A standardised questionnaire was developed addressing reasons and patterns of CAM provision. The questionnaire was sent by post to 2396 general practitioners and specialists in 9 selected German districts, of which 553 (23%) physicians participated in the survey. 63% of the respondents (n=350) answered that they had provided some sort of CAM to their patients within a period of 12 months preceding the study. The one of the most frequently provided methods was homeopathy. In the sample, 90% of the orthopaedists were CAM providers, the highest rate among the participating disciplines. Several reasons for offering CAM were identified: conviction of therapeutic effectiveness regarding the patient's situation (68%), aspects of therapeutic freedom (47%) or less harmful side effects than conventional therapies (34%) and 6% provide CAM for monetary reasons. Findings suggest that the provision of CAM is widespread in the German outpatient setting. However, it has to be taken into account that a selection bias may apply which may lead to an overestimation of CAM provision.</p> <p>Source:http://www.ncbi.nlm.nih.gov/pubmed/2456</p> |

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| 28 | THE USE OF COMPLEMENTARY AND ALTERNATIVE MEDICINE BY WOMEN TRANSITIONING THROUGH MENOPAUSE IN GERMANY: RESULTS OF A SURVEY OF WOMEN AGED 45-60 YEARS | | Complementary Therapies in Medicine, Volume 22, Issue 1, 2014, Pages 94-98. | Buhling KJ, Daniels BV, Studnitz FS, Eulenburg C, Mueck AO. | | <p>A self-administered questionnaire was sent to 9785 randomly selected women in Germany aged between 45 and 60 year of which total of 1893 (19.3%) questionnaires have been sent back. 81% (n=1517) of the responding women stated that they had experienced menopausal complaints at least once. Symptoms ranged from vasomotor symptoms, including hot flushes and night sweats, in 71.2% of cases, to bladder problems in 42.7%. The average symptom score (MRS II total score, range 1-44) among the respondents was 12.76±9.6. More than half (56%; n=1049/1872) of the responding women had used some form of therapy to alleviate their symptoms at least once. The majority of women undertaking a therapy (64.8%; n=679/1049) had used only CAM interventions (either one or more type of CAM), 14.2% (n=149) had used hormone replacement therapy (HRT) only, while 21.1% (n=221/1049) had tried both CAM and HRT. Homeopathy (14.9%) was one of the popular and perceived to be effective (73.7%; n=205) CAM interventions stated by the respondents. CAM interventions to alleviate menopausal complaints are popular among German women, with 48.2% (n=900/1872) of respondents reporting having used CAM either alone or in combination with HRT.</p> <p>Source:http://www.ncbi.nlm.nih.gov/pubmed/24559823</p> |

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| 29 | EXPLORING FRONTIERS: USE OF COMPLEMENTARY AND ALTERNATIVE MEDICINE AMONG PATIENTS WITH EARLY-STAGE BREAST CANCER | | Breast, 2014, pii: S0960-9776(14)00010-1. | Saghatchian M, Bihan C, Chenailler C, Mazouni C, Dauchy S, Delalogue S. | <p>The transversal, prospective study evaluated the use of CAM among patients receiving adjuvant chemotherapy or endocrine therapy for early stage breast cancer. 69/184 responders (37.5%) reported using at least one CAM. CAM use was associated with younger age ($p = 0.03$) and higher education level ($p < 0.001$). Pharmacological substances (e.g., homeopathy, phytotherapy) were the most commonly used (79.7%). A total of 65.8% of users felt that these treatments have demonstrated evidence of efficacy and 74.8% that they were not associated with side effects. The main goal for use was improvement of treatment-related symptoms (28.3%); secondary goal was increasing the general health status (20.5%). Patients reported high needs for information on CAMs. CAM use was associated with mild differences in secondary adverse events reported by patients. Breast cancer patients are common users of CAM concomitantly to their conventional cancer treatments and should be investigated regarding their current consumption of CAM. Furthermore, they need advice evidence-based data on these treatments and potential interactions with on-going treatments.</p> <p>Source: http://www.ncbi.nlm.nih.gov/pubmed/24529905</p> |
| 30 | HEALTHCARE PROFESSIONAL VIEWS AND EXPERIENCES OF COMPLEMENTARY AND ALTERNATIVE | | British Journal of Obstetrics and Gynecology, 2014, doi: | Stewart D, Pallivalappila A, Shetty A, Pande B, McLay J. | A prospective questionnaire based survey on all healthcare professionals (135) involved in the care of pregnant women (midwives, obstetricians, anaesthetists) in Maternity services in Grampian, North East Scotland, to investigate the use of |

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| | THERAPIES IN OBSTETRIC PRACTICE IN NORTH EAST SCOTLAND: A PROSPECTIVE QUESTIONNAIRE SURVEY. | | 10.1111/1471-0528.12618. | | complementary and alternative medicines (CAMs) therapy by UK healthcare professionals involved in the care of pregnant women, and to identify key predictors of use. Out of 87% respondents, 32.5% had recommended (prescribed, referred, or advised) the use of CAMs to pregnant women. Homeopathy (50%) was one of the most frequently recommended CAMs. Although univariate analysis identified that those who recommended CAMs were significantly more likely to be midwives who had been in post for more than 5 years, had received training in CAMs, were interested in CAMs, and were themselves users of CAMs. Despite the lack of safety or efficacy data, a wide variety of CAM therapies are recommended to pregnant women by approximately a third of healthcare professionals, with those recommending the use of CAMs being eight times more likely to be personal CAM users. Source: http://www.ncbi.nlm.nih.gov/pubmed/24512627 |
| 31 | MANAGEMENT OF UPPER RESPIRATORY TRACT INFECTIONS BY DIFFERENT MEDICAL PRACTICES, INCLUDING HOMEOPATHY, AND CONSUMPTION OF ANTIBIOTICS IN PRIMARY CARE: THE EPI3 COHORT STUDY IN FRANCE 2007-2008 | | PLoS One, Volume 9, Issue 3, 2014, Pages e89990. | Grimaldi-Bensouda L, Bégaud B, Rossignol M, Avouac B, Lert F, Rouillon F, Bénichou J, Massol J, Duru G, Magnier AM, Abenheim L, Guillemot D. | Prescribing of antibiotics for upper respiratory tract infections (URTI) varies substantially in primary care. The authors intended to describe and compare antibiotic and antipyretic/anti-inflammatory drugs use, URTI symptoms' resolution and occurrence of potentially-associated infections in patients seeking care from general practitioners (GPs) who exclusively prescribe conventional medications (GP-CM), regularly prescribe homeopathy within a mixed practice (GP-Mx), or are certified homeopathic GPs (GP-Ho). The EPI3 survey was a nationwide population-based study of a representative sample of |

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| | | | | | <p>825 GPs and their patients in France (2007-2008). GP recruitment was stratified by self-declared homeopathic prescribing preferences. Adults and children with confirmed URTI were asked to participate in a standardized telephone interview at inclusion, 1, 3, and 12-month follow up. Study outcomes included medication consumption, URTI symptoms' resolution and potentially-associated infections (sinusitis or otitis media/externa) as reported by patients. Analyses included calibration to account for non-respondents and groups were compared using multivariate analyses adjusting for baseline differences with a propensity score. 518 adults and children with URTI (79.3% rhinopharyngitis) were included (36.9% response rate comparable between groups). As opposed to GP-CM patients, patients in the GP-Ho group showed significantly lower consumption of antibiotics (OR = 0.43, 95% CI 0.27-0.68) and antipyretic/anti-inflammatory drugs (OR = 0.54, 95% CI: 0.38-0.76) with similar evolution in related symptoms (OR = 1.16, 95% CI: 0.64-2.10). An excess of potentially-associated infections (OR = 1.70, 95% CI: 0.90-3.20) was observed in the GP-Ho group (not statistically significant). No difference was found between GP-CM and GP-Mx patients. Patients who chose to consult GPs certified in homeopathy used less antibiotics and antipyretic/anti-inflammatory drugs for URTI than those seen by GPs prescribing conventional medications. No difference was observed in patients consulting GPs within mixed-practice. A non-statistically significant excess was estimated through</p> |
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| | | | | | <p>modelling for associated infections in the GP-Ho group and needs to be further studied.</p> <p>Source: http://www.ncbi.nlm.nih.gov/pubmed/24642965 http://www.plosone.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pone.0089990&representation=PDF</p> |
| 32 | Lert et al; | | | | <p>Characteristics of patients consulting their regular primary care physician according to their prescribing preferences for homeopathy and complementary medicine; Homeopathy (2014) 103, 51-57</p> |
| | | | | | <p>Miglani A. and Manchanda R. K; Observational study of Arctium lappa in the treatment of acne vulgaris; Homeopathy (2014) 103, 203-07</p> |
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| | | | | | <p>Chand K. S., Manchanda RK, Mittal R., Batra S., Banavaliker J.N. and De I.; Homeopathic treatment in addition to standard care in multi-drug resistant pulmonary tuberculosis: a randomized, double blind, placebo controlled clinical trial; Homeopathy (2014) 103, 97-107</p> |

CHAPTER VIII

Drug Proving (HPTs)

Homeopathy is a medical practice aiming at strengthening the natural homeostasis of the body and stimulating the immune system. Homeopathy acts following the similarity principle; that means that the symptomatic patient is treated with a medicine containing a substance causing similar symptoms in a healthy person. For example onion can be the cause of a watery discharge of the nose and eyes. A medicine prepared from onion, namely *Allium cepa*, can treat patients who have these symptoms during a coryza or allergic rhinitis accompanied by irritating watery discharge from the nose.

The law of similars has to be respected during clinical and fundamental studies. Twenty years ago a new paradigm allowing explanation of the homeopathic effects had been developed. It is the paradigm of the “Body signifiers”.³¹⁴ It explains why the law of similars has to be respected in research protocols on homeopathy; the tested medicine must be significant for the research subject (cell, plant, animal or human). A databank of experiments on homeopathy is regularly updated and available today.³¹⁵

A. Homeopathic pathogenetic trials or provings

Hahnemann conducted repeated experimental drug studies on himself and the sixty-four volunteers whose names are listed in his *Materia Medica Pura*. In total he investigated 101 remedies over a period of about half a century, establishing the method which has come to be known as 'Proving'. His immediate followers, Hering, Stapf and others, carried out their own provings, but

continued to turn to Hahnemann for advice, as is shown by their correspondence. The first generations of homeopaths continued this tradition. During the 19th century provings multiplied in Germany, France, England and above all in the United States, under the powerful influence of Hering. In Austria, from 1842 on, the Homoeopathic Society of Vienna undertook numerous reprovings, as well as establishing new pathogeneses, including *Argentum nitricum*, *Kalium bichromicum* and *Coccus cacti*. In France, Petroz, and the amazing Benoit Mure, with his Brazilian pathogeneses, stand out.³¹⁶ Fortier-Bernoville has described the proving scene in America in the last century as the ‘zenith of proving’. He informs in his paper that in America, the method became very refined and proving on the healthy continued on a large scale. In the homoeopathic colleges, young people voluntarily intoxicated themselves and remained for days or sometimes several weeks in their rooms, or even took to their beds. They noted all the symptoms they experienced. On comparing the symptoms reported it was possible to rank them according to their frequency.³¹⁷

Historically, HPTs have been methodologically innovative. The first double-blind placebo controlled homeopathic ‘proving’ was conducted in 1835, and was one of the first double-blind placebo controlled trials in the history of medicine.³¹⁸ In 1895 the suggestion of including a pre-observation ‘run-in’ period to prepare the volunteer was made,³¹⁹ and one of the earliest multicentre double-blind clinical trials was an HPT of *Belladonna* conducted by Bellows, published in 1906.³²⁰ Modern provings are

³¹⁴Bastide M. & Lagache A. *Revue Intern. Systémique*, 1995;9 :237-249 + *Altern Ther Health Med*. 1997;3:35-9

³¹⁵Van Wijk R, Albrecht H. Proving and therapeutic experiments in the HomBReX basic homeopathy research database. *Homeopathy*. 2007;96:252-257.

³¹⁶ Demarque D., The development of proving methods since Hahnemann; *The British Homoeopathic Journal*; April 1987. Vol. 76. pp. 71-75

³¹⁷ Fortier-Bernoville: *Propagateur de l'Homeopathie*. February 1934.

³¹⁸ Stolberg M. Die Homo“opathie auf dem Pru“ fstein. Der erste Doppelblindversuch der

Medizingeschichte im Jahr 1835. *Mu“nchener Medizinische Wochenschrift* 1996; 138: 364–366.

³¹⁹ The Medical Investigation Club of Baltimore. *A Pathogenetic Materia Medica*. Philadelphia: Boericke & Tafel, 1895.

³²⁰ Bellows HP. The Test Drug-Proving of the O. O. & L. Society: A Reproving of *Belladonna* Being an Experimental Study of the reactions to newly marketed drugs in general practice in England: analysis of 48 cohort studies. *Br J Clin Pharmacol* 1998; 46: 505–511.

conducted in the same spirit. However, early in the 20th century, Hughes³²¹ critically analysed Hahnemann's conclusions. A modern analysis of Hahnemann's guidelines found many flaws, which could not have been anticipated by Hahnemann, all likely to lead to an over-estimation of pathogenetic effects.³²² A review of HPTs published in the UK included 45 studies, and showed a great variability in terms of the medicines tested, methodology, volunteers, sample size and outcome.³²³ More recently, a systematic review by Dantas et al reveals that the homeopathic pathogenetic trials (HPTs) conducted between 1945 and 1995 were generally of low methodological quality. There is a high incidence of pathogenetic effects in publications and volunteers but this could be attributable to design flaws. Homeopathic medicines, tested in HPTs, appear safe. However, the central question of whether homeopathic medicines in high dilutions can provoke effects in healthy volunteers has not yet been definitively answered, because of methodological weaknesses of the reports.³²⁴

Dantas et al revealed concluded through their review that the evidence for the occurrence of pathogenetic effects in HPTs is contaminated. They opinionated that homeopathic practitioners expect useful information from HPTs. Yet we do not even know the pattern of symptoms produced in HPTs. Do they occur in most volunteers or only in a minority? To resolve this initially it would suffice to do randomized trials with good intraindividual placebo control, with clear criteria for inclusion/exclusion and attribution of causality. However, if only a small minority of volunteers manifest changes (and the better designed studies suggest that this is the case) then new designs are required, perhaps drawing on experience for the detection of type II, or idiosyncratic, adverse drug reactions, with much larger samples and more qualitative detail of the reported symptoms.

Alternatively, one could screen to find apparently sensitive volunteers and then conduct series of randomized, doubleblinded, placebo-controlled single case trials with multiple cross-over on these volunteers using different dilutions and exploring not only the occurrence of symptoms but the quality of the symptoms. One possible objection to this procedure is that sensitive volunteers may progressively loose their sensitivity in the course of such a procedure. In any case new HPTs should be conducted by competent investigators and include a definition of a healthy volunteer and an assessment of health status. The populations should be described, the methods should minimize bias, suggestion and the incorrect attribution of spontaneous or unrelated changes to the medicine, clear instructions for volunteers and supervisors, sensitive and valid outcomes measurements, and of course conform to ethical standards for human experimentation. Qualitative as well as quantitative evaluation may be required if we are to understand what happens to healthy volunteers taking homeopathic medicines compared to placebo. The use of an exclusively quantitative statistical analysis probably leads to an underestimate of pathogenetic effects but on the other hand inadequate use of control and failure to use placebo symptoms as a comparator within each individual leads to false-positive results. 'Rare, strange and peculiar' or idiosyncratic symptoms are believed to be of crucial importance in homeopathic prescribing, yet they occur in only a few or no volunteers in small HPTs. Qualitative criteria to discriminate verum from placebo effects in HPTs need to be validated. In HPTs of traditional parallel group design such idiosyncratic effects would be drowned in statistical 'noise' arising from spontaneous, incidental or irrelevant sources. We need methods to detect them. The answers to these problems are not yet clear, and the lessons that can be learnt from traditional trials few. They are important areas for methodological

³²¹ Hughes R. *A Manual of Pharmacodynamics*, 6th edn. London: Leath and Ross, 1912.

³²² Dantas F. How can we get more reliable information from homeopathic pathogenetic trials? *Br Hom J* 1996; 85: 230–236.

³²³ Dantas F, Fisher P. A systematic review of homeopathic pathogenetic trials ('provings') published in the United Kingdom from 1945 to 1995. in: Ernst E, Hahn EG

editors. *Homeopathy: A Critical Appraisal*. London: Butterworth- Heinemann, 1998. p. 69–97.

³²⁴ Dantas et al; A systematic review of the quality of homeopathic pathogenetic trials published from 1945 to 1995; *Homeopathy* (2007) 96, 4–16

development.³²⁵

On the evidence Dantas et al have reviewed, they inferred it was not possible to answer to the main questions posed in HPTs: do homeopathic medicines in high dilution, cause changes in healthy volunteers? If they do, how can we discriminate the effects due to the substance tested from incidental effects? If appropriate, rigorous and well-designed research gives a negative answer to the first question, we should relegate HPTs of highly diluted homeopathic medicines to be purely historical and expunge information deriving from them from the homeopathic database. But if high-quality research shows that they can produce specific effects, we will need to refine the methodology of HPTs in order to clearly identify effects attributable to the substance tested.³²⁶ However, over the recent years, the proving process has evolved and grown into a multi-facetted mode of investigation. Many good quality HPTs have yielded significant information regarding the above questions. A recent HPT by Dominici et al demonstrated the nonequivalence between homeopathic medicines in high dilution and placebo and contributed to the improvement of proving methodology and evaluation. The authors have sought more confirmatory studies.³²⁷ Another HPT was able to link the effect of homeopathic medicines *Coffea cruda* and *Nux vomica* in 30c potencies to short-term nonlinear dynamic parameters of slow wave sleep EEG in healthy young adults, concluding that MSE may provide a more sensitive NDS analytic method than D2 for evaluating homeopathic remedy effects on human sleep EEG patterns.³²⁸

The most important tool to emerge from review by Dantas et al is the Methodological Quality Index (MQI) used to assess the quality of published HPTs, the MQI

could also be used as a checklist to improve the methodology of HPTs at the design stage. The four components on which the MQI is based on aspects such as randomization, inclusion and exclusion criteria, blinding and criteria for selection of pathogenetic effects, with values ranging from 1 to 4 for each component, giving a range from 4 to 16. These factors are very important to improve methodology of HPTs.³²⁹ On the flipside, though, Quirk and Sherr raise a number of important and controversial issues concerning the systematic review of Homeopathic Pathogenetic Trials by Dantas et al.³³⁰ However, since this review was designed, new ideas and data have emerged. These suggest that perhaps a nonlocal model should be applied to homeopathy as a whole. If such nonlocal models are validated it might be doubtful whether blinded placebo controls actually act as an adequate filter for noise, as specific symptoms have to be expected in those groups as well. We have seen such effects in more recent homeopathic pathogenetic trials and this has raised doubts as to whether placebo controls can actually control properly for what they are supposed to control within homeopathic pathogenetic trials.³³¹ Perhaps another review of the HPTs of the last decade would be potentially contributory as they are expected to fall in the evolved methodologies suggested in the review by Dantas et al.

In moving forward and evaluating the usefulness of provings, it can be thus concluded, we should combine innovative research strategies that respect both homeopathy and qualitative research as well as the more

³²⁵ Dantas et al; A systematic review of the quality of homeopathic pathogenetic trials published from 1945 to 1995; *Homeopathy* (2007) 96, 4–16

³²⁶ Dantas et al; A systematic review of the quality of homeopathic pathogenetic trials published from 1945 to 1995; *Homeopathy* (2007) 96, 4–16

³²⁷ Dominici G., Bellavite P., Stanislao C d., Gulia P and Pitari G., Double-blind, placebo-controlled homeopathic

³²⁸ Bell I.R., Howerter A., Jackson N., Aickin M., Bootzin R.R. and Brooks A.J., Nonlinear dynamical systems effects of homeopathic remedies on multiscale entropy and correlation

dimension of slow wave sleep EEG in young adults with histories of coffee-induced insomnia; *Homeopathy* (2012) 101, 182–192

³²⁹ Dantas et al; A systematic review of the quality of homeopathic pathogenetic trials published from 1945 to 1995; *Homeopathy* (2007) 96, 4–16

³³⁰ Sherr J. and Quirk T., Systematic review of homeopathic pathogenetic trials: an excess of rigour?; *Homeopathy* (2007) 96, 273–278

³³¹ Walach H; Response: potential nonlocal mechanisms make placebo controls in pathogenetic trials difficult; *Homeopathy* (2012); 278

well known tools of quantitative research.^{332,333, 334}

At LMHI Congresses new, or confirmation of previous, provings are presented.

In May 2008 the following provings were presented (see Proceedings):

Hydrogenium peroxidatum – H₂O₂. Dominici G. Double-blind, randomized, placebo controlled design; 16 provers revealing several symptoms clinically verified on human and animals.

Latrodectus Mactans Tredecimguttatus. AFADH – Fayeton S. Open design; 8 provers revealing groups of symptoms clinically verified.

Potentilla Anserina. Jansen JP. Multi-centric, prospective, double-blind design; 10 provers revealing 27 groups of symptoms.

Plutonium's Peaceful Brother: **Neptunium muriaticum**. Lustig D. Placebo-controlled design; 19 provers revealing 315 symptoms distributed into 12 groups of characteristic symptoms.

Brazilian Pathogeneses: **Helleborus Niger**. Marim M. Third confirmation, multicentric international design; 4 groups of symptoms are regularly recorded.

Sutherlandia Frutescens. Ross A, Webster H, van der Hulst N. Double-blind, placebo-controlled design; 24 provers revealing 15 symptoms correlated with the traditional use of the plant (restorative tonic in HIV patients).

Erythrina Lysistemon (African Coral Tree). Ross A, de Beer E. Triple-blind, placebo-controlled design; 32 provers revealing 25 symptoms.

Lobelia Cardinalis. Scheepers L. Open design; 7 provers revealing 293 symptoms.

Galium Aparine. Scheepers L. Open design; 8 provers revealing 18 groups of symptoms.

Ytterbium Nitricum. Vicol M, Cristescu LM, Ivanciu NV, Dobre

ML, Sumbasacu M, Oprea AM, Goiceanu DM, Dragusanu O, Binder-Hampel A, Stanciu AM, Struza CM. Open design; 13 provers revealing 32 symptoms.

Hecla Lava. Multicentric international design.

In May 2010 (LMHI Congress) the following proving was presented (see Proceedings):

Protea cynaroides. Botha I. Double-blind design; 70 provers (60 verum, 10 placebo) revealing 4 Mind stages and many specific symptoms.

At the same congress the same team answered the question: "Are provings reproducible?"

To answer this question the group of the Durban University (South Africa) (Botha I.) did a comparative survey between groups using different proving methodologies (C4 trituration, Sherr and Dream proving methodology) for a same homeopathic medicine. These results are also in the Proceedings of the 2010 LMHI Congress. The end result was the formulation of 1373 rubrics utilized for analysis purposes, resulting in 881 verified rubrics of *Protea cynaroides*. The hypothesis "0": "there is no difference in the symptoms experienced between two consecutive years (symptoms are reproducible)" $p > 0.05$ has been confirmed and is the highest in the group using C4 methodology. The C4 and Sherr methodologies are the most reproducible based on rubric presence.

In May 2010 (European Parliament Strasbourg Congress on Homeopathy) see Proceeding:

Morpho Menelaus Occidentalis. Renoux H. A double blind design (7,9,15,30CH, 200K, placebo) pathogenetic trial. 30 provers, 16 supervisors.

In December 2011 (LMHI Congress) the following provings were presented (see proceedings):

Strychnos henningsii. Ross A.H.A. A triple-blind proving design (30CH, placebo) using also blood testing and clinical measurements to assess the effects.

Malus communis. Jansen JP. A multi-center, prospective, double

³³²Signorini A, Lubrano A, Manuele G, et al. Classical and new proving methodology: provings of *plumbum metallicum* and *piper methysticum* and comparison with a classical proving of *plumbum metallicum*. *Homeopathy* 2005; 94(3): 164–174.

³³³Walach H, Sherr J, Schneider R, Shabi R, Bond A, Rieberer G. "Homeopathic Proving Symptoms: result of a local, non-local, or placebo process? A blinded,

placebo-controlled pilot study". *Homeopathy* 2004; 93: 179–185.

³³⁴David Riley; Thoughts on Homeopathic Drug Provings; *Homeopathy* (2007) 96, 231–232

blind proving design (12K, 30Kn 200K). *Eriodyction californicum*. Scheepers L. Double blind proving design (30K)

Bacopa monnieri (Brahmi). Gupta V. Double blind placebo controlled proving design.

Proving: Publications in International Journals 2008

Argemone mexicana. Dey NR, Das KC, Rai Y. Multicentric double-blind design, 38 provers (6C, 30C, 200C). Indian Journal of Research in Homeopathy. January-March 2008; Vol2, n°1:13-18.

Cephalandra Indica. Dey NR, Das KC, Rai Y. Multicentric double-blind design, 17 provers (6c, 30c, 200c). Indian Journal of Research in Homeopathy. April-June 2008; Vol2, n°2:20-24.

Ficus religiosa. Dey NR, Das KC, Rai Y, Siddiqui VA, Singh R. Multi-centric double blind homeopathic pathogenetic trial. Indian Journal of Research in Homeopathy. July-September 2008; Vol2, n°3:10-14.

Paraffin. Rajpal, Siddiqui VS, Dey NR, Das KC, Rai Y, Singh VK. Multi-centric double-blind design, 43 provers (6C, 30C, 200C). Indian Journal of Research in Homeopathy. October-December 2008; Vol2, n°4:20-25.

Proving: Publications in International Journals 2009

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Rajesh Shah presented a double blind placebo controlled drug proving on a HIV Nosode (22 volunteers). Proceedings 67th LMHI Congress.

Proving: Publications in International Journals 2012

Plumbum metallicum. Signorini and Pichler presented the complete 2000 trial with a synthesis of and a comparison with the original 1828 trial. The used a 30CH dilution in a multicentric setting and found 37 new symptoms above the confirmation of already well knowed symptoms. Indian Journal of Research in Homeopathy. January-June 2012. Vol 6; n°1 & 2:32-46.

Buxus sempervirens. Rajpal, Vinay Kr.Singh, Siddiqui V.A., Nayak C, Majumdar A.K., Chandra P.K., Dey S.K. A multi-centric, double-blind randomized, homeopathic trial. Using 6 and 30CH dilution in 40 provers producing 160 different symptoms (new or confirmation). Indian Journal of Research in Homeopathy. July-September 2012. Vol6; n°3:1-9.

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2014 –New publications

1. **Shah R. Hepatitis C Nosode: The preparation and homeopathic pathogenetic trial. Homeopathy 2013;102:207-14.**

- A double blind, randomized placebo controlled homeopathic pathogenetic trial of Hepatitis C (Hep C) nosode in 30c potency was conducted on 22 volunteers (verum 15, placebo 7). The Hep C nosode was associated with qualitatively and quantitatively distinct symptoms, which can be applied in clinical practice.

2. **Rakshit G, Singh JP, Pathak SD, Banoth CK, Chandra PK, Rajpal, et al. A multi-centric double-blind randomized homoeopathic pathogenetic trial of *Gymnema sylvestre*. Ind J Res Hom. 2013;7(1):9-21.**

- The Central Council for Research in Homeopathy conducted a multi-centre, double-blind placebo-controlled proving of *Gymnema sylvestre* in two

potencies (6C and 30C) on 63 apparently healthy volunteers. Out of 37 provers who were on actual drug trial, 16 manifested symptoms. The drug was able to produce symptoms in each potency in most of the parts of the body.

3. **Shah R. Hydroquinone: homoeopathic pathogenetic trial. Ind J Res Hom. 2013;7(2):47-61.**

- The Central Council for Research in Homeopathy conducted a double-blind, randomized, placebo-controlled drug proving of Hydroquinone in 30c potency using the Quantitative and Qualitative Pathogenetic Index on 22 volunteers (verum 15; placebo 7). The preparation could be used for vitiligo on the basis of its toxicological effects, supported by the anecdotal study.

4. **Rakshit G, Vichitra AK, Rajpal, Choudhury SK, Singh VK. A multi-centric double-blind homoeopathic pathogenetic trial of Cyclosporin. Ind J Res Hom. 2013;7(3):109-15.**

- To elicit the pathogenetic response of the drug Cyclosporin in homoeopathic potencies on apparently healthy human beings, Central Council for Research in Homeopathy conducted a double-blind, placebo-controlled trial in two potencies (6C and 30C) on 50 apparently healthy volunteers (verum 33; placebo 17) were on placebo. Eleven provers manifested symptoms. The drug was able to produce symptoms in each potency in most parts of the body.

5. **Teut M, Dahler J, Hirschberg U, Luedtke R, Albrecht H, Witt CM. Homeopathic drug proving of *Okoubaka aubrevillei*: a randomised placebo-controlled trial. Trials 2013;14:96.**

- This multicentre, randomised, double-blind, placebo-controlled phase 1 trial evaluated pathogenetic actions of *Okoubaka aubrevillei* (potency C12) on 31 subjects (verum 19; placebo 12). Data for 29 participants could be analysed. No significant differences in number of characteristic symptoms in

both groups were observed. The odds ratio for observation of a characteristic symptom was 1.11 (95% CI 0.4-3.05, P = 0.843). The qualitative analysis showed an inter-coder reliability of 0.69 (95% CI 0.62-0.76). The qualitative comparison of symptom profiles

was inconclusive. The 'nocebo' effect might be a plausible explanation for most of the phenomena observed in this trial.

CHAPTER IX

Clinical verification

One of the other scientific pillars of homeopathy, beside the homeopathic pathogenetic trial or proving, is clinical experience. Due to over-emphasis of RCT the value of clinical experience has become under-estimated.³³⁵ Each separate case gives some qualitative information and collections of similar cases allow quantitative analysis. One case can reveal a very peculiar symptom indicating a specific symptom; for more common symptom, like chilliness, we need a larger number of cases to indicate to what degree patients responding well to a particular medicine are chilly.

Clinical experience shows that a homeopathic medicine cannot be prescribed on indication alone. Recently, conventional medicine is adapting this centuries old homeopathic insight in personalised medicine. Researching the influence of multiple variables on outcomes requires a suitable strategy.³³⁶ Symptoms and personal characteristics are prognostic factors for a favourable response to a specific medicine. Homeopathic practitioners know that a specific symptom/characteristic is an indication for a specific medicine if this symptom/characteristic occurs more frequently in the population that responds well to that medicine than in the remainder of the population.

According to Hering, a drug should have undergone four phases to be called validated; *Possibility*: Symptoms that follow when a substance is taken in health; these may also be toxic; *Probability*: Depends on the frequency of appearance³³⁷ of the same/similar symptoms when the substance is diluted and dynamised; more the frequency of symptoms, higher the probability; *Confirmation*: When

the same substance, diluted and dynamised, confirms the symptoms known from previous pathogenesis and provokes probable new symptoms; *Corroboration*: when the symptoms so obtained are corroborated pathologically and physiologically as per the existing medical notions. All this but only magnifies probability, but the ultimate is – *Verification*: When at the bed of the sick, the correspondence of the probable symptom, confirmed and corroborated, is verified by the obtained clinical results.³³⁸ This reflects the sheer importance of clinical verification in homeopathy. The final aim of the clinical verification of homeopathic symptoms is to evaluate the strength of the link between a symptom and the efficiency of a remedy verifying at the same time the principle of similar and the totality rule.³³⁹

Materia Medica is fundamental to homoeopathic prescription. Clinicians largely depend their choice of drug based on the information recorded in the source books. However, many symptoms recorded in the literature are included or graded not from drug proving findings but upon retrospective observation made by experts based on their clinical experiences. Over the time, the clinical symptoms, whether or not verified, have found a place in Materia Medica. This is true even for Jahr's 1840 manual and significant number of Kent's first degree symptoms. In order to keep in tune with times and to uphold the excellence in clinical results through prescribing drugs on most indicated symptoms, there is dire need to verify these symptoms. Even the symptoms proven by human

³³⁵ Vandenbroucke JP. In defense of case reports and case series. *An n Intern Med.* 2001;134:330-334.

³³⁶ Riley RD, Hayden JA, Steyerberg EW, Moons KG, Abrams K et al. Prognosis research strategy (PROGRESS) 2: Prognostic Factor Research. *PLoS Med* 2013;10(2): e1001380. doi: 10.1371/journal.pmed.1001380

³³⁸ Hering C., *The guiding symptoms of our Materia Medica*; B.Jain Publishers Pvt. Ltd., Reprinted 1989; pp 4-10

³³⁹ Wassenhoven M.V., *Third Edition of LMHI Guidelines on Clinical Verification of Homeopathic Symptoms*; March 2013; Available on: http://www.lmhi.org/dokumente/upload/e2dd4_2013_Guidelines_Clinical_verif_hom_symptoms_third_edition.pdf

volunteers centuries ago need verification as per the contemporary times. People are changing, morbidity patterns are changing, nature of our source material is also changing. Our Repertory and Materia Medica should remain living texts responding to these changes and provide contemporary information in contemporary language.³⁴⁰

The origin and reliability of symptoms in our Materia Medica and Repertory is not always clear. The influence of variance is not enough guarded, especially in symptoms that occur frequently. If, say, 10% of the patients that respond well to Arsenicum album are warm-blooded against 40% of the remainder of the population, being warm-blooded cannot be seen as an indication for Arsenicum album (although some of the Arsenicum album patients are indeed warm-blooded, this is due to natural variance). The influence of variance can be measured by quantitative research.

Efforts to verify and refine the abundant literature of Materia Medica are being made. In the Netherlands a group of experienced homeopathic doctors started discussing successful cases retrospectively concerning specific homeopathic medicines in 1997. The purpose was to validate existing Materia Medica by qualitative analysis of successful cases. Data collection was done for two projects assessing homeopathic prescribing; one qualitative, the other quantitative. A Dutch commercial database program (HARP) and three database programs made by doctors for their own practice facilitated retrieving successful cases. The first project, Materia Medica Validation (MMV), comprised consensus meetings from 1997 to 2007. Twice a year experienced (> 5 years) Dutch homeopathic physicians were invited to bring in their best cases concerning two specified homeopathic medicines to reflect on how to improve homeopathic prescribing. The meetings were structured as open discussions, but on a pre-structured format for each case, describing reasons for prescribing the

homeopathic medicine and the effects ascribed to the medicine. The cases had a follow-up of at least one year considering the assessed medicine and the relation between effect and the medicine should be clarified. There were no other inclusion or exclusion criteria to allow an open discussion about different methods in homeopathy. All participants, however, were trained in classical homeopathy. These meetings were attended by 10-25 doctors, presenting in total between five (concerning Naja) and 23 (concerning Sulphur) best cases. Each case was discussed regarding causality (was the improvement really due to the medicine?), about the type of person and the symptoms present in the case. The GHOS scale was used as an instrument to assist the discussion about causality. The participants had the patient's file with them, so there was the possibility to confirm symptoms that were not mentioned at first by hindsight if the symptom came up in other cases. An attempt was made to estimate the prevalence of the most important symptoms. One of the outcomes that surprised the participants was the fact that some expected symptoms were not present in all cases. Only four out of ten Causticum patients were sensitive to injustice, five out of 12 Stramonium patients were afraid of the dark. Apparently, the absence of these symptoms is no absolute contra-indication for the respective medicines. Opinions appeared to differ about what results should be entered and when. Some participants thought that only good results were relevant, some recorded the first result three months after starting treatment, others after one month. The second project, the Likelihood Ratio project (LR project), was a prospective observational study in 10 Dutch practices from 2004 to 2007, assessing six homeopathic symptoms ('Diarrhoea from anticipation', 'Fear of death', 'Grinding teeth during sleep', 'Recurrent herpes of the lips', 'Loquacity' and 'Sensitivity to injustice'). The purpose of this project was to assess the relationship between these symptoms and positive

³⁴⁰ Swayne J., Data collection and research in homeopathic

medicine, *British Homeopathic Journal* 1986 (75), pp 157-161

results of respective medicines, avoiding influencing daily practice and minimising time necessary for recording data. There was no interference with usual practice, ethical approval was not required, but patients were informed that their data would be used anonymously for practice evaluation. All symptoms were checked in each consecutive new patient. All patients older than two years with checked symptoms were included. Patients with acute pathology and with no grounds for homeopathic therapy were excluded. Only chronic cases were recorded. Results regarding prescribed medicines were frequently monitored and feedback was organised in newsletters and consensus meetings. In the end 4094 patients were included and 4074 prescriptions were evaluated. Results of treatment (per medicine) were recorded after at least three months following a modified Glasgow Homeopathic Hospital Outcome Scale (GHHOS). If the last GHHOS score within a year for a specific medicine was ≥ 2 , with probable causal relationship between medicine and result, the patient was attributed to that medicine population.³⁴¹

Wassenhoven in his book on clinical verification adopted both traditional and statistical methods to retrospectively analyse 80.625 symptoms of 100 drugs with respect to their recovery in 2,148 patients. He carried out this task over 16 years and compared his results with respect to the existing values of the symptoms in the literature (Synthesis repertory, Allen's Encyclopedia and Rixhard Hughes's Cyclopedia of Drug Pathogenesis). He recommends a prospective analysis on larger scale, involving more physicians, for validation of his findings.³⁴² Central Council for Research in Homoeopathy has been conducting clinical verification studies of indigenous and

fragmentarily proved drugs since its inception in 1975. The programme is as per open clinical trial design in which patients are enrolled from O.P.D. as and when they come, after confirmation of their inclusion criteria as per a standard protocol. The homeopathic medicines are prescribed on the basis of symptom similarity. The individualistic symptoms of each case are evaluated as per the Materia Medica & Repertorial index. Clinical Verification of symptomatic data of 108 drugs has been conducted so far. 16 other drugs proved by the Council are being verified presently.³⁴³

The task of clinical verification of homeopathic medicines is enormous and no one method is likely to verify all the symptoms. The approach to such a task has to be flexible and varied, wherein traditional verification, as explained by Hahnemann, needs to be adopted for the unquestionable cases where either spectacular recoveries or failures are taken into account. The statistical method, based on Bayes theorem, which studies the existing relation between two elements and calculates the likelihood ratio of a symptom, is another method. This method, created in 1958, takes into account all the cases, including the intermediate ones, and therefore, allows more detailed analysis.³⁴⁴ A clinical verification guidelines drafted by LMHI provides a hands on information on the subject and explains how to take up and contribute to the task of verification. Much remains to be done on this front and information sharing and methodological tool development on larger scale are needed to expedite this work. Through a systematic clinical verification, an Evidence Based Repertory will be soon a reality, starting in your own office using your own daily results.³⁴⁵

³⁴¹Rutten ALB, Data collection: treat every variable as a treasure; personal communication, pp 1-11

³⁴²Wassenhoven M.V., Clinical verification – Verification of homeopathic symptoms; B.Jain Publishers 2008

³⁴³ Official website of CCRH: http://ccrhindia.org/Clinical_verification.asp; Accessed on October 7, 2014

³⁴⁴Wassenhoven M.V., Clinical verification – Verification of

homeopathic symptoms; B.Jain Publishers 2008

³⁴⁵ Wassenhoven M.V., Third Edition of LMHI Guidelines on Clinical Verification of Homeopathic Symptoms; March 2013; Available on: http://www.lmhi.org/dokumente/upload/e2dd4_2013_Guidelines_Clinical_verif_hom_symptoms_third_edition.pdf; last accessed on 6 October 2014

However, to achieve this, it is important that we start to contribute. A web programme titled Cli-Fi-Col for “Clinical Files Collections” is one such platform where the doctors can contribute their cases for analysis. It is important to collect our clinical cases in a central site in order to improve our daily practice in Homeopathy. The programme allows to search for special cases treated by our colleagues and to send the most relevant cases by ourselves. One can also use this instrument as a tool for studying Homeopathy in the practice, to collect systematically the clinical cases that allow the clinical

verification of the pathogenetic symptoms and consequently the improvement of our basic tools (the Repertory and Materia Medica), and for specific projects. By contributing to the clinical verification programmes, one can become a hinge in the improvement of the future homeopathic practice.³⁴⁶

³⁴⁶ Information available on <http://www.femh.org/wp-content/uploads/2013/01/clificol.pdf>; last accessed on 6

Table of recent publications of clinical vification of homeopathic symptoms.

| Condition/Study | N | Design | N Symp | N Rem | Results |
|--|------|------------------|--------|-------|--|
| Van Wassenhoven ³⁴⁷ (2005) | 2148 | LR retrospective | >230 | 100 | Symptoms – Similarity – Globality |
| CCRH ³⁴⁸ Damiana (2007) | 3032 | Trad. Method | ? | 1 | Symptoms |
| Rutten & all ³⁴⁹ (2008) | 4094 | LR Prospective | 6 | 75 | Similarity |
| Araujo (*). Anacardium orientale (2008) | 5 | Trad. Method | ? | 1 | 16 groups of symptoms – Similarity (constitution) |
| Gnaiger & all (*) ³⁵⁰ Petroleum (2008) | 25 | Trad. Method | ? | 1 | 6 groups of symptoms – Similarity (constitution) |
| Dominici (*) Hydrogenium peroxidatum (2008) | 18 | Trad. Method | 10 | 1 | Symptoms of proving – Similarity |
| AFADH (*) Latrodectus Tredicim Guttatus (2008) | 4 | Trad. Method | ? | 1 | 24 groups of symptoms – Similarity (constitution) |
| AFADH (*) Tarentula Lycosa (2008) | 5 | Trad. Method | ? | 1 | 36 groups of symptoms – Similarity (constitution) |
| Louis (*) Borax (2008) | 12 | Trad. Method | ? | 1 | 6 groups of symptoms – Similarity (constitution) |
| Lustig (*) Neptunium muriaticum (2008) | 2 | Trad. Method | ? | 1 | 1 groups of symptoms – Similarity (constitution) |
| Marim & all (*) (2008) | 5 | Trad. Method | ? | 4 | 5 groups of symptoms – Similarity (constitution) |
| Petrucci (*) Falcon Peregrinus Disciplinatus (2008) | 8 | Trad. Method | 8 | 1 | Symptoms of proving – Similarity |
| Pla (*) Salix Fragilis (2008) | 2 | Trad. Method | 95 | 1 | 7 groups of symptoms - Similarity (constitution) |
| Scheepers & all (*) (2008) | 37 | Trad. Method | 38 | 6 | Symptoms + 13 groups of symptoms – Similarity (constitution) |
| Servais & all (*) Petroleum (2008) | 11 | Trad. Method | 220 | 1 | Symptoms |
| Stolper & all (*) (2008) | 26 | Trad. Method | 23 | 2 | Symptoms of proving – Similarity |
| Uyttenhove (*) Cheirantus cheiri (2008) | 300 | Trad. Method | 6 | 1 | Symptoms of proving – Similarity |
| Uyttenhove & all (*) Hecla Lava (2008) | 262 | Trad. Method | ? | 1 | Symptoms of proving – Similarity |
| Chakraborty & all ³⁵¹ Blatta orientalis (2008) | 6184 | Trad. Method | 80 | 1 | Symptoms |

³⁴⁷Van Wassenhoven M. Towards an evidence-based repertory: clinical evaluation of Veratrum Album. *Homeopathy* 2004;93, 71-77./ First line medicine – Clinical verification – Verification of homeopathic symptoms ISBN (2008) 978-2-87491-003-6 /Van Wassenhoven M. Clinical verification of symptoms of Natrium salts.Proceedings 2010 LMHI Congress LA-USA.

³⁴⁸CCRH. Damiana – A Multicentric Clinical Verification Study. *Indian Journal of Research in Homeopathy* 2007 vol 1 n°1,17-23

³⁴⁹Rutten ALB, Stolper CF, Lugten RFG, Barthels RWJM. New repertory, new considerations. *Homeopathy* 2008;97:16-21.

³⁵⁰Gnaiger – Rathmanmer J, Schneider A, Loader B, Böhler M, Frass M, Singer SR, Oberbaum M. Petroleum a serie of 25 Cases. *Homeopathy*2008; 97:83-88.

³⁵¹Chakraborty PS & all. Clinical verification of Baltta orientalis. *Indian Journal of Research in Homeopathy*. April-June 2008;Vol 2 n°2:25-30.

| | | | | | |
|--|------|--|-----|----|--|
| Chakraborty & all ³⁵² Amoora rohituka (2008) | 4706 | Trad. Method | 89 | 1 | Symptoms |
| Chakraborty & all ³⁵³ Mentha piperita (2008) | 6372 | Trad. Method | 105 | 1 | Symptoms |
| Chakraborty & all ³⁵⁴ Ferrum picricum (2008) | 3465 | Trad. Method | 70 | 1 | Symptoms |
| Chakraborty & all ³⁵⁵ Fagopyrum esculentum (2009) | 6675 | Trad. Method | 95 | 1 | Symptoms |
| Chakraborty & all ³⁵⁶ Alstonia constricta (2009) | 3854 | Trad. Method | 66 | 1 | Symptoms |
| Chakraborty & all ³⁵⁷ Ephedra vulgaris (2009) | 1657 | Trad. Method | 47 | 1 | Symptoms |
| Chakraborty & all ³⁵⁸ Tarentula Hispanica (2009) | 2794 | Trad. Method | 148 | 1 | Symptoms |
| Chakraborty & all ³⁵⁹ Iris Tenax (2010) | 2279 | Trad. Method | 29 | 1 | Symptoms |
| Faingnaert Y. (**) Galium aparine | 1 | Trad. Method | ? | 1 | Link between proving symptoms, botany and clinical case. |
| Nayak & all ³⁶⁰ Glycyrrhiza glabra (2010) | 278 | Trad. Method | 109 | 1 | Symptoms |
| Nayak & all ³⁶¹ Glycyrrhiza glabra (2010) | 340 | Trad. Method | 43 | 1 | Symptoms |
| Chakraborty P.S. & all ³⁶² Staphylococcinum (2012) | 411 | Trad. Method | 24 | 1 | Symptoms of proving – Similarity |
| Ross A.H.A. (*) | ? | Comparison with the use of the plant by tradi- tional healers | ? | 1 | Symptoms and syndromes Strychnos henningsii |
| Chakraborty P.S., Ali S.A. (*) | ? | Concomitant symptoms | ? | 19 | Concomitant symptoms (modalities) |

³⁵²Chakraborty PS & all. Clinical verification of Amoora rohituka. *Indian Journal of Research in Homeopathy*. January-March 2008;Vol 2 n°1:19- 25.

³⁵³Chakraborty PS & all. Clinical verification of Mentha piperita. *Indian Journal of Research in Homeopathy*. October-December 2008;Vol 2 n°4:26-33.

³⁵⁴Chakraborty PS & all. Clinical verification of Ferrum picricu. *Indian Journal of Research in Homeopathy*. July-September 2008;Vol 2 n°3:15-21.

³⁵⁵Chakraborty & all. A multicentric Clinical Verification Study conducted by CCRH. *Indian Journal of Research in Homeopathy*. January-March 2009;Vol 3 n°1:23-33.

³⁵⁶Chakraborty & all. A multicentric Clinical Verification Study conducted by CCRH. *Indian Journal of Research in Homeopathy*. Apri-I-J une 2009;Vol 3 n°2:38-43.

³⁵⁷Chakraborty & all. A multicentric Clinical Verification Study conducted by CCRH. *Indian Journal of Research in Homeopathy*. July-September 2009;Vol 3 n°3:14-20.

³⁵⁸Chakraborty & all. A multicentric Clinical Verification Study conducted by CCRH. *Indian Journal of Research in Homeopathy*. October-December 2009;Vol 3 n°4:25-36.

³⁵⁹Chakraborty & all. A multicentric Clinical Verification Study conducted by CCRH. *Indian Journal of Research in Homeopathy*. Apri-I-J une 2010;Vol 4 n°4:18-22.

³⁶⁰Nayak & all. A multicentric Clinical Verification Study conducted by CCRH. *Indian Journal of Research in Homeopathy*. July-September 2010;Vol 4 n°3:22-33.

³⁶¹Nayak & all. A multicentric Clinical Verification Study conducted by CCRH. *Indian Journal of Research in Homeopathy*. October-December 2010;Vol 4 n°4:12-18.

³⁶²Chakraborty & all. A multicenter Clinical Verification Study conducted by CCRH. *Indian Journal of Research in Homeopathy*. January-June 2012. Vol 6 n°1 & 2:15-21.

CHAPTER X

Basic Research

Homeopathy is progressively receiving scientific validation, not only as a result of significant clinical research outcomes, but also due to evolved understanding of various concepts in physics, chemistry and biomedicine, which has forced the scientific community to notice various homeopathic concepts in new light. Basic research in Homeopathy investigates a particular set of questions, chiefly the presence of therapeutic powers of original substances in ultra-high-diluted potencies, mechanism of action of the medicine, once administered, in a biological system, be it human, animal or plant, both its pharmacokinetic and pharmacodynamics aspects and the relevance of negative controls in basic researches in order to validate the findings.

Physicochemical aspects

The major part of scepticism towards Homeopathy springs from the high dilutions of homeopathic medicines achieved through the process of potentisation. The scientific knowledge of the physical cessation of any substance diluted beyond the level of yoctomole that is 10^{-24} moles/L, makes Homeopathy rather intriguing to the curious and unscientific to those who abide by the book of physical science. However, many postulations have challenged the concept of Avogadro constant and proposed that there could be non-molecular (or rather, meta-molecular) information imprinted on the structure of the solvent (water, or mixture of water and alcohol) which can interact through resonance with the

biophysical regulation systems of the target organism.³⁶³ In fact, among the ever-puzzling features of water, lies the possibility that it can act as a repository and transmitter of biologically significant information. When a given molecule is dissolved or immersed in water, the structure of water changes in a manner dependent on the properties of the added molecule. At the interface between the macromolecules and solvent, an enormous restructuring of water takes place, resulting into entirely new configurations even at a considerable distance from the solute molecule. 'Vicinal water', water near a solid surface or macromolecules, is known to have alteration in its structure over distances ranging from 5 to 200 diameters from the surface in question.³⁶⁴

Additionally, the process of potentisation, as reflected in many basic research papers on Homeopathy, seem to alter the physico-chemical properties of the solvent permanently, thus rendering the unique therapeutic properties to homeopathic medicines.^{365,366,367} The impact of repeated strong shaking and fluid dynamics have been reviewed in inter-molecular solvent-solute and solvent-particle interactions, whereby it is argued, that the information exchange occurs between the solute and solvent, a process already known as epitaxy.³⁶⁸

Therefore, in order to understand the physico-chemical dynamics of homeopathic drugs, it is important that these drugs are explored in the light of new-age understanding of physics (quantum physics) with concepts like effects of

³⁶³ Bellavite P., Marzotto M., Oliosio D., Moratti E. and Conforti A.; High-dilution effects revisited 1:Physicochemical aspects; Homeopathy (2014) 103, 4-21

³⁶⁴ Cheng YK, Rossky PJ. The effect of vicinal polar and charged groups on hydrophobic hydration. Biopolymers 1999; 50:742-50.

³⁶⁵ Elia V, Napoli E, Niccoli M, Nonatelli L, Ramaglia A, Ventimiglia E. J New physico-chemical properties of extremely diluted aqueous solutions. A calorimetric and conductivity study at 25C; Thermal Anal Calorim 2004;331-

342.

³⁶⁶ Voeikov VL. The possible role of active oxygen in the memory of water. Homeopathy 2007; 96: 196-201.

³⁶⁷ Ives JA, Moffett JR, Arun P, et al. Enzyme stabilization by glass derived silicates in glass-exposed aqueous solutions. Homeopathy 2010; 99: 15e24.

³⁶⁸ Rao ML, Roy R, Bell IR, Hoover R. The defining role of structure (including epitaxy) in the plausibility of homeopathy. Homeopathy 2007; 96: 175e182.

magnetic fields on dilution^{369,370,371}, aggregation of water molecules as explained in the clathrate model³⁷², coherence domains inside which the whole matter (atoms, molecules, electrons and nuclei) oscillates in tune with a macroscopic electromagnetic field³⁷³, nanoparticles that could be an integral characteristic of the homeopathic dilutions^{374,375}, entanglement^{376,377} and fractals.³⁷⁸

Pharmacodynamic mechanisms

Pharmacokinetics is the branch of pharmacology that studies the fate of a substance administered to a living organism up to the end point of elimination from the body. Pharmacodynamics, on the other hand, studies the effect of the administered substance on the body. The two approaches are usually studied in conjunction. The pharmacologic activity of mother tinctures and low potencies (e.g., 2C, 3C, containing relatively high doses of active principles) poses no problems of interpretation and requires analysis of the components and identification of their targets in the organism, in a way not dissimilar from that of herbal products, snake toxins, or mineral oligoelements. The action of medium potencies, that contain low doses of active principles (from about 4C or 5C to approximately 12C, close to the Avogadro limit) entails high sensitivity of living organisms and inversion of drug effects, in the framework of models not much

distant from modern pharmacology, like hormesis. The action of ultra-high-dilutions (HDs, namely homeopathic dilutions beyond the Avogadro constant) requires the identification of possible 'non-molecular' or 'meta-molecular' information transfer mechanisms.³⁷⁹ However, the specificity of any drug is based on its interaction with the biological targets. The mechanism by which it is achieved has been studied using animals, cells, tissues, plants and even at molecular level. A famous study observed the effect of lung histamine (5C and 15C) and *Apis mellifica* (9C) on in vitro human basophil degranulation and found significant results.³⁸⁰ Similar results have been reproduced elsewhere. The effect was inhibited by histamine H2 receptor antagonists cimetidine, supporting the hypothesis that homeopathic dilutions may act through modulation of cell receptors and protein synthesis. Khuda-Buksh's works speak of similar effect as he proposes a model whereby the dilutions bring about repair of chromosomes and sperm head morphology in mice through regulation of genetic activity.³⁸¹ In support of this hypothesis, is a study that reveals that in presence of a transcription blocker, Actinomycin D, potentized homeopathic medicines failed to act.³⁸² Another theory that Majewsky et al postulates, as a result of reported positive effects of potentised 'plant growth substances' or 'plant hormones', is that homeopathic medicines act through hormonal

³⁶⁹ Benveniste J. Further biological effects induced by ultra high dilutions. Inhibition by a magnetic field. In: Endler PC, Schulte J (eds). *Ultra High Dilution*. Dordrecht: Kluwer Acad. Publ., 1994, p.35-38.

³⁷⁰ Benveniste J, Guillonnet D. QED and digital biology. *Riv Biol* 2004; 97: 169-172

³⁷¹ Weber S, Endler PC, Welles SU, et al. The effect of homeopathically prepared thyroxine on highland frogs: influence of electromagnetic fields. *Homeopathy* 2008; 97: 3-9.

³⁷² Anagnostatos GS. Small water clusters clathrates in the preparation process of homeopathy. In: Endler PC, Schulte J (eds). *Ultra High Dilution*. Dordrecht: Kluwer Acad. Publ., 1994, p. 121-128.

³⁷³ Preparata G. Regimi coerenti in Fisica e Biologia. In: *Il problema della forma*. Biology Forum, 1997434e436.

³⁷⁴ Chikramane PS, Suresh AK, Bellare JR, Kane SG. Extreme homeopathic dilutions retain starting materials: a nanoparticulate perspective. *Homeopathy* 2010; 99: 231-242.

³⁷⁵ Oleinikova A, Weingartner H, Chaplin M, Diemann E, Bogge H, Muller A. Self-association based on interfacial structured water leads to {Mo154}approximately 1165 super clusters: a dielectric study. *Chemphyschem* 2007; 8: 646-649.

³⁷⁶ Milgrom LR. Patient-practitioner-remedy (PPR) entanglement. Part 1: a qualitative, non-local metaphor for homeopathy based on quantum theory. *Homeopathy* 2002; 91: 239-248.

³⁷⁷ Walach H. Entanglement model of homeopathy as an example of generalized entanglement predicted by weak quantum theory. *Forsch Komplementarmed Klass Naturheilkd* 2003; 10: 192-200

³⁷⁸ Davenas E, Beauvais F, Amara J, et al. Human basophil degranulation triggered by very dilute antiserum against IgE. *Nature* 1988; 333: 816-818.

³⁷⁹ Bellavite P., Marzotto M., Deborra Oliosio D., Elisabetta Moratti E. and Anita Conforti A.; High-dilution effects revisited 2: Pharmacodynamic mechanisms; *Homeopathy* (2014) 103, 22-43

³⁸⁰ Poitevin B, Davenas E, Benveniste J. In vitro immunological degranulation of human basophils is modulated by lung histamine and *Apis mellifica*. *Br J Clin Pharmacol* 1988; 25: 439-444.

³⁸¹ Anisur Rahman Khuda-Bukhsh; Mice as a model for homeopathy research; *Homeopathy* (2009) 98, 267-279

³⁸² Chakrabarti J, Biswas SJ, Khuda-Bukhsh AR. Cytogenetical effects of sonication in mice and their modulations by actinomycin D and a homeopathic drug, *Arnica* 30. *Indian J Exp Biol* 2001; 39:1235-1242.

stimulation. Since even stronger responses were observed in basic research animal models after application of potentised animal hormones, one might setup the hypothesis, that human hormones – unknown at Hahnemann’s times – might be promising substances for human homeopathic therapy.³⁸³

Challenges

Sensitive nature of basic research experiments

It has, however, been pointed out that the effects described in many basic research experiments in homeopathy are difficult to reproduce because the experiments are markedly affected by minimal technical differences and conditions, including the skill of the operator, the type of blood donors, the season and the day of the experiment, perhaps atmospheric pressure, the electromagnetic ‘pollution’ of the laboratory, the time left between a dilution and the subsequent, and similar factors.

In addition to these methodological problems, the ‘ingredients’ of the homeopathic HDs may vary due to trace compounds present in the triturations and in water solutions used to make the remedies and to different methods of succussion and storage of solutions.³⁸⁴ In order to provide strong evidence in favour of homeopathic dilutions and identify their specific effects, it is important to demonstrate the absence of false-positive effects arising from the influence of laboratory or ambient conditions. For this reason, it is necessary to perform systematic negative control experiments.³⁸⁵ A review of *in vitro* researches, Witt et al suggest that to

prove that high potencies have a specific effect, they should only differ from controls in being a potentized stock preparation.³⁸⁶

Interestingly, the sensitive nature of homeopathic preparations is also revealed by a pilot study that has suggested the blocking effect of certain magnetic fields, such as microwave oven and cell phone derived fields on homeopathic preparations of T4.³⁸⁷ This further emphasises the need of environment controlled experiments under strict conditions for best reproducible results.

The ‘similia’ principle

There is a need to explain the ‘similia’ principle through experimentation. The Similia Principle has been discussed in mainstream biomedicine in relation to hormesis, in which an originally toxic substance is said to become a stimulating agent at low concentration. There is adequate evidence in support of the phenomenon of hormesis.^{388,389,390} Hormesis is not limited to chemical substances. The hormetic effect via low doses of ionizing radiation has also been confirmed.³⁹¹ Calabrese et al introduced the term ‘post-conditioning hormesis’ to indicate the possibility that small stimuli could exert a beneficial effect when applied to cells or organisms even after a severe stress.³⁹² The new field of ‘post-conditioning hormesis’ is not only a new development with possible important biomedical implications for patient treatment, it also brings hormesis and the homeopathic similia principle closer together. However, the discussion of hormesis with reference to homeopathy has raised many unsolved questions. Hormesis acts at

³⁸³ Majewsky V. et al; Use of homeopathic preparations in experimental studies with healthy plants; *Homeopathy* (2009) 98, 228–243

³⁸⁴ Bellavite P., Marzotto M., Oliosio D., Moratti E. and Conforti A.; High-dilution effects revisited 1: Physicochemical aspects; *Homeopathy* (2014) 103, 4–21

³⁸⁵ Betti L., Use of homeopathic preparations in phytopathological models and in field trials: a critical review; *Homeopathy* (2009) 98, 244–266

³⁸⁶ Witt C.M., Bluth M., Albrecht H., Weißhuhn T.E.R., Baumgartner S., Willich S.N.; The *in vitro* evidence for an effect of high homeopathic potencies—A systematic review of the literature; *Complementary Therapies in Medicine* (2007) 15, 128–138

³⁸⁷ Weber S, Endler PC, Welles SU, et al. The effect of homeopathically prepared thyroxine on highland frogs: influence of electromagnetic fields. *Homeopathy* 2008; 97: 3–9.

³⁸⁸ Neafsey PJ. Longevity hormesis. A review. *Mech Ageing Dev* 1990;51(1): 1–31.

³⁸⁹ Calabrese EJ, Baldwin LA. Defining hormesis. *Hum Exp Toxicol*;2002; 21(2): 91–97.

³⁹⁰ Stebbing ARD. A mechanism for hormesis – a problem in the wrong discipline. *Crit Rev Toxicol* 2003; 33(3–4): 463–467.

³⁹¹ Luckey TD. Hormesis with ionizing radiation. Boca Raton: CRC Press Inc., 1980, pp 1–222.

³⁹² Calabrese EJ, Bachmann KA, Bailer AJ, et al. Biological stress response terminology: integrating the concepts of adaptive response and preconditioning stress within a hormetic dose–response framework. *Toxicol Appl Pharmacol* 2007; 222(1): 122–128.

concentrations much higher than those typically used in homeopathy and avoid the problem of ultra high-dilutions that (theoretically) do not contain a single molecule of the original substance. Contrary to homeopathy, hormesis also does not need any special technique to prepare the 'active agent'. Therefore, more research needs to be done to further explore the connection between the concept of hormesis and pharmacodynamics of homeopathic dilutions which comes into action on the basis of similia.

Overview

Data analysis of 1868 entries in basic research database, HomBRex (<http://www.carstens-stiftung.de/hombrex>), revealed that most publications on basic research were reported from France (n = 267), followed by Germany (n = 246) and India (n = 237). In the last ten years, the number of publications from Brazil dramatically increased from n = 13 (before 2004) to n = 164 (compared to n = 251 published in France before 2004, and n = 16 between 2004 and 2013). The oldest database entry was from Germany (1832)³⁹³.

Conclusion

A general adoption of succussed controls, randomization and blinding would strengthen the evidence of further experiments. More replications should be done independently to establish models that are stable across laboratories and teams. As the knowledge of the dynamic processes within living organisms and of various phenomena in the environment that influence these organisms advances, the understanding of the physicochemical and pharmacodynamics aspects of Homeopathy will grow further.

New results since 2007: references (147, 148, 149)

2008 – 63rd IMHI Congress' proceedings

Costa BGB, Siqueira CM, Barbosa GM, Portela MB, Soares RMA, Holandino C. Development of a new biotherapeutic of *Candida Albicans* to the treatment of oral candidiasis using yeast cells cultures, placebo and Nystatin® controlled design./

Siqueira CM, Costa B, Amorim AM, Conzalez M, Veiga VF, Lyrio C, Couceiro JN, Holandino C. Looking for a new biotherapeutic prepared from infectious influenza virus: an in vitro study. Virus H3N2, MDCK cells cultures, antiviral activity. Other references.^{394, 395, 396}

The peer reviewed journal *Homeopathy* (144), published two special issues on biological models of homeopathy in 2009 and 2010 and concluded as such: "Above all this field is exciting and dynamic: there is a remarkable range of biological models of relevance to homeopathy, with encouraging progress in terms of quality and a growing number of positive findings. And we have not covered all the models in depth: for instance the work of Christian Doutremepuich's group on the effects of dilution of aspirin on blood clotting, the subject of several repetitions, is discussed only briefly. The replicability of experiments is a crucial criterion for their credibility. The multinational group led by Christian Endler and involving coauthors from Austria, Switzerland and Brazil address in this issue their bibliometric study of repetitions of fundamental research models. They found that 24 experimental models have been repeatedly investigated, 22 with similar inter-experiment results. They classify repetitions according to whether they came from the same group as the original report, or multicentre or independent work; and

homeopathy in mice experimentally infected with *Trypanosoma cruzi*. *Homeopathy*. 2008;97:65-69.

³⁹⁶Almeidia JD, Arisawa EAL, Balducci I, Rocha RF, Carvalho YD. Homeopathic treatment for bone regeneration: experimental study on rats. *Homeopathy*. 2009;98:92-96.

³⁹³ Clausen J., Wijk R.v. and Albrecht H.; Geographical and temporal distribution of basic research experiments in *Homeopathy*; *Homeopathy* (2014) 103, 193-197

³⁹⁴Bresler A, Hawkins D, Razlog R, Abrahamse H. Effect of Low Level Laser Therapy and *Calendula officinalis* 3CH on Wound Healing in Human Skin Fibroblasts. *Indian Journal of Research in Homeopathy*. April-June 2008; Vol 2, n°2:7-15.

³⁹⁵Almeida LR, Campos MCO, Herrera HM, Bonamin LV, Fonseca AH. Effects of

results as positive and similar, positive but qualitative different or negative. The most frequently and consistently replicable model is inhibition of basophil activation by high dilutions of histamine. But as Madeleine Ennis shows significant methodological issues remain. Methods vary between laboratories, although the same can be said of conventional studies. She suggests that following standardization another multicentre experiment be performed.”

Once again results are very encouraging and are able to reach a significant evidence level, but more systematic standardized research is needed.

Medicine Nobel Prize winner Prof Luc Montagnier, does not hesitate now to support the idea of information transmitted through water solvent. This is the result of his findings published already in *Interdiscip Sci Comput Life Sci* (2009) 1:81-90 “Electromagnetic Signals Are Produced by Aqueous Nanostructures Derived from Bacterial DNA Sequences”. In Strasburg, during the Congress “Homeopathy, a chance for Europe” (May 2010) he concluded: “Since 2005 we discovered that plasma from patients suffering of chronic degenerative diseases can emit low frequencies electromagnetic signals at high dilutions in water corresponding to the same frequencies of bacteria’s DNA. These findings are confirming the idea of Water Memory and previous results obtained with, as example, the basophil activation model.” At the XXIV GIRI symposium in Monaco (Nov. 2010) he presented also a second publication: *Electromagnetic Detection of HIV DNA in the Blood of AIDS Patients Treated by Antiretroviral Therapy*. *Interdiscip Sci Comput Life Sci*. 2009;1: 245–253 and he concluded that there is a highly sensitive detection system for chronic bacterial infections in human beings and

animals. He also noted that serial dilution and agitation have found to be critical for the generation of electromagnetic signals.

A new area for research is now very active in laboratories in the world about the use of Homeopathy in viral infections? A first result has been published in 2010. Bhaswati Bandyopadhyay & all. Decreased intensity of Japanese Encephalitis virus infection in chick chorioallantoic membrane under influence of ultradiluted Belladonna extract.

Indian Journal of Research in Homeopathy. Vol 4, N°2, April-June 2010.

2011 – New publications

EEG as control of the effects of homeopathic medicines! Totally independently of each other, two teams arrived to a similar conclusion; EEG can be a very objective “control tool” for the effects of homeopathic medicines. The first team³⁹⁷ could demonstrate objective and specific changes in EEG of healthy volunteers during drug provings and the second team³⁹⁸ did the same in laboratory rats; the effect of the homeopathic medicines are comparable to the effects of neurologic conventional drugs.

Guedes JRP, Carrasco S, Ferreira CM, Bonamin LV, Souza W, Goldenstein-Schainberg C. Ultra High Dilution of Triiodothyronine (T3 10CH) modifies cellular apoptosis in *Rana catesbeiana* tadpole tail in vitro. *Homeopathy* (2011) 100, 220-227.

2013 – New publications

In a replication of the experiments on extremely diluted thyroxine and highland amphibians, obtained results are in line with the previous experiments. Harrer B. *Homeopathy* (2013) 102:25-30.

³⁹⁷Bell IR & all. Short-term effects of repeated olfactory administration of homeopathic Sulphur or Pulsatilla on electroencephalographic alpha power in healthy young adults. *Homeopathy* (2011) 100, 203-211.

³⁹⁸Dimpfel W, Biller A. In vivo and in vitro neurophysiological findings in the rat in the presence of Coffea D6, Gelsemium D4 and Veratrum D6 extracts. 2012 in publication. / Dimpfel W. Homeopathy in the light of state of the art experimental setups. A comparison between the effects of a homeopathic medicine Neurexan and conventional neurologic drugs such as Diazepam, Fentanyl, Haloperidol etc. 2012 in publication. / Dimpfel W, Dalhoff B, Hofmann W, Schlüter G. Electrically evoked potentials in the rat hippocampus slice in the presence of aminophylline alone

and in combination with quinolones. *European Neuropsychopharmacology*. 1994; 4:151–56. / Dimpfel W Effects of memantine on synaptic transmission in the hippocampus in vitro. *Arzneimittelforschung*. 1995; 45:1-5. Dimpfel W. Preclinical data base of pharmaco-specific rat EEG fingerprints (tele-stereo-EEG). *Eur J Med Res*. 2003; 8:199-207. / Dimpfel W, Hoffmann JA. Electropharmacograms of Rasagiline, Its Metabolite Aminoindan and Selegiline in the Freely Moving Rat. *Neuropsychobiol*. 2010; 62:213–220. / Dimpfel W, Hoffmann JA. Effects of rasagiline, its metabolite aminoindan and selegiline on glutamate receptor mediated signalling in the rat hippocampus slice in vitro. *BMC Pharmacol*. 2011; 11:2.

1. **Saha S, Hossain DMS, Mukherjee S, Mohanty S, Mazumdar M, Mukherjee S, et al. Calcarea carbonica induces apoptosis in cancer cells in p53-dependent manner via an immuno-modulatory circuit. BMC Complement Altern Med. 2013;13:230.**
 - The findings of the study indicated a “two-step” mechanism of the induction of apoptosis in tumor cells by *Calcarea carbonica* i.e., activation of the immune system of the host; and induction of cancer cell apoptosis via immuno-modulatory circuit in p53-dependent manner by down-regulating Bcl-2:Bax ratio. The observations delineate the significance of immuno-modulatory circuit during *Calcarea carbonica* mediated tumor apoptosis.
2. **Betti L, Zurla M, Trebbi G, Brizzi M, Borghini G, Borghini F. Extremely low doses of arsenic affect in vitro pollen germination. Forsch Komplementmed. 2013;20:254-60.**
 - The findings of this study seem to indicate the in vitro pollen performance as adequate to study the effects of physicochemical sub-threshold stimuli (extremely low doses or high dilutions of pharmacological compounds, weak extremely low frequency magnetic fields), mediated through water.
3. **de Lima LF, Rocha RMP, Alves AMCV, Saraiva MVA, Araújo VR, Lima IMT. Dynamized follicle-stimulating hormone affects the development of ovine preantral follicles cultured in vitro. Homeopathy 2013;102:41-8.**
 - FSH 6cH (24 h) treatment maintained the viability, and promoted the activation and in vitro growth of ovine pre-antral follicles.
4. **Harrer B. Replication of an experiment on extremely diluted thyroxine and highland amphibians. Homeopathy 2013;102:25-30.**
 - The number of animals entering the juvenile stage with reduced tail was smaller for thyroxine (T30x) than for control water (W30x). There was a clear trend of T30x animals developing more slowly than W30x animals.
5. **Siqueira CM, Costa B, Amorim AM, Gonçalves M, da Veiga VF, Castelo-Branco M, et al. H3N2 homeopathic influenza virus solution modifies cellular and biochemical aspects of MDCK and J774G8 cell lines. Homeopathy 2013;102:31-40.**
 - Influenzinum 30dH was found to alter cellular and biochemical features of Madine Darby Canine Kidney (MDCK) and J774G8 cells.
6. **Bell IR, Koithan M, Brooks AJ. Testing the nanoparticle-allostatic cross-adaptation-sensitization model for homeopathic remedy effects. Homeopathy 2013;102:66-81.**
 - Homeopathic treatment is a form of nanomedicine acting by modulation of endogenous adaptation and metaplastic amplification processes in the organism to enhance long-term systemic resilience and health.
7. **de Camargo, da Costa ED, Catisti R. Effect of the oral administration homeopathic *Arnica montana* on mitochondrial oxidative stress. Homeopathy 2013;102:49-53.**
 - When administered orally, *Arnica* 30cH protects against hepatic mitochondrial membrane permeabilization induced by Ca^{2+} and/or Fe^{2+} -citrate-mediated lipid peroxidation and fragmentation of proteins due to the attack by reactive oxygen species.
8. **Demangeat JL. Nanosized solvent superstructures in ultramolecular aqueous dilutions: twenty years' research using water proton NMR relaxation. Homeopathy 2013;102:87-105.**
 - Proton Nuclear Magnetic Resonance (NMR) relaxation demonstrated modifications of the solvent throughout the low to ultramolecular range of dilution and suggested the existence of superstructures that originate stereospecifically around the solute after an initial destructuring of the solvent, developing more upon dilution and persisting beyond 12c.

9. **Sampath S, Narasimhan A, Chinta R, KR Nair KRJ, Khurana A, Nayak D, et al. Effect of homeopathic preparations of *Syzygium jambolanum* and *Cephalandra indica* on gastrocnemius muscle of high fat and high fructose-induced type-2 diabetic rats. *Homeopathy* 2013;102, 160-71.**
- In this study, homeopathic preparations of *S. jambolanum* and *C. indica*, including ultramolecular dilutions exhibit antidiabetic effects, improving insulin action through activation of insulin signaling molecules in skeletal muscle of type-2 diabetic rats.
10. **Jyothilakshmi V, Thellamudhu G, Kumar A, Khurana A, Nayak D, Kalaiselvi P. Preliminary investigation on ultra high diluted *B. vulgaris* in experimental urolithiasis. *Homeopathy* 2013;102: 172-8.**
- Homeopathic *B. vulgaris* root bark was found to have strong anti-urolithiasis potential at ultra-diluted dose in experimental rats.
11. **Arora S, Aggarwal A, Singla P, Jyoti S, Tandon S. Anti-proliferative effects of homeopathic medicines on human kidney, colon and breast cancer cells. *Homeopathy* 2013;102:274-82.**
- This study provides preliminary laboratory evidence indicating the ability of homeopathic medicines as anticancer agents in the forms of mother tincture, and ultramolecular dilution (30C, 200C, 1M and 10M) against cell lines deriving from tumors of particular organs, Sarsaparilla (*Sars*) on ACHN cells (human renal adenocarcinoma), *Ruta graveolens* (*Ruta*) on COLO-205 (human colorectal carcinoma), and *Phytolacca decandra* (*Phyto*) on MCF-7 (human breast carcinoma).
12. **ahata CR. Dielectric dispersion studies of some potentized homeopathic medicines reveal structured vehicle. *Homeopathy* (2013) 102, 262-7.**
- The range of resonance frequencies originated from the 6c and 30c potencies of Graphites and Cuprum metallicum in liquid form suggest that dielectric dispersion might originate from oscillation of dipoles caused by electric field in variously structured and polarised water. Also, there is reasonable evidence that frequencies change with materials and potency.
13. **Huh YH, Kim MJ, Yeo MG. Homeopathic *Rhus toxicodendron* treatment increased the expression of cyclooxygenase-2 in primary cultured mouse chondrocytes. *Homeopathy* 2013;102:248-53.**
- Homeopathic treatment with *Rhus tox* 4X, 30X and 30c induced chondrocyte dedifferentiation and inflammatory responses, such as COX-2 expression and PGE2 production, in primary cultured chondrocytes.
14. **Pal A, Misra BB, Das SS, Gauri SS, Patra M, Dey S. Antidiabetic effect of *Cephalandra indica* Q in diabetic rats. *Ind J Res Hom.* 2013;7(2):81-90.**
- The present study clearly indicates a significant anti-diabetic effect of *Cephalandra indica* mother tincture and potencies on blood glucose level, cholesterol level, body weight, and beta-cells of pancreatic islets of Langerhans, in streptozotocin (STZ)-induced diabetic Wistar rats and lend support for its usage as a homeopathic medicine.
15. **Korukanti VP, Ponnam H, Akondi BR. Evaluation of antiobesity activity of *Fucus vesiculosus*. *Ind J Res Hom.* 2013;7(3):126-32.**
- *Fucus vesiculosus* treatment prevented the adult female Wistar albino rats from becoming obese and the biochemical and physical parameters were maintained to normal levels.
16. **Ghosh S, Bishayee K, Paul A, Mukherjee A, Sikdar S, Chakraborty D, et al. Homeopathic mother tincture of *Phytolacca decandra* induces apoptosis in skin melanoma cells by activating caspase-mediated signaling via reactive oxygen species elevation. *J Integr Med.* 2013; 11(2): 116-124.**
- The study demonstrated anticancer potentials of ethanolic extract of *Phytolacca decandra* on A375 cells through activation of caspase-mediated signaling and ROS generation.
17. **Mukherjee A, Boujedaini N, Khuda-Bukhsh AR. Homeopathic Thuja 30C ameliorates**

- benzo(a)pyrene-induced DNA damage, stress and viability of perfused lung cells of mice in vitro.** *J Integr Med.* 2013;11(6):397-404.
- Thuja 30C ameliorates benzo(a)pyrene induced toxicity, stress and DNA damage in perfused lung cells of mice and it apparently has no effect on normal lung cells.
18. **Csupor D, Boros K, Hohmann J. Low potency homeopathic remedies and allopathic herbal medicines: is there an overlap?** *PLoS ONE* 2013;8(9):e74181.
- Homeopathic products containing active agents in allopathic doses should be treated the same way as allopathic medicines from the point of view of quality assurance and pharmacovigilance.
19. **Soumyajit Maiti, Kazi M. Ali, Kishalay Jana, Kausik Chatterjee, Debasis De, and Debidas Ghosh. Ameliorating effect of mother tincture of *Syzygium jambolanum* on carbohydrate and lipid metabolic disorders in streptozotocin-induced diabetic rat: Homeopathic remedy.** *J Nat Sci Biol Med.* 2013;4(1):68–73.
- The homeopathic drug *Syzygium jambolanum* mother tincture has a protective effect on diabetic induced carbohydrate and lipid metabolic disorders in streptozotocin-induced diabetic Wistar rats.
20. **Samadder A, Das S, Das J, Paul A, Boujedaini N, Khuda-Bukhsh AR. The potentized homeopathic drug, *Lycopodium clavatum* (5C and 15C) has anti-cancer effect on hela cells in vitro.** *J Acupunct Meridian Stud.* 2013;6(4):180-7.
- The highly-diluted, dynamized homeopathic remedies *Lycopodium clavatum* 5C and 15C demonstrated their capabilities to induce apoptosis in cancer (HeLa) cells, which was evident from the induction of DNA fragmentation, the increases in the expressions of protein and mRNA of caspase 3 and Bax, and the decreases in the expressions of Bcl2 and Apaf and in the release of cytochrome-c, signifying their possible use as supportive medicines in cancer therapy.
21. **Rajan A, Bagai U. Antimalarial potential of China 30 and Chelidonium 30 in combination therapy against lethal rodent malaria parasite: *Plasmodium berghei*.** *J Complement Integr Med.* 2013;7:10.
- Findings of the study point to the significant antiplasmodial and preventive efficacy of the combination of homeopathic drugs *Cinchona officinalis* 30C and *Chelidonium majus* 30C against *Plasmodium berghei*.
22. **Bishayee K, Paul A, Ghosh S, Sikder S, Mukherjee A, Biswas R, Boujedaini N, Khuda-Bukhsh AR. Condurango-glycoside - a fraction of *Gonolobus condurango* induces DNA damage associated senescence and apoptosis via ROS-dependent p53 signalling pathway in HeLa cells.** *Mol Cell Biochem.* 2013;382(1-2):173-83.
- Condurango-glycoside-A initiates ROS generation, promoting up-regulation of p53 expression, thus resulting in apoptosis and pre-mature senescence associated with DNA damage in cervix carcinoma cells (HeLa).
23. **Lenger K, Bajpai RP, Spielmann M. Identification of unknown homeopathic remedies by delayed luminescence.** *Cell Biochem Biophys.* 2013[Epub ahead of print].
- Six unknown homeopathic remedies could be identified as increasing potency levels of *Argentum metallicum* from 100MK to 1.000MK which indicates a calibration curve. A quality control of homeopathic remedies is possible by comparing the different B_2 -values of Bajpai's equation derived from the Hamiltonian equation of the remedies and their carrier substances.
24. **Nitzsche D, Melziq MF, Arlt VM. Evaluation of the cytotoxicity and genotoxicity of aristolochic acid I - a component of Aristolochiaceae plant extracts used in homeopathy.** *Environ Toxicol Pharmacol.* 2013;35(2):325-34.

- The medicinal plants *Aristolochia clematitis* and *Asarum europaeum*. The mother tinctures of the drugs inhibited DNA synthesis in human hepatoma HepG2 cells in a dose-dependent manner. One of the components of the plant extract, aristolochic acid I (AAI), is linked to the development of nephropathy and urothelial cancer in humans. Therefore the cytotoxicity and genotoxicity of AAI in HepG2 cells were evaluated. Cell proliferation was inhibited concentration-dependently by AAI using BrdU-ELISA and colony forming assay. AAI formed DNA adducts (measured by (32)P-postlabeling), induced chromosomal aberrations (micronuclei) and DNA strand breaks. DNA damage induced by AAI led to an arrest of cells in the S-phase which was associated with the increased expression of p53 and p21 proteins.
25. Bell IR, Schwartz GE. **Adaptive network nanomedicine: an integrated model for homeopathic medicine.** *Front Biosci (Schol Ed)*. 2013;5:685-708.
- Homeopathic remedies act by stimulating hormetic adaptive rather than conventional pharmacological effects. Updating terminology from "homeopathy" to "adaptive network nanomedicine" reflects the integration of this historical but controversial medical system with modern scientific findings.
26. Chakraborty D, Ghosh S, Bishayee K, Mukherjee A, Sikdar S, Khuda-Bukhsh AR. **Antihyperglycemic drug *Gymnema sylvestris* also shows anticancer potentials in human melanoma A375 cells via reactive oxygen species generation and mitochondria-dependent caspase pathway.** *Integr Cancer Ther*. 2013;12(5):433-41.
- The study findings indicate *Gymnema sylvestris* to have significant anticancer effect on A375 cells (human skin melanoma) apart from its reported anti-diabetic effect, indicating possibility of its palliative use in patients with symptoms of both the diseases.
27. Chakraborty I, Sukul NC, Mesripong R, Chaothanaphat N, Dhummaupakorn P, Sukul A. **High dilutions of homeopathic remedies induce relaxation of rat aorta precontracted with Noradrenalin.** *Int J High Dilution Res*. 2013; 12(43):44-51.
- Both *Lycopus virginicus* 30 CH and *Aurum metallicum* 30 CH were found effective in reducing nor-adrenalin induced contraction of rat aorta.
28. Saha SK, Roy S, Khuda-Bukhsh AR. **Evidence in support of gene regulatory hypothesis: Gene expression profiling manifests homeopathy effect as more than placebo.** *Int J High Dilution Res*. 2013; 12(45):162-167.
- Results indicate that action of the potentized drugs *Condurango* 30c and *Hydrastis canadensis* 30C used in the treatment of cancer was "more than placebo" and these ultra-highly diluted drugs acted primarily through modulation of gene expression.
- 2014: New publications**
1. EXPLORING THE EFFECTS OF HOMEOPATHIC APIS MELLIFICA PREPARATIONS ON HUMAN GENE EXPRESSION PROFILES
- Journal reference:** *Homeopathy*. 2014 Apr;103(2):127-32
- Authors:** Bigagli E., Luceri C., Bernardini S., Dei A., Filippini A. and Dolara P.
- Summary:** Diluted preparations obtained from *Apis mellifica* are reported in the homeopathic literature to have anti-inflammatory activity. The study was designed to explore the effects on global gene expression profiles of human cells by means of microarrays, using *Apis mellifica* mother tincture (TM) and its 3C, 5C, 7C dynamized dilutions; the technique employed allowed us to study the changes in gene expression at concentrations much lower than those associated with pharmacological responses. An RWPE-1 cell line (human immortalized prostate epithelial cells) was used to study the effects on global gene expression by transcriptomic analysis. *Apis mellifica* TM and its 3C, 5C, 7C dynamized

dilutions modulated hundreds of genes; using cluster analysis we observed groups of genes up- or down-regulated with similar expression profiles among treatments; other genes showed opposite regulation profiles at low and high dilutions of *Apis mellifica*, suggesting a hormetic response. In particular, genes involved in cytokine expression, inflammatory processes, anti-oxidative responses and proteasome degradation were differentially, and sometimes divergently expressed by the TM or by *Apis mellifica* 3C, 5C and 7C dilutions. The authors confirmed these data by RT-PCR analyses on 5 selected candidate genes (IL1 β , CD46, ATF1, UBE2Q2 and MT1X). The authors concluded that *Apis mellifica* TM modifies gene expression in human cells and has inhibitory effects on regulatory processes of inflammation; in addition, extremely diluted dynamized dilutions (3C, 5C and 7C) still exert significant effects on genes involved in inflammation and oxidative stress.

2. EXTREME SENSITIVITY OF GENE EXPRESSION IN HUMAN SH-SY5Y NEUROCYTES TO ULTRA-LOW DOSES OF GELSEMIUM SEMPERVIRENS;

Journal reference: BMC Complementary and Alternative Medicine 2014, 14:104

Authors: Marzotto M., Oliosio D., Brizzi M., Tononi P., Cristofolletti M. and Bellavite P.

Summary: This work investigates the gene expression of a human neurocyte cell line treated with increasing dilutions of *Gelsemium s.* extract. Starting from the crude extract, six 100 \times (centesimal, c) dilutions of *Gelsemium s.* (2c, 3c, 4c, 5c, 9c and 30c) were prepared according to the French homeopathic pharmacopoeia. Human SH-SY5Y neuroblastoma cells were exposed for 24 h to test dilutions, and their transcriptome compared by microarray to that of cells treated with control vehicle solutions. Exposure to the *Gelsemium s.* 2c dilution (the highest dose employed, corresponding to a gelsemine concentration of 6.5×10^{-9} M) significantly changed the expression of 56 genes, of which 49 were down-regulated and 7 were overexpressed. Several of

the down-regulated genes belonged to G-protein coupled receptor signaling pathways, calcium homeostasis, inflammatory response and neuropeptide receptors. Fisher exact test, applied to the group of 49 genes down-regulated by *Gelsemium s.* 2c, showed that the direction of effects was significantly maintained across the treatment with high homeopathic dilutions, even though the size of the differences was distributed in a small range. The authors concluded that the study shows that *Gelsemium s.*, a medicinal plant used in traditional remedies and homeopathy, modulates a series of genes involved in neuronal function. A small, but statistically significant, response was detected even to very low doses/high dilutions (up to 30c), indicating that the human neurocyte genome is extremely sensitive to this regulation.

3. EFFECTS OF GELSEMIUM SEMPERVIRENS L. ON PATHWAY-FOCUSED GENE EXPRESSION PROFILING IN NEURONAL CELLS

Journal reference: Journal of Ethnopharmacology; 2014 Apr 28;153(2):535-9

Authors: Oliosio D, Marzotto M, Moratti E, Brizzi M. and Bellavite P.

Summary: This study investigated for the first time by a real-time PCR technique (RT-PCR Array) the gene expression of a panel of human neurotransmitter receptors and regulators, involved in neuronal excitatory signaling, on a neurocyte cell line. Human SH-SY5Y neuroblastoma cells were exposed for 24h to *Gelsemium sempervirens* at 2c and 9c dilutions (i.e. 2 and 9-fold centesimal dilutions from mother tincture) and the gene expression profile compared to that of cells treated with control vehicle solutions. Exposure to the *Gelsemium sempervirens* 2c dilution, containing a nanomolar concentration of active principle gelsemine, induced a down-regulation of most genes of this array. In particular, the treated cells showed a statistically significant decrease of the prokineticin receptor 2, whose ligand is a neuropeptide involved in nociception, anxiety and depression-like behavior. Overall, the

results indicate a negative modulation trend in neuronal excitatory signaling, which can suggest new working hypotheses on the anxiolytic and analgesic action of this plant.

4. CONTRIBUTION OF THE ROS-P53 FEEDBACK LOOP IN THUJA-INDUCED APOPTOSIS OF MAMMARY EPITHELIAL CARCINOMA CELLS

Journal reference: Oncology Reports, Volume 31, Issue 4, 2014, Pages 1589-1598.

Authors: Saha S, Bhattacharjee P, Mukherjee S, Mazumdar M, Chakraborty S, Khurana A, Nayak D, Manchanda R, Chakrabarty R, Das T, Sa G.

Summary: In this study, the anti-tumorigenic activity of *Thuja occidentalis* was evaluated, and the molecular mechanisms underlying thuja-induced apoptosis of functional p53-expressing mammary epithelial carcinoma cells were elucidated. Results showed that thuja successfully induced apoptosis in functional p53-expressing mammary epithelial carcinoma cells. Abrogation of intracellular reactive oxygen species (ROS), prevention of p53-activation, knockdown of p53 or inhibition of its functional activity significantly abridged ROS generation. Notably, under these conditions, thuja-induced breast cancer cell apoptosis was reduced, thereby validating the existence of an ROS-p53 feedback loop. Elucidating this feedback loop revealed bi-phasic ROS generation as a key mediator of thuja-induced apoptosis. The first phase of ROS was instrumental in ensuring activation of p53 via p38MAPK and its nuclear translocation for transactivation of Bax, which induced a second phase of mitochondrial ROS to construct the ROS-p53 feedback loop. Such molecular crosstalk induced mitochondrial changes to maintain and amplify the thuja signal in a positive self-regulatory feedback manner; and to promote the mitochondrial death cascade through cytochrome c release and caspase-driven apoptosis. These results open the horizon for developing a targeted therapy by modulating the redox status of functional p53-expressing mammary epithelial carcinoma cells by

thuja.

Source: <http://www.ncbi.nlm.nih.gov/pubmed/24482097>

5. EXPERIMENTAL EVIDENCE OF STABLE WATER NANOSTRUCTURES IN EXTREMELY DILUTE SOLUTIONS, AT STANDARD PRESSURE AND TEMPERATURE

Journal reference: Homeopathy, Volume 103, Issue 1, 2014, Pages 44-50.

Authors: Elia V, Ausanio G, Gentile F, Germano R, Napoli E, Niccoli M.

Summary: This paper presents the results of several experimental methods (FT-IR spectroscopy, UV-vis spectroscopy, fluorescence microscopy (FM), Atomic Force Microscopy (AFM)) evidencing structural changes induced in extremely diluted solutions (EDS), which are prepared by an iterated process of centesimal (1:100) dilution and succussion (shaking). The iteration is repeated until an extremely high dilution is reached, so that the composition of the solution becomes identical to that of the solvent – in this case water – used to prepare it. The experimental observations reveal the presence of supramolecular aggregates hundreds of nanometres in size in EDS at ambient pressure and temperature, and in the solid state. These findings confirm the hypothesis – developed thanks to previous physico-chemical investigations – that formation of water aggregates occurs in EDS. The experimental data can be analyzed and interpreted with reference to the thermodynamics of far-from-equilibrium systems and irreversible processes.

Source: <http://www.ncbi.nlm.nih.gov/pubmed/24439454>

6. HIGH-DILUTION EFFECTS REVISITED (1 & 2)

Journal reference: Homeopathy, Volume 103, Issue 1, 2014, Pages 22-43, 4-21.

Authors: Bellavite P, Marzotto M, Oliosio D, Moratti E, Conforti A.

Summary (Physicochemical aspects): Several lines of evidence suggest that homeopathic high dilutions (HDs) can effectively have a pharmacological action, and so cannot be considered merely placebos. However, until now there has been no unified explanation for these observations within the dominant paradigm of the dose-response effect. Here the possible scenarios for the physicochemical nature of HDs are reviewed. A number of theoretical and experimental approaches, including quantum physics, conductometric and spectroscopic measurements, thermoluminescence, and model simulations investigated the peculiar features of diluted/succussed solutions. The heterogeneous composition of water could be affected by interactive phenomena such as coherence, epitaxy and formation of colloidal nanobubbles containing gaseous inclusions of oxygen, nitrogen, carbon dioxide, silica and, possibly, the original material of the remedy. It is likely that the molecules of active substance act as nucleation centres, amplifying the formation of supramolecular structures and imparting order to the solvent. Three major models for how this happens are currently being investigated: the water clusters or clathrates, the coherent domains postulated by quantum electrodynamics, and the formation of nanoparticles from the original solute plus solvent components. Other theoretical approaches based on quantum entanglement and on fractal-type self-organization of water clusters are more speculative and hypothetical. The problem of the physicochemical nature of HDs is still far from to be clarified but current evidence strongly supports the notion that the structuring of water and its solutes at the nanoscale can play a key role.

Summary (Pharmacodynamic mechanisms): The pharmacodynamics aspects of homeopathic remedies are appraised by laboratory studies on the biological effects at various levels (cellular, molecular and systemic). The major question is how these medicines

may work in the body. The possible answers concern the identification of biological targets, the means of drug-receptor interactions, the mechanisms of signal transmission and amplification, and the models of inversion of effects according to the traditional 'simile' rule. These problems are handled by two experimental and theoretical lines, according to the doses or dilutions considered (low-medium versus high dilutions). Homeopathic formulations in low-medium dilutions, containing molecules in the range of ultra-low doses, exploit the extreme sensitivity of biological systems to exogenous and endogenous signals. Their effects are interpreted in the framework of hormesis theories and paradoxical pharmacology. The hypotheses regarding the action mechanisms of highly diluted/dynamized solutions (beyond Avogadro-Loschmidt limit) variously invoke sensitivity to bioelectromagnetic information, participation of water chains in signalling, and regulation of bifurcation points of systemic networks. High-dilution pharmacology is emerging as a pioneering subject in the domain of nanomedicine and is providing greater plausibility to the puzzling claims of homeopathy.

Source: <http://www.ncbi.nlm.nih.gov/pubmed/24439452>; <http://www.ncbi.nlm.nih.gov/pubmed/24439453>

7. CURRENT CONCEPTS ON INTEGRATIVE SAFETY ASSESSMENT OF ACTIVE SUBSTANCES OF BOTANICAL, MINERAL OR CHEMICAL ORIGIN IN HOMEOPATHIC MEDICINAL PRODUCTS WITHIN THE EUROPEAN REGULATORY FRAMEWORK

Journal reference: Regulatory Toxicology and Pharmacology, Volume 68, Issue 2, 2014, Pages 193-200.

Authors: Buchholzer ML, Werner C, Knoess W.

Summary: For active substances of botanical, mineral or chemical origin processed in homeopathic medicinal products for human use, the adequate safety principles as with other human medicinal products are applied in line with the European regulatory framework. In homeopathy, nonclinical safety assessment is facing a

particular challenge because of a multitude and diversity of source materials used and due to rarely available toxicological data. Thus, current concepts applied by the national regulatory authority in Germany (BfArM) on integrative safety assessment of raw materials used in homeopathic medicinal products involve several evaluation approaches like the use of the Lowest Human Recommended Dose (LHRD), toxicological limit values, Threshold of Toxicological Concern (TTC), data from food regulation or the consideration of unavoidable environmental or dietary background exposure. This publication is intended to further develop and clarify the practical use of these assessment routes by exemplary application on selected homeopathic preparations. In conclusion, the different approaches are considered a very useful scientific and simultaneously pragmatic procedure in differentiated risk assessment of homeopathic medicinal products. Overall, this paper aims to increase the visibility of the safety issues in homeopathy and to stimulate scientific discussion of worldwide existing regulatory concepts on homeopathic medicinal products.

Source:<http://www.ncbi.nlm.nih.gov/pubmed/24384395>

8. IDENTIFICATION OF UNKNOWN HOMEOPATHIC REMEDIES BY DELAYED LUMINESCENCE

Journal reference: Cell Biochemistry and Biophysics, Volume 68, Issue 2, 2014, Pages 321-334.

Authors: Lenger K, Bajpai RP, Spielmann M.

Summary: A quality control method of highly diluted and potentized homeopathic remedies is important for curing patients applying homeopathic therapy. Lenger detected photons in highly potentized homeopathic remedies by delayed luminescence. The photons of Argentum metallicum 100MK and Cantharis 100MK magnetically bound to their carrier substances ethanol or saccharose were separated by their resonating magnetic field of about 2.06 MHz. The photons of these 100MK potency levels and of their reference substances were determined to be standard values calculated by the B2-values of Bajpai's equation derived from the

Hamiltonian equation. The stability of ethanolic Argentum metallicum 100MK and Cantharis 100MK declined to 1/3 of their photons within a month in contrast to saccharose globules with Argentum metallicum 100MK having been stable during the period of these investigations for almost 1 year. Some remedies delivered as CMK potency had been proved to be ethanol. The testing amount of high ethanolic potencies is limited to 40 µl because 80 µl resulted in an attenuation of the photons; 40 µl equal 16 medicated saccharose globules. Six unknown homeopathic remedies could be identified as increasing potency levels of Argentum metallicum from 100MK to 1.000MK which indicates a calibration curve. The homeopathic factories having sent the unknown remedies confirmed the measurements. A quality control of homeopathic remedies is possible by comparing the different B2-values of the remedies and their carrier substances.

Source:<http://www.ncbi.nlm.nih.gov/pubmed/23872840>

9. INTER-GROUP TRANSFER OF ANTI-ALCOHOLIC EFFECT OF NUX VOMICA 200 CH THROUGH THE BODY OF A LIVE TOAD

Journal reference: International Journal of High Dilution Research, Volume 13, Issue 46, 2014, Pages 3-12.

Authors: Chakraborty I, Sukul NC, Sukul A, Chakravarty R.

Summary: Using a toad model, the authors demonstrated that the anti-alcoholic effect of Nux vomica 200 cH could be transferred from one group of toads to another through capillary water carrying the information of Nux-v. Homeopathic potencies show UV spectra distinct from the hydro-ethanolic diluent medium. The authors intended to demonstrate that a potency effect might be transferred through the body of a live toad to other groups of toads connected to it through water. In addition, they sought to establish whether the UV spectra of the drug solution and the water connected

to the drug are similar in nature. The anti-alcoholic effect of Nux-v 200 cH could be transferred through the body of a live toad to other groups of toads. The drug did not undergo denaturation during its passage through the living body. The fact that water carries the information of the original drug was further evidenced by the spectral properties of the water connected to the drug solution through capillary water.

Source:<http://www.feg.unesp.br/~ojs/index.php/ijh-dr/article/view/684/689>

10. RAD50 TARGETING IMPAIRS DNA DAMAGE RESPONSE AND SENSITIZES HUMAN BREAST CANCER CELLS TO CISPLATIN THERAPY

Journal reference: Cancer Biology and Therapy, Volume 15, Issue 6, 2014.

Authors: Flores-Pérez A, Echarte Rafaelli L, Ramírez-Torres N, Aréchaga-Ocampo E, Frías S, Sánchez S, Marchat LA, Hidalgo-Miranda A, Quintanar-Jurado V, Rodríguez-Cuevas S, Bautista-Piña V, Carlos-Reyes A, López-Camarillo C.

Summary: In tumor cells, the effectiveness of anti-neoplastic agents that cause cell death by induction of DNA damage is influenced by DNA repair activity. RAD50 protein plays key roles in DNA double strand breaks repair (DSBs), which is crucial to safeguard genome integrity and sustain tumor suppression. However, its role as a potential therapeutic target has not been addressed in breast cancer. The authors aimed to analyze the expression of RAD50 protein in breast tumors, and evaluate the effects of RAD50-targeted inhibition on the cytotoxicity exerted by cisplatin and anthracycline and taxane-based therapies in breast cancer cells. Immunohistochemistry assays on tissue microarrays indicate that the strong staining intensity of RAD50 was reduced in 14% of breast carcinomas in comparison with normal tissues. Remarkably, RAD50 silencing by RNA interference significantly enhanced the cytotoxicity of cisplatin. Combinations of cisplatin

with doxorubicin and paclitaxel drugs induced synergistic effects in early cell death of RAD50-deficient MCF-7, SKBR3, and T47D breast cancer cells. Furthermore, the authors found an increase in number of DSBs, and delayed phosphorylation of histone H2AX after cisplatin treatment in RAD50-silenced cells. These cellular events were associated to a dramatical increase in the frequency of chromosomal aberrations and decrease of cell number in metaphase. Data showed that RAD50 abrogation impairs DNA damage response and sensitizes breast cancer cells to cisplatin-combined therapies. Development and use of inhibitors to manipulate RAD50 levels might represent a promising strategy to sensitize breast cancer cells to DNA damaging agents.

Source:<http://www.ncbi.nlm.nih.gov/pubmed/24642965>

11. EXTREME SENSITIVITY OF GENE EXPRESSION IN HUMAN SH-SY5Y NEUROCYTES TO ULTRA-LOW DOSES OF GELSEMIUM SEMPERVIRENS

Journal reference: BMC Complementary and Alternative Medicine, Volume 14, 2014, Pages 104.

Authors: Marzotto M, Oliosio D, Brizzi M, Tononi P, Cristofolletti M, Bellavite P.

Summary: Gelsemium sempervirens L. (Gelsemium s.) is a traditional medicinal plant, employed as an anxiolytic at ultra-low doses and animal models recently confirmed this activity. However the mechanisms by which it might operate on the nervous system are largely unknown. This work investigates the gene expression of a human neurocyte cell line treated with increasing dilutions of Gelsemium s. extract. Starting from the crude extract, six 100x (centesimal, c) dilutions of Gelsemium s. (2c, 3c, 4c, 5c, 9c and 30c) were prepared according to the French homeopathic pharmacopoeia. Human SH-SY5Y neuroblastoma cells were exposed for 24 h to test dilutions, and their transcriptome compared by microarray to that of cells treated with control vehicle solutions. Exposure to the Gelsemium s. 2c dilution

(the highest dose employed, corresponding to a gelsemine concentration of 6.5×10^{-9} M) significantly changed the expression of 56 genes, of which 49 were down-regulated and 7 were overexpressed. Several of the down-regulated genes belonged to G-protein coupled receptor signaling pathways, calcium homeostasis, inflammatory response and neuropeptide receptors. Fisher exact test, applied to the group of 49 genes down-regulated by Gelsemium s. 2c, showed that the direction of effects was significantly maintained across the treatment with high homeopathic dilutions, even though the size of the differences was distributed in a small range. The study shows that Gelsemium s., a medicinal plant used in traditional remedies and homeopathy, modulates a series of genes involved in neuronal function. A small, but statistically significant, response was detected even to very low doses/high dilutions (up to 30c), indicating that the human neurocyte genome is extremely sensitive to this regulation.

Source:<http://www.ncbi.nlm.nih.gov/pubmed/24642002>;

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3999908/pdf/1472-6882-14-104.pdf>

12.EFFECTS OF GELSEMIUM SEMPERVIRENS L. ON PATHWAY-FOCUSED GENE EXPRESSION PROFILING IN NEURONAL CELLS

Journal reference: Journal of Ethnopharmacology, Volume 153, Issue 2, 2014, Pages 535- 539.

Authors: Olioso D, Marzotto M, Moratti E, Brizzi M, Bellavite P.

Summary: This study investigated by a real-time PCR technique (RT-PCR Array) the gene expression of a panel of human neurotransmitter receptors and regulators, involved in neuronal excitatory signaling, on a neurocyte cell line. Human SH-SY5Y neuroblastoma cells were exposed for 24h to Gelsemium sempervirens at 2c and 9c dilutions (i.e. 2 and 9-fold centesimal dilutions from mother tincture) and the gene expression profile compared to that of cells treated with control vehicle solutions. Exposure to the Gelsemium sempervirens 2c dilution, containing a nanomolar concentration of active principle gelsemine, induced a down-regulation of most genes of this array. In particular, the treated cells showed a statistically significant decrease of the prokineticin receptor 2, whose ligand is a neuropeptide involved in nociception, anxiety and depression-like behavior. Overall, the results indicate a negative modulation trend in neuronal excitatory signaling, which can suggest new working hypotheses on the anxiolytic and analgesic action of this plant.

Source:<http://www.ncbi.nlm.nih.gov/pubmed/24613275>

Chapter : XI

Homeopathy in veterinary practice

When in 1813 Dr. Hahnemann hinted upon the fact that Homeopathy could be beneficial to animals³⁹⁹ just as well as to people, little did he realise that veterinary homeopathy would become a major offshoot of mainstream homeopathy. Interest and acceptance of complementary and alternative veterinary medicine (CAVM) within the veterinary profession has continued to increase in all parts of world, reported use being available from Europe⁴⁰⁰, USA⁴⁰¹ and India⁴⁰². Most member countries of European Council for Classical Homeopathy (Armenia, Belgium, Bosnia and Herzegovina, Bulgaria, Czech Republic, Finland, Germany, Greece, Ireland, Israel, Norway, Serbia, Spain, Sweden, Switzerland, United Kingdom) report use of homeopathy for animals to some extent, while other few report of a more common use. This is in particular true for Germany and Sweden, where training courses in animal homeopathy have been established. Such courses also exist in Finland, Norway and Switzerland.⁴⁰³ In USA, the academy of Veterinary Homeopathy offers courses in veterinary classical homeopathy. In other places, there are associations of veterinary homeopaths. In India, however, neither such association nor any specialized courses exist. Whatever is being practised has been borrowed from human homeopathy and used in veterinary clinics.⁴⁰⁴

Homeopathy has gained the reputation of an effective alternative therapy in veterinary practice. High cost of modern medicine, their inherited side effects and problems of antimicrobial residues in animal products have caused an apparent discomfort to animal owners invoking their interest in alternative approaches of animal health care. The Veterinary Medicines Division of European Medicines Agency advocates reduction in the use of antimicrobials as their use in animals – for treatment and disease prevention – may give rise to treatment failures in veterinary medicine as well as project a potential food safety problem. Furthermore, it may cause contamination as resistant bacteria and resistance genes can spread from food animals or food derived thereof to humans through the food-chain, through direct contact from animals to animal keepers but also to the environment. As genetic mutations, gene selection and movements in bacteria are associated with the use of antimicrobial agents, efforts to contain antimicrobial resistance must focus on avoiding unnecessary use of antimicrobial agents and promoting their responsible use. Prevention and containment of antimicrobial resistance requires a holistic, multifaceted and inter-sectorial approach.⁴⁰⁵ Since homeopathic medicines are non-toxic and result in reduced use of antibiotics and other medicines, and, therefore, lesser medicine residues in, European Union recommended the homeopathic and phytotherapeutic medicines as the first

³⁹⁹Hahnemann C.F.S. *Homeopathische Heilkunde der Haustiere*. Karl-Marx Universitätsbibliothek Leipzig, (Handschriftenabteilung), c1813.

⁴⁰⁰European Council for Classical Homeopathy; *The Homeopathic Treatment of Animals in Europe*; Third Edition November 2007

⁴⁰¹Budgin J.B. and Flaherty M.J.; *Alternative therapies in veterinary dermatology*; *Vet Clin Small Anim* 43 (2013); pp 189-204

⁴⁰²Madrewar B.P.; *A scientific clinical research veterinary Homeopathy*; first edition 2006; pp 1-5

⁴⁰³European Council for Classical Homeopathy; *The Homeopathic Treatment of Animals in Europe*; Third Edition November 2007

⁴⁰⁴Madrewar B.P.; *A scientific clinical research veterinary Homeopathy*; first edition 2006; pp 1-5

⁴⁰⁵Veterinary Medicines Division, European Medicines Agency; *Revised ESVAC reflection paper on collecting data on consumption of antimicrobial agents per animal species, on technical units of measurement and indicators for reporting consumption of antimicrobial agents in animals*; 10 October 2013; EMA/286416/2012-Rev.1; pp 5-6

choice in the healthcare of animals being raised organically.⁴⁰⁶ Further, farmers in developing countries look for a cheaper, eco-friendly, safe and effective alternative as a 'firstline' therapy.⁴⁰⁷

In most European countries both pets and farm animals are treated homeopathically. Most commonly pets include cats and dogs, and farm animals mainly include cattle and horses, but to some extent pigs and birds such as canaries and parrots are given homeopathic medicines. Animals are treated homeopathically for both acute and chronic conditions. Acute conditions include injuries. Both physical and behavioural problems are treated. Physical problems include conditions of the skin such as eczemas, eye inflammations, allergies, cough, gastrointestinal disorders, urinary tract diseases including infections and diseases of the kidneys, diabetes, problems of the liver and thyroid, diseases of the loco motor system, neurological complaints such as paralysis and epilepsy, and hormonal disturbances. More specifically cows and sheep are treated for mastitis, calves for diarrhoea, pigs for respiratory difficulties and birds for eye infections. Complaints arising from vaccination and breeding problems are also treated. In India, a survey conducted in Kerala (India) revealed most veterinarians used homeopathic medicines for diseases like mastitis, wart, posterior paralysis, FMD lesion, hemagalactia, tetanus etc. and found good results.⁴⁰⁸

More formal trials with homeopathic medicines have shown encouraging results in the management of bovine mastitis among other conditions.⁴⁰⁹ In fact, mastitis, a frequently encountered disease in veterinary clinics, is such an economic burden that the search for cost-

effective complementary and alternative treatment approaches for management of mastitis is being pursued throughout the world.⁴¹⁰ According to the survey of WHO and Food and Agriculture Organization 2000, 85% of animals in developing countries are given alternative therapies for their ailments; main alternatives being Homeopathy and Ayurveda.⁴¹¹ More research articles have been published on the subject in countries such as Germany, Norway, Sweden and the United Kingdom. Examples include projects on treatment of eczema in horses in Finland, utilisation, effects and implications of homeopathy in health and productivity of dairy cows in Norway, and a number of trials in farming animals in Sweden. These include a survey of 41 dairy farmers reporting 76 % improvement in their animals. Results indicate significant reduction in the use of antibiotics in animals. This was also the main reason why farmers opted for homeopathy.⁴¹²

Overall, the last three decades have seen a considerable increase in the number of clinical trials. This could be attributed to the ongoing argument over the placebo effect, and its role in the homeopathic treatment process. The presumption behind this is that by showing effects on animals, Homeopathy could rise above the 'mere placebo' label. The minimal or no placebo effect, although true to an extent, has further been debated of late. With respect to the classical concept of placebo, animals cannot discriminate between drug and food or verum and placebo and therefore have no expectation regarding recovery (provided they have not been conditioned). But with respect to modern concepts of the placebo effect or context effects, various aspects have been reported to

⁴⁰⁶European Council for Classical Homeopathy; The Homeopathic Treatment of Animals in Europe; Third Edition November 2007

⁴⁰⁷Madrewar B.P.; A scientific clinical research veterinary Homeopathy; first edition 2006; pp 1-5

⁴⁰⁸Madrewar B.P.; A scientific clinical research veterinary Homeopathy; first edition 2006; pp 1-5

⁴⁰⁹Upadhyaya AK, Sharma SP. Management of bovine mastitis by homeopathy.

Indian Vet Med J 1999; 23: 71-72.

⁴¹⁰Varshney JP, Ram Naresh; Buffalo udder diseases and homeopathy; Homeopathy (2004) 93, 17-20

⁴¹¹Madrewar B.P.; Scientific Clinical Research: Veterinary Homeopathy; B Jain Publishers 2006

⁴¹²European Council for Classical Homeopathy; The Homeopathic Treatment of Animals in Europe; Third Edition November 2007

elicit a placebo response in animals.⁴¹³

Clinical research in veterinary homeopathy has some inherent advantages compared to clinical research in human homeopathy. The environmental conditions can be considered as rather stable and comparable for all patients when located in the same isolated pen, kennel, etc. It is easier, in principle, to acquire larger numbers of participants, at least of livestock animals, and to maintain blinding. Therefore, studies of veterinary homeopathy that account for the above mentioned adaptations of the study design may be more useful in investigating whether homeopathic remedies have specific effects over and above those of placebo. However, the challenges like interview-based repertorisation being limited to objective parameters and interrogations of the animal owners, only a few drug provings available in animals and a small number of remedies enlisted for animals in the *MateriaMedica* make the procedure rather cumbersome. In several cases, a human repertory and *MateriaMedica* are used to find the *similimum*, an approach that is questioned by some authors.⁴¹⁴

Several clinical trials and systematic reviews have been carried out to see the response of homeopathic treatment in animals. The Veterinary Clinical Research Database for Homeopathy enlists 405 studies on use of homeopathy in veterinary including case reports, case series, controlled trials etc.⁴¹⁵ By the end of 2013, the total number of peer-reviewed RCTs had risen to 44. Nineteen RCTs were placebo controlled; the remaining 25 were controlled by

another comparator. These trials were conducted on conditions including mastitis, diarrhoea, endometritis, infertility in cattle; fear of firework noises and osteoarthritis in dogs; immune response in goats and diarrhoea, growth rate, induction of farrowing, infectious diseases and reproductive performance in pigs. Out of the 19 placebo-controlled trials, 12/19 (63%) were positive; while 7/19 (37%) were non-conclusive. In the studies that did not include a control group, positive results were found for conditions like mastitis in cattle, Kennel cough in dogs, Epilepsy in dogs, Cushing's disease in dogs and horses and Stillbirth in pigs.⁴¹⁶ In a recent systematic review by Clausen et al, it was pointed out that cattle were the study subjects most often employed, followed by pigs and dogs and horses. Most trials investigated the benefit of homeopathic prophylaxis or treatment in mastitis control and postpartum disorders. In addition, 29 trials investigated the effects of homeopathy application for performance improvement (health, growth, reproduction).

A secondary analysis of the data existing on the Veterinary Clinical Research database until early 2013 revealed the following:

The encouraging findings in the analyses above clearly call for more organised researches in veterinary stream. This resonates with the earlier findings in various researches.^{417,418,419,420,421,422}

Central Council for Research in Homeopathy⁴²³, India, has

⁴¹³J. Clausena, H. Albrechta, R.T. Mathie; Veterinary Clinical Research Database for Homeopathy: Placebo-controlled trials; *Complementary Therapies in Medicine* (2013) 21, 115–120

⁴¹⁴Upadhya AK, Sharma SP. Management of bovine mastitis by homeopathy. *Indian Vet Med J* 1999; 23: 71–72.

⁴¹⁵<http://www.carstens-stiftung.de/clinresvet/ergebnis.php>; Last accessed on June 24, 2014

⁴¹⁶<http://www.facultyofhomeopathy.org/research/veterinary-research/>; Last accessed on June 24, 2014

⁴¹⁷European Council for Classical Homeopathy; *The Homeopathic Treatment of Animals in Europe*; Third Edition November 2007

⁴¹⁸Budgin J.B. and Flaherty M.J.; *Alternative therapies in veterinary*

dermatology; *Vet Clin Small Anim* 43 (2013); pp 189-204

⁴¹⁹Madrewar B.P.; *Scientific Clinical Research: Veterinary Homeopathy*; B Jain Publishers 2006

⁴²⁰Upadhya AK, Sharma SP. Management of bovine mastitis by homeopathy. *Indian Vet Med J* 1999; 23: 71–72.

⁴²¹RT Mathie, L Hansen, MF Elliott and J Hoare; Outcomes from homeopathic prescribing in veterinary practice: a prospective, research-targeted, pilot study; *Homeopathy* (2007) 96, 27–34

⁴²²Robert T Mathie¹, Elizabeth S Baitson, Lise Hansen, Mark F Elliott and John Hoare; Homeopathic prescribing for chronic conditions in feline and canine veterinary practice; *Homeopathy* (2010) 99, 243-48

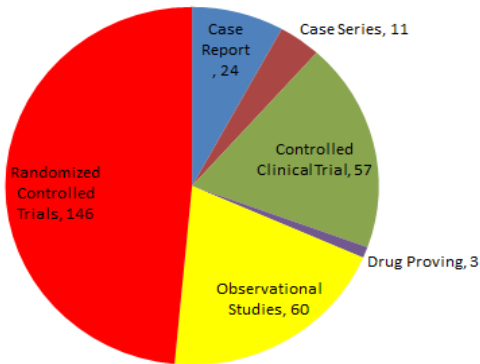
⁴²³<http://ccrindia.org/index.asp>

identified a few priority areas for research in veterinary science. These include subclinical mastitis, diarrhoea, skin diseases, reproductive disorders (metritis, infertility etc.), wound/injury management and problems concerning productivity of animals. Further, a new data outlines the future vision for veterinary search.¹⁰ It confirms that individualised prescribing is the usual approach to homeopathic management of both cats and dogs. This individualised approach to therapy is less amenable to explanatory, placebo-controlled, double-blinded, trial design and the challenge to overcome the methodological difficulties must be met. Another novel approach would be to research the efficacy of a given, well-indicated, homeopathic medicine for a specific condition (such as RRA in arthritis, as perhaps suggested by the present study's findings), where only patients matching that medicine's symptom picture would be randomised to

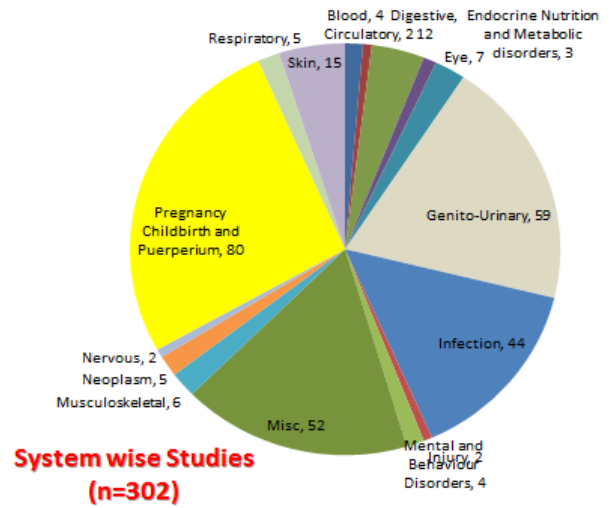
verum or to placebo. Suitably designed pragmatic trials are also necessary to establish the effectiveness of individualised homeopathy in routine clinical practice.

Since Homeopathy is still to go a long way in order to establish its role in veterinary science, there is a vast scope for research. High-quality research can only be taken up when veterinary scientists and conventional practitioners are willing to collaborate for homeopathic projects on priority basis.

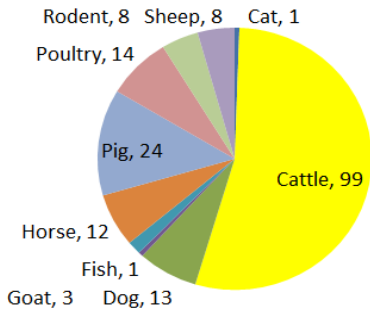
A secondary analysis of the data existing on the Veterinary Clinical Research database until early 2013 revealed the following:



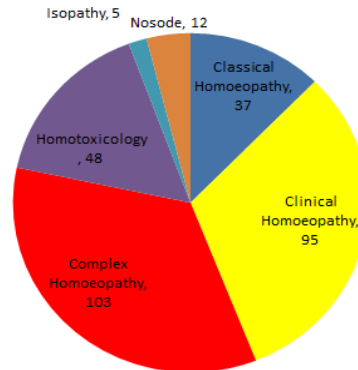
Major Study Design already undertaken (n=301)



System wise Studies (n=302)



No. of Controlled Studies in Different Species (n=183)



Type of Homoeopathy used in Veterinary (n=300)

Veterinary research updates

European regulation of organic farming implies an extension of this type of research in the coming years. http://ec.europa.eu/agriculture/organic/animal-welfare/health_en

http://ec.europa.eu/agriculture/organic/eu-policy/legislation_en

Council regulation (EC) N°834/2007 is binding and directly applicable in all EU Member States (applied from 1 January 2009).

European Parliament – Budget 2012 “AGRI/5227”. Pilot project – Coordinate research on the use of homeopathy and phytotherapy in livestock farming. Justification: antibiotic resistance is a growing worldwide problem. One reason is the use of antibiotics in livestock farming. This is why research on alternative methods has to be moved forward.

Source: www.europarl.europa.eu/meetdocs/2009_2014/documents/agri/dv/2012_agri_budg_amends_txt_/2012_agri_budg_amends_txt_sl.pdf

Other examples of veterinary research: See references.^(424,425,426,427,428,429,430,431,432,433,434)

2008 – 63rd LMHI Congress' Proceedings:

⁴²⁴Chaudhuri S, Varshney JP. Clinical management of babesiosis in dogs with homeopathic *Crotalus horridus* 200C versus allopathy. *Homeopathy*. 2007;96:90-94.

⁴²⁵Varshney JP. Clinical management of idiopathic epilepsy in dogs with homeopathic *Belladonna* 200 C: A case series. *Homeopathy*. 2007;46-48.

⁴²⁶Lira-Salazar G, Marines-Montiel E, Torres-Monzon J, Hernandez-Hernandez F, Salas-Benito JS. Effects of homeopathic medications *Eupatorium perfoliatum* and *Arsenicum album* on parasitemia of *Plasmodium berghei*-infected mice (Malaria). *Homeopathy*. 2006;95:223-228.

⁴²⁷Rajkumar R, Srivastava SK, Yadav MC, Varshney VP, Varshney JP, Kumar H. Effect of a Homeopathic complex on oestrus induction and hormonal profile in anoestrus cows. *Homeopathy*. 2006;95:131-135.

⁴²⁸Berchieri A, Turco WCP, Paiva JB, Oliviera GH, Sterzo EV. Evaluation of isopathic treatment of *Salmonella enteritidis* in poultry. *Homeopathy*. 2006;95:94-97.

Aboutboul R. Snake remedies and eosinophilic granuloma complex in cats. *Homeopathy*. 2006;95:15-19.

⁴²⁹Werner C, Sobiraj A, Sundrun A. Efficacy of homeopathic and antibiotic treatment strategies in cases of mild and moderate bovine clinical mastitis. *Journal of Dairy Research*. PubMed

Magnani P, Conforti A, Bellavite P. Effects of homeopathic drugs on the anxiety-like behaviour in mice. Blind design, Diazepam and placebo controlled./ Boujedaini N. Action de *Gelsemium sempervirens* sur la synthèse d'allopregnanolone. Blind design versus placebo./

Castilhos. Effect of the *Arnica Montana* 200CH followed by *Medicago Sativa* 6CH and *Calcarea Phosphorica* 6CH usage in the feed consumption and weight gains of goat weaned kids. Double-blind placebo controlled trial./

Weber S, Endler PC, Welles SV, Suanjak-Traidl E, Scherer-Pongratz W, Frass M, Spranger H, Peithner G, Lothaller H. Thyroxine 30X, Electromagnetic field influence (microwave, mobile phone, x-ray) and highland frogs. Multi-centric, blinded controlled study on 2980 animals./

Payen L. The effect of the homeopathic drug PVB® *Phytolac* in mastitis of cows. Preventive double-blind design on 187 cows./

Issautier. Prevention of cold-intolerance in Guinea Fowl by homeopathic treatment and analysis of its effects. Single-blind study on 10.640 animals, homeopathy versus allopathy./

Psychev L. Changes in rat's learning and memory after a long treatment with four homeopathic medicines. Placebo-controlled study on 130 animals./ Sommer MA, Blaha T.

2010.

⁴³⁰Soto FRM & all. A randomized controlled trial of homeopathic treatment of weaned piglets in a commercial swine herd. *Homeopathy*. 2008;97:202-205.

⁴³¹Zacharias F & all. Effect of homeopathic medicines on helminth parasitism and resistance of *Haemonchus contortus* infected sheep. *Homeopathy*. 2008;97:145-151.

⁴³²Klocke P, Ivemeyer S, Butler G, Maeschli A, Hail F. A randomized controlled trial to compare the use of homeopathy and internal Teat Sealers for the prevention of mastitis in organically farmed dairy cows during the dry period and 100 days post-calving. *Homeopathy*. 2010;99:90-98.

⁴³³Camerlink I, Ellinger L, Bakker EJ, Lantinga EA. Homeopathy as replacement to antibiotics in the case of *Escherichia coli* diarrhea in neonatal piglets. *Homeopathy*. 2010;99:57-62.

⁴³⁴Magnani P, Conforti A, Zanolin E, Marzotto M, Bellavite P. Dose-effect study of *Gelsemium Sempervirens* in high dilutions on anxiety-related responses in mice. *Psychopharmacology* 2010;210:533-545.

Epidemiological investigations on the use of homeopathic remedies in swine under special consideration of the comparison of homeopathic and antimicrobial therapies. Open study including 36 sows./

Zalla Neto R, Bonamin LV. Lymphoid response and granuloma development in mice inoculated with BCG and treated with Thymulin in homeopathic preparations.

2011 – 66th LMHI Congress' Proceedings :

Kumar S. comparative treatment of clinical mastitis in bovines with homeopathy and antibiotics.

2012 – Publication in International Journal:

Mathie T.T. retrieved 150 published papers, only 38 were of sufficient quality to allow a systematic review including 7 different animal species and 27 different species-specific medical conditions. A systematic review will be organized in the following time. *Homeopathy* (2012);101:196-203.

de Souza MFA et al. studied the effect of individualized homeopathic treatment on the semen quality of bulls with reproductive disorders (a case series). *Homeopathy* (2012);101:243-245.

Coelho et al. did an evaluation of homeopathic and biotherapeutic treatments in a swine farm to control *Escherichia coli* infection at long term. The homeopathic treated group passed from 75 % of diarrhea incidence to 8,3 %; weight gain in homeopathic group was 15 % higher than in the control group. *Int J of High Dil Res* (2012); Vol 11 n°40:136-137.

2012 – 67th LMHI Congress' Proceedings

Shelley R. Epstein presented an overview of case reports, case series and clinical trials in Veterinary Homeopathy

around the world including five species including mastitis, enteric pathogens, reproduction and parasitism.

Peter Gregory presented a talk about the cancer miasm and Carcinosis in Animals, there is always an element of excessive control in the history and behaviour of such animal.

2013 – Publication in International Journal

Ferreira de Lima L & all. A treatment with FSH (6CH) during 24h maintained the viability and promoted the activation and in vitro growth of ovine FPs. Dynamized follicle-stimulating hormone affects the development of ovine preantral follicles cultured in vitro. *Homeopathy* (2013) 102:41-48.

2014 – New publications

Aubry E, Issautier MN, Champomier D, Terzan L. Early udder inflammation in dairy cows treated by a homeopathic medicine (Dolisovet®): a prospective observational pilot study. *Homeopathy* 2013;102:139-44.

Ointment Dolisovet® (Belladonna 1 dH, Calendula MT, Echinacea 1 dH, Dulcamara 1 cH) was tested in a prospective, uncontrolled, observational pilot study involving the collection and analysis of data from 31 udder quarters identified as being inflamed by an automated milking system (AMS). Inflamed quarters were identified when milk quality started to deteriorate, via an alert generated by the AMS, on the basis of electrical conductivity (EC). A significant reduction in EC was observed 4-7 days following the first treatment. An increase in milk yield was also observed following the first treatment. Dolisovet® may have a beneficial therapeutic effect in the early stages of udder inflammation and for restoring udder health and function. This medicine may be an effective first line treatment for sub-clinical bovine mastitis, reducing the need for antibiotics.

Braccini GL, Natali MRM, Ribeiro RP, Ricardo Hideo Mori RH, Riggo R, Oliveira CAL, et al. Morpho-functional response of Nile tilapia (*Oreochromis niloticus*) to a homeopathic complex. Homeopathy 2013;102:233-41.

This randomized four-armed controlled study evaluated the performance, prevalence of ectoparasites and morpho-functional response of the liver and the branchiae of Nile tilapia (*Oreochromis niloticus*) raised on fish meal with added of the homeopathic complex Homeopatila 100® at different concentrations. Significant differences in the mixed parasite conditions were found within the different Homeopatila 100® treatments. The hepatosomatic ratio of fish treated with Homeopatila 100® was significantly lower than that of fish from the control group. The best results in the liver and branchiae occurred in fish receiving Homeopatila 100® at 40 mL/kg in terms of the number of

hepatocytes/mm², the intercellular glycogenic behaviour, the rates of histological changes (hyperplasia, lamella fusion and telangiectasia) and the percentage of neutral and acidic mucin-producing cells.

de Oliveira Feitosa KC, Povh JA, de Abreu JS. Physiological responses of pacu (*Piaractus mesopotamicus*) treated with homeopathic product and submitted to transport stress. Homeopathy 2013;102:268-73.

Transport resulted in stress responses in juvenile pacu (*Piaractus mesopotamicus*) and the homeopathic complex, administered in the water or diet, did not minimize these responses. Sucrose supplementation altered the cortisol and blood glucose levels, suggesting a moderating effect on these stress indicators.

Chapter: XII

Agrohomeopathy

In developed countries modern, intensive agriculture has improved crop yields but also, due to its reliance on large amounts of non-renewable energy and raw materials, frequently resulted in soil degradation, environmental pollution and damage to wildlife. For this reason, there has been growing interest in agricultural methods that are both environmentally and economically sound, in recent years. Among these, the emerging discipline of 'agrohomeopathy' – the application of homeopathy to agriculture – is currently being widely developed.⁴³⁵ The potential benefits of using homeopathy for plants are their cost-effectiveness and the absence of side-effects on plants and the ecological system. Therefore, Homeopathy is optimally suited to the holistic approaches of organic and, above all, biodynamic agriculture, in which plants and their interactions with the environment are treated as a unified 'living organism'.⁴³⁶

Homeopathy is known to enhance the nutritional properties of plants,⁴³⁷ and contribute productively to physiological and qualitative characteristics of plants. In addition, homeopathic medicines increase the resistance of plants to biotic (insects and pathogens) and abiotic (physical and chemical damage) stress.⁴³⁸ However, the research scenario of agrohomeopathy is still in its infancy and additional research needs to be done to clearly define the role of homeopathy in farming at commercial level. About half of the papers reviewed by Bettiet al⁴ do not provide sufficient information or suffer from shortcomings in

terms of statistical analysis, replications, experimental methodology and blinding. The results presented are mostly, therefore, not fully reliable.

However, the work carried out so far in the field of agrohomeopathy provides enough ground for more comprehensive and better controlled trials in future.

Research updates

Tichavsky R. Perspectives of Agro-homeopathy and overview of results. Proceedings 64th LMHI Congress.

Hribar-Marko S, Graunke H, Scherer-Pongratz W, Lothaller H, Endler PC. Prestimulation of wheat seedlings with gibberellic acid followed by application of an agitated high dilution of the same hormone. *Int J High Dilution Res.* 2013; 12(42):26-39.

The hypothesis that pre-treatment of grains with high concentrations of gibberellic acid would enhance the growth inhibiting effect of G30x had to be rejected.

Dragicevic V, Spasic M, Simic M, Dumanovic Z, Nikolic B. Stimulative influence of germination and growth of maize seedlings originating from aged seeds by 2,4-D potencies. *Homeopathy* 2013;102:179-86.

Homeopathic potencies of 2,4-D (2,4-dichlorophenoxyacetic acid) appear to have a beneficial effect on artificially aged maize seeds: they stimulate growth through better substance conversion from seed rest, and shift the redox capacity towards a reduced environment.

⁴³⁵Betti L., Use of homeopathic preparations in phytopathological models and in field trials: a critical review; *Homeopathy* (2009) 98, 244–266

⁴³⁶Reganold JP. Soil quality and profitability of biodynamic and conventional farming system: a review. *Am J Alternative Agr* 1995; 10: 36–45.

⁴³⁷Marques Fonseca MC, Dias Casali VW, Cecon PR. Efeito de aplic,ã~ou´nica dos preparadoshomeopa´ticos calcareo carbonica, kaliunphosphoricum,

magnesium carbonicum, natriummuriaticum e siliceaterra no teor de taninoem Porophyllumruderale (Jacq.) Cassini. *Cultura Homeopatica* 2006; 14: 6–8.

⁴³⁸ Betti L., Use of homeopathic preparations in phytopathological models and in field trials: a critical review; *Homeopathy* (2009) 98, 244–266

CHAPTER XIII

HOMEOPATHY AND EPIDEMIC DISEASES

History

Although its efficacy has been demonstrated in the treatment of several individuals suffering from acute or chronic diseases, a historical review shows homeopathy's greatest asset appears to be in the treatment of epidemic diseases. There are impressive examples of such broader applications of homeopathy in the 19th and 20th centuries. The founder of homeopathy, Dr. S. Hahnemann, initiated the methodology for the treatment epidemic diseases with homeopathy. This approach he called the genus epidemicus, meaning that a treatment protocol of an epidemic disease is designed based on the collected signs and symptoms of a large group of patients. This is opposed to the treatment of non-epidemic diseases in which for each different patient an individual remedy is selected based on the unique expression of the disease in the individual. In giving an historical overview on the use of homeopathy in epidemic diseases, Bedayn⁴³⁹ writes:

"The curative results of the genus epidemicus were so positive during the epidemics in the ensuing decades that they not only cured the majority of those affected where nothing else had worked, but they also drew international acclaim towards homeopathy, the new, the rational, medicine. There is something intrinsically powerful about the success of homeopathy in curing large populations that is undeniably attractive to anyone gifted with the power of observation, and it was through these early cures with epidemics that Hahnemann was able to quickly and widely spread the word: Homeopathy."

Using the genus epidemicus principle, homeopaths

impressed the medical establishment with their results. Here are a few quotes to illustrate this:

General: "In epidemics the mortality per 100 patients is 1/2 to 1/8 in homeopathic hospitals (a century ago there were several homeopathic hospitals in the US) compared to allopathic hospitals." (Bradford, 1900)⁴⁴⁰

General: "Homeopathy had become very popular in North America during its early years due to its amazing successes obtained by the 'old guard' during the epidemics – epidemics of diphtheria, scarlet fever, cholera, malaria, yellow fever." (From its Roots Upwards, Interview with André Saine, N.D., D.H.A.N.P., Vienna January 1994)⁴⁴¹

- General: "Ever since Samuel Hahnemann homeopathy has time and again been able to successfully treat epidemics/pandemics with a small number of remedies." (Stahl, Hadulla, Richter, 2006)⁴⁴²

- Cholera: "In Russia in the years 1830 and 1831 homeopathy was used to treat 1270 cholera patients in the provinces Saratoff, Tambtoff and Twer: 1162 of those were cured, 108 died... similar rates in the results of homeopathic treatment for cholera were observed in Hungary, Mähren and Vienna." (Gebhardt, 1929)⁴⁴³

- Cholera: "When in the year 1854 cholera came to Palermo 1513 soldiers fell ill ... Of these 902 were treated with allopathy of which 386 died, a bit more than 42 %; 611 were treated with homeopathy, of which only 25, so almost 4 %, died.

In the abovementioned years cholera also visited the Caribbean, and on the 'pearl' of these islands, Barbados,

⁴³⁹Bedayn, Greg, 'As If One Patient', *The American Homeopath* 1998

⁴⁴⁰Dr. Thomas L. Bradford's 'The Logic of Figures ...' (1900)

⁴⁴¹Saine, André, 'From its Roots Upwards', Interview with André Saine, N.D., D.H.A.N.P., Vienna January 1994

⁴⁴²Stahl E., Hadulla M.M., Richter E., *Homöopathische Behandlung der Influenza – Vogelgrippe, Allgemeine Homöopathische Zeitung*, 2006

⁴⁴³Gebhardt, A. v., *Handbuch der Homöopathie*, Leipzig, Germany 1929

2113 people fell ill. Of the 346 treated with allopathy 154 died, but of the 1767 treated with homeopathy only 370." (Gebhardt, 1929)⁴⁴⁴

- Cholera: "3 % of the cholera patients under homeopathic treatment died (Cincinnati USA 1849). Mortality rate of cholera patients under allopathic treatment was 40-70 %." (Humphreys 1849)⁴⁴⁵
- Spanish influenza: "Perhaps the most recent use of homeopathy in a major epidemic was during the Influenza Pandemic of 1918. The Journal of the American Institute for Homeopathy, May, 1921, had a long article about the use of homeopathy in the flu epidemic. Dr. T A McCann, from Dayton, Ohio reported that 24,000 cases of flu treated allopathically had a mortality rate of 28.2 % while 26,000 cases of flu treated homeopathically had a mortality rate of 1.05 %. This last figure was supported by Dean W.A. Pearson of Philadelphia (Hahnemann College) who collected 26,795 cases of flu treated with homeopathy with the above result." (Winston 2006)⁴⁴⁶
- Spanish influenza: "Homeopathy has been used with great degree of success in influenza and other epidemics for 200 years ... In 1918 flu pandemic homeopaths reported around 1 % mortality in their cases, while conventional doctors were losing 30 % of their patients." [www.lifemedical.us/flu]NB: The Spanish influenza virus we know now was an avian virus. Approximately 40 million people died in just 18 months.
- Spanish influenza: "Dean W.A. Pearson of Philadelphia collected 26,795 cases of influenza treated by homeopathic physicians with a mortality of 1.05 %, while the average old school mortality was 30 %. Explanation: conventional treatment of folks with flu caused at least 8038 deaths while the homeopaths lost only 281

patients. That is a statistically significant difference." "Thirty physicians in Connecticut responded to my request for data. They reported 6,602 cases with 55 deaths, which is less than 1 %. In the transport service (during WWI) I had 81 cases on the way over. All recovered and were landed. Every man received homeopathic treatment. One ship (using conventional therapy) lost 31 on the way. H.A. Roberts, MD, Derby, Connecticut." [Explanation: a number of homeopathic physicians served in the Armed Forces during WW1 and made use of their homeopathic training. (Dearborn, 1923)⁴⁴⁷; (Dewey, 1921)⁴⁴⁸

- Spanish influenza: "The most severe epidemic of all time was the Great Influenza Pandemic of 1918. Twenty percent of the entire world population was infected and 20-40 million people died. The epidemic was so devastating that the average lifespan in the United States was decreased by ten years. During this epidemic homeopathic medicines were used widely both for treatment and as prophylaxis. The average mortality under standard treatment ran from 2.5-10 %, while 1 % or fewer patients died under homeopathic treatment." (Hoover, 2006)⁴⁴⁹
- Yellow Fever in USA: "Homeopathy had become very popular in North America during its early years due to its amazing successes obtained by the 'old guard' during the epidemics – epidemics of diphtheria, scarlet fever, cholera, malaria, yellow fever – especially yellow fever; the death rate for that was 55 % when allopathic treatment was used, but less than 5 % in cases with homeopathic treatment; and it was the same for cholera. It is here with the 'old guard' that homeopathy obtained its golden letters." ('From its Roots Upwards', Interview with André Saine, ND, DHANP, Vienna, January

⁴⁴⁴Gebhardt, A. v., *Handbuch der Homöopathie*, Leipzig, Germany 1929

⁴⁴⁵Humphreys, F., *Cholera and its homoeopathic treatment*, New York: William Radde Publisher, 1849

⁴⁴⁶Winston, J., *Some history of the treatment of epidemics with Homeopathy by Julian Winston*, 2006, www.whale.to/v/winston.html

⁴⁴⁷Dearborn, Frederick M. MD, *American Homeopathy in the World War*; 1923

⁴⁴⁸Dewey, W.A., *Homeopathy in Influenza- A Chorus of Fifty in Harmony*, *Journal of the American Institute of Homeopathy* in 1921

⁴⁴⁹Hoover, Todd A., *Homeopathic prophylaxis*, *The American Homeopath*, October 2006

1994.)⁴⁵⁰

These are clearly impressive figures, certainly if we compare them with the results of contemporary regular treatment. Considering the advances made in conventional medicine in the past century the question arises though whether homeopathy should still play a role in treating epidemic diseases.

Homeopathy and Epidemic Diseases Today

Towards the end of the 1880's, Homeopathy and conventional medicine were equally well accepted by the public. Conventional medical doctors in the US lobbied the government in the early 1900s and legislation was passed giving them the exclusive right to diagnose and treat medical conditions. With the US taking the lead in the world, homeopathy went into a decline. Homeopathic hospitals were closed. The light of homeopathy was kept alive by smaller number of homeopaths, but many lost track of what is called Hahnemannian homeopathy and as a science little progress was made.

This changed in the last decades of the 20th century. Homeopathy flourished again and, especially in the treatment of chronic diseases, great advances were made.

If we look at homeopathy today, the use of the genus epidemicus approach for epidemic diseases is marginal. In part, this is because epidemic diseases like those mentioned above hardly play a role anymore in the West. Homeopaths that went to developing countries to help those for whom often no medical care is available at all were strongly confronted with epidemic diseases. They once again started to treat epidemic diseases and experienced how successful homeopathy still is for these conditions.

⁴⁵⁰Saine, André, 'From its Roots Upwards', Interview with André Saine, N.D., D.H.A.N.P., Vienna January 1994

⁴⁵¹Marani, Dr Lyndon, (Ministry of Health): Nairobi, 8 October 2007 (PlusNews)

Why Homeopathy Should Play a Role in Treating Epidemics?

Homeopathy does not stand in the way of effective treatment for patients but rather complements available conventional treatment.

- It is not the policy of the major homeopathic organizations in the world to advise patients against the use of conventional medicine and this includes the treatment of epidemic diseases. Patients that are not on conventional therapy because their case has not reached a critical level yet are observed to get improved health and increased immunity, thus postponing the need for conventional therapy. Homeopathic treatment boosts the immune system and side effects from conventional treatments are reduced significantly if patients also take homeopathic treatment. This represents a clear win-win situation.
 - Conventional medical care is non-existent or limitedly available in many areas or only available to the very rich. Homeopathy can at least help this situation. Also when conventional therapy does not work any more homeopaths have regularly observed that these patients do respond to homeopathic treatment.
 - Therapy resistance is an increasing problem making conventional medicine inactive and alternative approaches dearly needed. For the major epidemics in Africa – malaria, TB and HIV – this is a serious problem. The problems surrounding resistance are finding increasing acknowledgment within the healthcare community. "The threat of large-scale drug resistance is 'real and scary.' " (Marani 2007)⁴⁵¹
- "Resistance develops naturally, in response to the selective pressure from drugs or from the body's own immune system." (World Bank 2003)⁴⁵²

⁴⁵²World Bank, Global HIV/AIDS Program of the World Bank 17-18 June 2003.

- Vaccination programs are not available for many diseases that keep undermining the health and development of developing countries. Homeopathy can help these populations as seen before.

We suggest that homeopathy could play an important role in the treatment of these diseases and that funds would be available to study this further. The above data from history support this idea, and current observations confirm that also for the epidemics today homeopathy is still effective.

There are several reasons why the homeopathic option for epidemic diseases deserves serious consideration:

- Homeopathic remedies create no side-effects
- Homeopathy is safe for pregnant women, babies and elderly people
- Homeopathic remedies are inexpensive
- Production, storage and distribution of homeopathic remedies is simple
- Homeopathy does not induce therapy resistance
- Homeopathic treatment does not create more dangerous viruses and bacteria
- Homeopathy has been effective in many epidemics in the past and indications are very strong that it is effective in today's epidemics as well

To prepare future surveys Kirkby R and Herscu P published the paper "Homeopathic trial design in influenza treatment" in the journal *Homeopathy* 2010;99:69-75 reviewing the published studies on this topic.

Some examples of contemporary publications on homeopathy in epidemic diseases:

Cholera: A pilot study of homeopathic treatment of cholera during an epidemic in Peru appeared to show that it was effective. A subsequent double blind study showed no difference between active homeopathic treatment and placebo treatment. Various technical problems were encountered⁴⁵³. Further research is

certainly needed.

We would remember here that results of such research depend largely of the sample size. Looking at childhood diarrhea, Dr J. Jacob. demonstrated this very well and concluded: "Previous studies have shown a positive treatment effect of individualized homeopathic treatment for acute childhood diarrhoea, but sample sizes were small and results were just at or near the level of statistical significance. Because all three studies followed the same basic study design, the combined data from these three studies were analyzed to obtain greater statistical power. Methods: Three double blind clinical trials of diarrhoea in 242 children ages 6 months to 5 years were analyzed as 1 group. Children were randomized to receive either an individualized homeopathic medicine or placebo to be taken as a single dose after each unformed stool for 5 days. Parents recorded daily stools on diary cards, and healthworkers made home visits daily to monitor children. The duration of diarrhoea was defined as the time until there were less than 3 unformed stools per day for 2 consecutive days. A meta-analysis of the effect-size difference of the three studies was also conducted.

Results: Combined analysis shows a duration of diarrhoea of 3.3 days in the homeopathy group compared with 4.1 in the placebo group (P = 0.008). The meta-analysis shows a consistent effect-size difference of approximately 0.66 day (P = 0.008).

Conclusions

The results from these studies confirm that individualized homeopathic treatment decreases the duration of acute childhood diarrhoea and suggest that larger sample sizes be used in future homeopathic research to ensure adequate statistical power. Homeopathy should be considered for use as an adjunct to oral

⁴⁵³Gaucher C, Jeulin D, Peycru P, Pla A, Amengual C. Cholera and homeopathic medicine : The Peruvian experience. *Br. Hom. J.* 1993;82:155-163.

rehydration for this illness.”⁴⁵⁴

Leptospirosis: Homeopathy is associated with dramatic reduction in Leptospirosis infection in the Cuban population. This publication (July 2010) (240) provides fascinating evidence that a highly dilute substance, prepared according to homeopathic principles, may contribute to the prevention of Leptospirosis, also known as Weil’s Disease. In Cuba, Leptospirosis is recorded by an efficient national surveillance program. Its incidence correlates closely with heavy rainfall and subsequent flooding. In late 2007, in response to a developing epidemic, and with only enough vaccine to treat 15,000 high-risk people, the government decided to treat the entire population of the region, over one year of age, with a homeopathic medicine. This was prepared from the inactivated causative organism provided by the Cuban National Vaccine Institute.

In a recent study, the effect of the homeoprophylaxis interventions in 2007 and 2008 was found to be positive. The study involved huge population and the database was rigorously cleansed, the possible impact of vaccination and chemoprophylaxis campaigns was examined, and the possible impact of other confounders was also considered. No possible confounding factor appeared to have exerted any appreciable influence on the positive impact of the homeoprophylaxis interventions in 2007 and 2008, although the vaccination campaign in late 2008 in the intervened region targeting approximately 4% of the population may have prevented some cases. The Cuban experience with homeoprophylaxis against leptospirosis has been and remains a very positive one. It has given rise to further government-directed immunization against hepatitis A, swine flu, pneumococcal disease, and dengue fever using homeoprophylaxis. The Cuban health system in general demonstrates how orthodox and complementary medicine can be usefully integrated, and

their willingness to use both vaccination and homeoprophylaxis as evidence-based immunization options is an excellent example of this.⁴⁵⁵

“Infectious diseases are still the bane of humanity, particularly in the developing world”, states Dr Sara Eames, President of the Faculty of Homeopathy. “Anything which appears to reduce infection rates in a potentially fatal infection, particularly when it can be prepared and delivered quickly, safely and cost effectively, has to be taken seriously and studied further.”

Dr Peter Fisher, Editor of Homeopathy, notes “This is a very large study and its results, if confirmed, have huge potential impact. We need more research into the effectiveness of homeopathic preparations in preventing infectious diseases, complications, and the economic viability of a homeopathic approach.”

Influenza: Everybody is aware of the audit of the Cochrane organization about efficacy of a homeopathic medicine Oscillocochinum in the treatment of influenza (241). They updated the electronic searches on the Cochrane Central Register of Controlled Trials CENTRAL (The Cochrane Library Issue 1, 2006); MEDLINE (January 1966 to February 2006) and EMBASE (1980 to February 2006). The manufacturers of Oscillocochinum were contacted for information. Seven studies were included in the review, three prevention trials (number of participants (n) = 2265) and four treatment trials (n = 1194). Only two studies reported sufficient information to complete data extraction fully. There was no evidence that homeopathic treatment can prevent influenza-like syndrome (relative risk (RR) 0.64, 95 % confidence interval (CI) 0.28 to 1.43). Oscillocochinum treatment reduced the length of influenza illness by 0.28 days (95 % CI 0.50 to 0.06). Oscillocochinum also increased the

⁴⁵⁴Jacobs J. Treatment of acute childhood diarrhoea with homeopathic medicine: a randomized clinical trial in Nicaragua. *Pediatrics* 1994; 93: 719-725. Jacobs J., Jimenez M., Malthouse S., Chapman E., Crothers D., Masuk M., Jonas W.B., Acute Childhood Diarrhoea – A Replication., *Journal of Alternative and Complementary Medicine*, 6, 2000, 131-139.

⁴⁵⁵Golden I. and Gustavo Bracho G.; A Reevaluation of the Effectiveness of Homeoprophylaxis Against Leptospirosis in Cuba in 2007 and 2008; *Journal of Evidence-Based Complementary & Alternative Medicine* 2014 19: 155 originally published online 11 March 2014; URL: <http://chp.sagepub.com/content/19/3/155>

chances that a patient considered treatment to be effective (RR 1.08; 95 % CI 1.17 to 1.00). Influenza (the flu) is a highly infectious respiratory disease caused by viruses. Other than treatments for complications (such as pneumonia) conventional medical treatment is bed rest. Homeopathy is a system based on 'curing like with like', often using highly diluted sub-stances. Oscilloccinum is a homoeopathic preparation manufactured from wild duck heart and liver (common sources of influenza). It is claimed that Oscilloccinum (or similar homeopathic medicines) can be taken either regularly over the winter months to prevent influenza or as a treatment. Trials do not show that homoeopathic Oscilloccinum can prevent influenza. However, taking homoeopathic Oscilloccinum once one has influenza might shorten the illness, but more research is needed.

During winter 2009/2010 a flu pandemic situation was recorded and followed day by day by the W.H.O. and all national authorities. As international organization, the LMH I asked to report about the use of homeopathy during this pandemic period.

For France: 17 physicians participated, 259 cases were collected and the most prescribed (123 times) remedy was Bryonia (symptoms, including high fever and asthenia, are aggravated by motion), followed by Nux vomica, Pulsatilla, Gelsemium, Arsenicum album, Baptisia, China, Hepar sulphuris calc., Phosphorus, Eupatorium perfoliatum, Belladonna, Sepia, Influenzinum, etc. When the personal global (simillimum) remedy was known for the patient it was almost efficient (5 times used). Most cases were solved in 2 or 3 days. Post-flu asthenia has been described and a second remedy was then needed. Vincent S et al. published a survey on the management of Influenza-like illness by homeopathic and allopathic general practitioners (GP) in France during the 2009-2010 influenza season. 65 homeopathic GP and 124 allopathic GP participated, 461 patients were incorporated and patient's satisfaction is greater when homeopathy has been used alone. Journal of

Alternative and Complementary Medicine (New York, N.Y.) 2012 PMID: 22803696

For Belgium: 92 patients were included in this report from only 3 physicians, 38 patients were between 15 and 40 years old. Gelsemium (headache, fever, asthenia, pain in muscles and bones) and Anisum stellatum (added to the same symptoms, deep and difficult cough, the disease seems to be more aggressive in Belgium than in France, this remedy is near Bryonia for general complaints) were prescribed 27 times each, followed by Euphrasia (11 times), Arsenicum album, Baptisia tinctoria, Influenzinum, Oscilloccinum. Only two complications developed, (bronchitis) one time easily treated with Anisum stellatum, antibiotics needed the other time. Most of cases solved in 2 or 3 days. It has been quoted that none of the patients having asked for a preventive treatment (once a week during the epidemic period) with Influenzinum, Mucococcinum or Oscilloccinum did present flu symptoms.

For Austria: The situation was evaluated and more than 300 patients were reported from 30 physicians. 27 different remedies were used adapted to the situation. Most quoted remedies were Bryonia alba, Belladonna, Gelsemium, Influenzinum, Eupatorium perfoliatum, Arsenicum album, Oscilloccinum, Nux vomica. Several times the intake of the known global personal remedy (simillimum) was sufficient to solve the case very fast. Most of the cases were solved in the 2 or 3 following days. Of course, these flu reports are not controlled systematic recording, more systematic and structured cases 'collections would be needed to assess the real value of homeopathy in case of epidemic situation. But the daily practice includes specific attention and treatments for these cases looking at each patient's symptoms individually. More research is needed and foreseen through the activities of the ISCHI (a scientific committee dedicated to Influenza and Homeopathy). This time no real genus epidemicus came out very clearly even if Bryonia (or Anisum stellatum) and Gelsemium seems to be the most frequently and

efficiently used remedies.

2012 – New publications

Flu pandemics: Homeopathic prophylaxis and definition of the epidemic genius. Renan M. Indian Journal of Research in Homeopathy. January)June 2012; Vol 6 n° 1&2:47-52.

Dengue: A survey in Thailand suggest that Eupatorium perfoliatum 200C may be beneficial for reducing individual susceptibility to dengue virus. Confirmation is needed. Teerachaisakul M. Proceedings of the 66th LMHI Congress in India.

Chikungunya: Bryonia alba 30C was better than placebo in decreasing the incidence of this viral fever in Kerala (n=19750 Bryonia group, n=18479 placebo group). Nair K.R.J. Proceedings of the 66th LMHI Congress in India.

2014- New publications

1. **Mathie RT, Baitson ES, Frye J, Nayak C, Manchanda RK, Fisher P. Homeopathic treatment of patients with influenza-like illness during the 2009 A/H1N1 influenza pandemic in India. Homeopathy 2013;102:187-92.**

The 2009 A/H1N1 influenza pandemic in India was characterised by several prominent symptoms and symptom/medicine associations, particularly temperature >38°C + cough + runny nose, associated with Arsenicum album.

Conclusion

It would be irresponsible not to investigate seriously the observations made over two centuries by thousands of homeopaths concerning the homeopathic treatment of a wide variety of epidemic diseases.

DEFINITIONS

Health definition:

WHO definition of Health: „Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.“

Coming from Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

ORGANON definition of health 6th Edition: „ § 9 In the healthy condition of man, the spiritual vital force (autocracy), the dynamis that animates the material body (organism), rules with unbounded sway, and retains all the parts of the organism in admirable, harmonious, vital operation, as regards both sensations and functions, so that our indwelling, reason-gifted mind can freely employ this living, healthy instrument for the higher purpose of our existence.“

Homeopathic remedy (see www.lmhi.org):

"A homeopathic remedy is prepared from a stock/raw material described in a homeopathic monograph/source, following a homeopathic method and administered to a living being according to the principle of "similia similibus curentur". It has a potential to support changes in the state of health of this living being. When such changes indeed happen and lead to an improvement in the state of health/full healing of a disease with recovery of the state of health, homeopathic medicines act as remedies."

Homeopathy (See Thesaurus ECH):

A therapeutic method of treating patients using preparations of substances whose effect on healthy subjects

is similar to the manifestation of the disorder in these patients.

The European pharmaceutical homeopathic medicinal product definition is:

"Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles."

The Indian pharmaceutical homeopathic medicinal product definition is:

"Homeopathic medicines include any drug which is recorded in Homeopathic provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative Homeopathic literature of India and abroad and which is prepared according to the techniques of Homeopathic pharmacy and covers combination of ingredients of such Homeopathic medicines but does not include a medicine which is administered by parenteral route"

The Indian Homeopathic Pharmacopoeia defined homeopathic medicines as:

"Homoeopathic medicines include any substance which is recorded in the standard books on Homoeopathic Materia Medica from Hahnemann down to the present day authorities with symptoms gathered from proving on healthy human beings; or symptoms, not found during provings but observed to have been actually cured (and verified by sufficient number of observations) by the substances during their administration to sick persons; or symptoms

observed either accidentally or by controlled experiments; or observed as toxicological effects on human beings or animals and which after being prepared according to the principle and technique peculiar to homoeopathic pharmacy and are administered to a sick person according to the law of similars”.

Indian definition of proving:

“Controlled experiments made upon relatively healthy human volunteers with substances prepared according to pharmaceutical technique peculiar to Homeopathy, in varying doses, produce “provings” which constitute the basis of Homoeopathic Materia Medica

SOME MODERN SCIENTIFIC BOOK REFERENCES

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[www.springer.com/medicine/complementary+%26+alt
 ernative+medicine/ book/978-3-642-20637-5](http://www.springer.com/medicine/complementary+%26+alternative+medicine/book/978-3-642-20637-5)

“Statistical tools for alternative research in plant experiments” by Maurizio Brizzi and Lucietta Betti (2010).

“Advances in methodology and statistics” (<http://mrvar.fdv.uni-lj.si/pub/mz/mz7.1/brizzi.pdf>)

Pharmacopoeias:

Homöopathisches Arzneibuch, see: www.oxalis-acetosella.com/glossar/homoeopathisches_arzneibuch.html

The Homoeopathic Pharmacopoeia of the United States; see: www.hpus.com/overview.php

EUROPEAN PHARMACOPOEIA 7TH EDITION, see: www.edqm.eu/site/European-Pharmacopoeia-1401.html

WHO INDEX of PHARMACOPOEIAS, see: www.who.int/medicines/publications/pharmacopoeia/en/pharmacop_index.pdf

“Working Party on “Control of Medicines and Inspections”. Guide to Good Manufacturing Practice