

EDITORIAL

Key Areas of Homoeopathic Research

Research architects today are grappling with new strategies to evaluate and assess different aspects of Homoeopathy. The research planning (in Homoeopathy) should be organized and managed in a systematic and comprehensive manner, and efforts to improve health should be based on evidence from research.^[1] It needs to meet the same requirement of research evidence as that of modern medicine, and at the same time, necessitates consideration of unique philosophy of Homoeopathy.^[2] The guiding principles of health research are quality (ethical, expertly reviewed, efficient, effective, accessible, carefully monitored, and evaluated), impact (potential to improve global health security, accelerate health-related development, redress health inequities, and help in attainment of Millennium Development Goals), and inclusiveness (partnership, a multisectoral approach, the participation of communities, and civil society).^[1] Here, we are stating some of the key areas concerning research in Homoeopathy.

GENERATING CLINICAL EVIDENCE

The initiation of clinical research study requires certain steps: literature review, protocol development, technical/administrative approval from experts, ethical clearance, selection of study design, and choosing the correct outcome measures. The outcomes may be quantitative and qualitative, primary and/or secondary, and generic and/or highly specific.^[3] The research findings need to be evaluated for appropriateness, reliability, validity, responsiveness, precision, interpretability, acceptability, and feasibility.^[4] In addition to these, there may be a number of other objectives specific to Homoeopathy such as validating its theoretical framework and comparison with the conventional system.^[5] The overall aim should be to add more evidence to the existing pool by systematic reviews, randomized controlled trials (RCTs), observational studies, high-quality case reporting, etc., as the case may be.

The systematic reviews and meta-analysis are positioned on top of the hierarchy. They answer a defined research question by collecting and summarizing all empirical evidence that fits pre-specified eligibility criteria. Well-done systematic reviews, with or without an included meta-analysis, are generally considered to provide the best evidence for all question types as they are based on the findings of multiple studies that were identified in comprehensive, systematic literature searches.^[6] In Homoeopathy, it has been a controversial tool because even small violations of certain rules (deliberately or otherwise) can lead to misleading conclusions. In fact, several decisions made when designing and performing a meta-analysis require personal judgment and expertise, thus creating personal biases or expectations that may often influence the result.^[7]

The RCTs are widely accepted as the most powerful research method for evaluating health technologies. There are factors that limit the number, quality, and progress of randomized trials. Barriers to clinician participation, inadequate compliance with study protocol, unsuccessful blinding, missed follow-ups, and poor reporting are some of the limiting factors of RCTs. Researchers should formulate a comprehensive systematic review of existing evidence before planning a new randomized trial, plan recruitment strategies in detail, create simple research protocols with straightforward data collection.^[8] The quality of protocol needs to be prejudged in accordance with the model validity parameters.^[9] Several observational studies^[10] have been conducted to assess the usefulness of Homoeopathy in several medical conditions wherein research participants receive homoeopathic therapeutic interventions and are assessed over a period for a particular health outcome which are published in journals of national and international repute. In this issue, we are sharing outcome of one such observational study conducted to evaluate the usefulness of

homoeopathic intervention in schizophrenia.^[11] We are also publishing a case report of multiple urinary calculi (16 mm, 09 mm) successfully treated at Central Research Institute, Kottayam, under Central Council for Research in Homoeopathy (CCRH).

BASIC/FUNDAMENTAL RESEARCH

Homoeopathy has been able to spark few scientific minds to explore the plausibility of action and nature of high dilutions *in vitro* and *in vivo* experimentation using valid models. The mechanism of action of homoeopathy has been the subject of basic research experiments carried out by biologists, physicists, and chemists.^[13] The fundamental research currently is aimed at on effects of homoeopathic preparations in bioassays as well as research on physicochemical effects of the preparation process (potentization). HomBrex, comprehensive database of basic research in Homoeopathy contains 2198 experiments published in 1645 original articles.^[13] To improve our knowledge of Homoeopathy (the Similia principle and specific preparation of remedies) and to increase the understanding of the working mechanism of its remedies, fundamental research is a prerequisite. From a strategic point of view, the existence of an imbalance between research aimed at demonstration of effects and explanatory research is far from optimal, especially when the (non) occurrence of effects cannot be explained in a satisfactory way.^[14]

The Homoeopathic Medicine Research Group (a joint group of researchers in mainstream medicine and Homoeopathy formed by the Directorate General XII of the European Commission) recommends the replication of previously used model systems, in which an effect of high potencies has been claimed in simple model systems by different workers in well-controlled (multi-center) trials.^[14] In line with global thinking, CCRH has published several studies with positive outcomes^[15-21] and is supporting a significant number of studies besides creating its own infrastructure for undertaking basic research on a regular basis as part of its strategy. In this issue, we are publishing a review article highlighting studies undertaken in an emerging medical discipline of genomic medicine;^[22] the article argues that the mechanism of action of homoeopathic high dilutions are linked to changes in gene expression and intricate process of gene regulation, and further studies on regular basis are desirable using various remedies in different diseases. This also has the

potential of development of new medicines based on DNA, RNA, and specific nucleic acids.

SAFETY AND QUALITY OF MEDICINE

The efficacy and safety of homoeopathic drug largely depend on their quality. Requirements and methods for the quality control of finished homoeopathic medicines are far more complex than for chemical drugs, particularly for the combined or mixed homoeopathic medicines.^[23] The regulations for ensuring the safety and quality of homoeopathic medicines and the good manufacturing practice (GMP) guidelines which offer standards for the manufacturing process, premises, personnel, packaging, and labeling so that users get quality Homoeopathy medicine. Failure to apply GMP may lead to major quality and safety concerns such as misidentification, impurity of starting material, cross-contamination, or incidental contamination.^[24]

To set gold standards to be followed in the preparation of homoeopathic medicine and nosodes, homoeopathic medicines may be subject to similar regulatory control applicable to conventional pharmaceutical products, with some adaptations to the particular requirements of homoeopathic medicines.^[24] Researches have been done to standardize the method of preparation of nosodes using modern technology and lay down clear guidelines for the same.^[24] In continuation of councils efforts to standardization of raw material^[25-27] this issue features pharmacognostic and physicochemical study of homoeopathic drug *Rumex Crispus* L. carried out on roots with the objective to enable the use of the correct species and standardize the raw material. The process of potentization is equally important for keeping pace with emerging research scenario, this issue features an interesting article wherein the author discussed the development of an electromechanical potentiometer and first time quantified the force parameters required to be used in the process of potentization.^[28]

HUMAN PATHOGENETIC TRIALS/DRUG PROVING

Also known as Human Pathogenetic Trial, these are similar to phase I clinical research trials in conventional medicine but with different and added objectives. Phase I trial is designed to reduce the risk of serious (drug) toxicity and avoid confounding

pharmacologic and adverse effects; whereas in Homoeopathy, in subphysiological/ultramolecular doses of potentially toxic or pathogenic substances are commonly used on healthy human beings to deduce characteristic symptoms of drugs for their clinical use in accordance with homoeopathic principles. Continuous research in testing new remedies and currently used remedies must be done with uniform standard updated protocols.^[29]

Drug Validation

Drug validation studies in Homoeopathy are symptom-specific as opposed to condition-specific in other systems. Homoeopathy drug validation has undergone immense evolution in the recent past, and there are various contemporary analytical tools available today in biostatistics for the purpose of validation. These studies need to be planned with two key objectives: to validate the effects of commonly used medicines in specific disease conditions as well as the reliability of prescribing symptoms of identified medicines. More details will be published in our next issue on drug proving and its validation.

Economic Evaluation

Apart from safety, Homoeopathy has added the advantage of cost-effectiveness^[30-31] for providing health care at primary health-care level. Potential cost savings are an important reason for individuals to opt for Traditional and Complementary Medicine Services.^[32] The purpose is to generate information that will assist decision-makers to determine the most efficient way of allocating their scarce resources between competing demands.^[33] Researchers should design an economic evaluation study alongside an effectiveness study to assess the potential to offer “value for money.” This will serve as the strong basis for integration of Homoeopathy in national healthcare.

Homoeopathy needs higher quality and evidence-based researches; the institutional framework of medical colleges, research council, and regulated clinical practice in India can contribute significantly in enriching Homoeopathy globally.

Raj K. Manchanda

Editor-in-chief
E-mail: rkmachanda@gmail.com

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Manchanda: Editorial

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