

# Clinical Research in Homoeopathy, it's Scope, Venues and Methodology<sup>1</sup>

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## PROLOGUE

It is saddening to note that a significant number of practitioners of Homoeopathy in the country do not appreciate the idea of clinical research. It seems to them against the doctrines of Homoeopathy as enunciated by Hahnemann. May be they think that clinical research in Homoeopathy is aimed at obtaining specifics for a given disease or diseases, as is the practice in modern medicine. It is the lack of knowledge which compels them to form a notion of this kind. They do not realize that concept of clinical research in Homoeopathy is not a discovery of Neo-homoeopaths but is an established one since the time of Hahnemann. In fact clinical research in Homoeopathy was started by Hahnemann himself. The first ever employment of a drug, based on homoeopathic principles, on a sick person, thereby confirming the symptoms which were originally proved by it in healthy human beings, was made by Hahnemann himself. The first ever confirmation of the symptoms, which a drug could produce in a healthy human being, was the result of clinical research. Our materia medica is rich as it is today, not only because of the fact that it contains true pathogenesis, of the drugs but because the pathogenesis of respective drugs have been confirmed on the sick and also as it contains a host of clinical symptoms, observed to

appear or disappear in a sick person after the employment of a drug, which were not observed during the course of proving. Now from where these clinical observations came? Certainly as a result of experimentation of a drug on the sick employed in order to effect a cure. Our materia medica is evolved that way. It would have been no good if its contents were not confirmed in the clinic. Any serious student of Homoeopathy find that some of the drug pictures are evolved through observations made in the clinic. They never had a regular proving on healthy human beings. For example: Drug picture of Carcinodin, a cancer nosode, as evolved by Foubister, is a gift to us from his clinical studies. Burnett used it in his clinic on the guidance provided to him by his instinct. Although Templeton has proved it, but major part of its drug picture has been evolved by Foubister through his clinical studies. Same is true about so many other drugs which are in common use in homoeopathic clinics the world over.

It is thus evident that the concept of clinical research in Homoeopathy is as old as Homoeopathy itself.

## SCOPE AND OBJECTIVES OF CLINICAL RESEARCH IN HOMOEOPATHY

There is a great scope of clinical research in Homoeopathy as it is more or less an observational

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science. Various observations as made by Hahnemann and his followers and as confirmed on various occasions, constitute the doctrines of Homoeopathy. Homocopathic materia medica is constituted of the data obtained as a result of proving of drugs on healthy human beings. This data required clinical confirmation to be valid. Obviously clinical observations form as important a basis for the evolution of materia medica as drug provings. However, clinical confirmation is not the only objective for clinical research, in fact there is a host of objectives for clinical research in Homoeopathy. Most important of these objectives are discussed below.

1. *Clinical confirmation of drug pathogenesis* : It is essential to confirm the symptoms obtained through drug provings in the clinic in order to establish their validity.

2. *Elicitation of new clinical symptoms* : When a homoeopathic medicine is employed on a sick person, it is very often seen that various such symptoms appear or disappear in him which were never observed during the course of drug proving. It is seldom that a sick person does not manifest one or more of such symptoms while he is under treatment for his ailments. These symptoms if found true, after deducting every source of error in their observation and after they are confirmed in other sick persons, play an important role in the construction of drug picture of the respective drugs. This objective can be fulfilled by any wise clinical observer who practices Homoeopathy. But unfortunately most of us are satisfied with the cure and do not bother about knowing the circumstances under which the cure is effected nor we tax our heads about observing anything new which may prove its usefulness in future. If we want to enrich our materia medica, we will have to do some organised research in order to achieve this objective.

3. *Evolution of clinical drug pictures* : There is a multitude of such drugs in Homoeopathy which never had a proper drug proving, but are used frequently in the clinics all over the world. These drugs are used on the basis of their toxicological effects as observed from time to time and on the presumption of their effectivity as

shown in other systems of medicine especially Ayurveda (ancient medical science of our country). This practice, truly speaking is not homoeopathic, but still some of the good results are obtained through it. There are various indigenous drugs which are used in tincture or even in potentised form on the basis of their established empirical use. We do not have to name all such drugs here, one has just to refer Boericke's materia medica or Ghose's Drugs of Hindustan.

These drugs require organised drug provings, but in the meantime, it is desired that whenever these drugs are employed on the basis of their empirical use, the changes they effect, the symptoms which appear or disappear under their influence should be carefully noted and subjected to confirmation in other sick persons. Once they are confirmed they can form a clinical drug picture. For this type of study indigenous drugs like *Holarrhena Antidysentrica* (Kurchi), *Psoralea Corylifolia* (Babchi) etc. may be given priority. Simultaneously regular provings of these drugs may also be undertaken.

4. *Classification of various complexions, temperaments and constitutions* : When we go through our materia medica we find that certain drugs have special adaptability for a particular complexion or temperament or constitution. For example, *Pulsatilla* is said to have special affinity for a person of phlegmatic temperament, sandy hair, blue eyes and is primarily a women's remedy; *Sepia* is specially adaptable to persons with dark hair; *Chamomilla* to children with light brown hair, of nervous and easily excitable character; *Baryta Carbonicum* to diseases of children and old people etc. Clinical research in Homoeopathy can embrace this field of action too, for it is in the clinic that we can make observations of this kind.

5. *Disappearance or appearance of any pathological condition under the influence of homoeopathic drugs* : The disappearance or appearance of any pathological condition in a sick person under the influence of a given remedy is of least interest to us as we believe that once the totality of symptoms is removed, whole of the disease is removed (Organon-aphorism

8 and 17). However, it will be of interest from the standpoint of modern medicine and in terms of science if studies are aimed at observing and proving that once the totality to symptoms is removed whole of the disease (including pathological changes) is removed.

The other important items which we can take up for clinical research are, (a) study of special affinities of a given drug or drugs to one or more parts or organs of the body ; (b) study of duration of action of a drug (in different potencies) on a sick person ; (c) study of relationship of drugs to each other ; (d) study of comparative efficacy of various modes of administration of homoeopathic drugs (oral, through epidermis or through inhalation).

#### PRE-REQUISITES OF CLINICAL RESEARCH

- (1) Motive for research
- (2) Hypothesis, and
- (3) Personnel.

(1) *Motive for research* : Behind every research there is a spiritual motive that is "quest of the unknown." This quest of unknown has made man to conduct research in all the times. This desire to know the unknown has forced him to endeavour in the past and it will do so in the future. Once the unknown is known it loses its charm, but the knowledge attained often opens new doors which lead to still other new discoveries. As Priestley very rightly said "Each discovery we make shows many other that should be made." This spiritual motive has always been a moving force which makes man to seek knowledge. A person who desires to conduct clinical research must have a burning desire for knowledge which can be used as means for elimination of or to minimize the sufferings of mankind. It should be his sole motive.

(2) *Hypothesis* : In medicine we make research only to see or prove or verify. In Homoeopathy experimental methods rest on the clinical verification of a given hypothesis. We have as many hypothesis as drugs whose pathogenesis have been obtained through drug proving or through clinical experimentation. When we conduct clinical research we do nothing but prove or disprove, confirm or reject the hypothesis of group of symptoms pertaining to respective drugs. To

make it more clear we illustrate the case of Cinchona Officinalis. Hahnemann took a sufficient quantity of powder of Cinchona bark and developed some symptoms simulating that of intermittant fever. He, through his observations evolved an hypothesis that a drug substance which can produce an artificial disease manifested through symptoms might cure the similar symptoms in a sick person. He used Cinchona on a sick person who manifested similar symptoms to test the validity of his hypothesis. The disappearance of the symptoms under its influence proved the validity of his hypothesis that Cinchona can cure the symptoms in a sick person which it is capable of producing in a healthy human being. So our drug pathogenesis are our hypothesis which we subject to test or confirmation in clinical research.

(3) *Personnel* : It is seen that most of the research workers take up research in Homoeopathy as career for simple reason of earning their bread. A few other feel attracted towards the charisma contained in the word research and so take up research. Very few persons take up research with the sole aim of contributing to the science of Homoeopathy. The latter are the assets to the science and the more we have of such persons the more our science will benefit.

A person who feels his responsibility to a given job is appreciated everywhere. It becomes all the more essential for persons engaged in clinical research, for his work is always aimed at finding better means for the elimination of the sufferings of the mankind. Sense of responsibility paves way for integrity, unprejudice and perseverance. These qualities collectively make a person able to concentrate effectively on his work.

He should possess a sound intellect so that he can make its good use at the time of observation which requires a good deal of knowledge and reasoning. It is said that there is either knowledge or ignorance. A person is either wise or ignorant. Fragmentary information does not constitute knowledge. But here for practical purpose we take knowledge as a relative term which can be improved upon day by day as new horizons of a given thing come to light. We keep finding

newer aspects of a thing and the results obtained thereby further increase our knowledge about that particular thing. This process of searching never ends as a new discovery opens doors to one or more venues for exploration which were just not there earlier. It is then imperative for a person engaged in clinical research to remain informed of the available knowledge of the disease as well as his drugs.

He must be able to interpret his findings in all respects in order to distinguish between the right and the wrong.

He is required to maintain absolute freedom of mind, for it is then and then only that he will arrive at valid conclusions. If he is prejudiced, there may crop up countless sources of error in his observations of the things/events that are there. He should not have any fixed ideas, must doubt his own findings and accept them only when they are confirmed. This act of doubting leads him to the right conclusions in the end.

#### Methodology

- (1) Material : Subjects (Patients) and Drugs,
- (2) Standardised Case Taking and Repertorisation,
- (3) Observation and collection of Data,
- (4) Data analysis and Conclusion, and
- (5) Communication.

(1) *Material* : The material in clinical research is constituted of subjects suffering from a given disease undertaken for study and the drugs to be employed in order to study sphere of their action. The subjects should be from both sexes and different age-groups. They should be available in sufficient number as may be required in order to obtain as much data as needed. If only one sex or age-group is involved in studies, the results will be limited to that particular group.

There is a controversy over the maintenance of control series simultaneously with the drug recipients. Many persons snuff over the idea and denounce it on humanitarian grounds. However, it is desirable, keeping in conformity with the standards of modern medicine that a group of the subjects selected for study may be maintained as control who receive placebo in order to rule out the possibility of spontaneous cure.

This becomes essential specially in acute diseases where possibility of a spontaneous cure is greater. In chronic diseases where disease has been running its course for a long time and there is no chance of spontaneous cure, the control series is not that essential, for progress can easily be assessed by comparing the condition of the subject before, during and after the treatment.

The drugs which are to be used should be pure. As it is not possible to standardise homoeopathic potentised dilutions till this date, it should be ensured that they are prepared from the mother tinctures that meet the standards specified by any recognised Homoeopathic pharmacopoeia. It is also to be ensured that they are potentised in correct manner as prescribed by the Homoeopathic Pharmacopoeia. If these standards are not maintained uniform results will be a farce.

Once the material as per the requirements is obtained the process of study starts. Here we will have to take all precautions as are necessary for the successful trial. Such dietary restrictions are to be imposed on the subject which may deem to be injurious to the action of drug used. Any substance which has medicinal properties and is likely to inhibit or alter the action of the given drug is to be forbidden (for details see footnote to the aphorism 260. Organon-6th Edition). The articles mentioned in the said footnote are to be forbidden unless proved otherwise through scientific studies.

Though selection of most suitable potency and the frequency of doses vary from subject to subject, it is desired that uniformity in their selection be maintained as far as possible in order to obtain uniform results.

(2) *Standardised case taking and Repertorisation* : No uniform data, which enables us to arrive at valid conclusions, is ever possible without a standardised case taking. In its absence we may gather varied information from different subjects which may serve our purpose to a limited extent, but will not serve any purpose when it comes to uniformity in results. And as the latter is essential to form a valid conclusion, it is indispensable. Any wise person who understands Homoeopathy will readily accept the necessity of stan-

standardised case taking in clinical research where uniformity of results is highly desirable. To achieve this we will have to evolve a standardised Case Taking Form which suits our needs and at the same time contains all the essential ingredients of homoeopathic case taking as suggested by the masters. There is too short a space at our disposal to deal with finer details of such self sufficient proforma. Hence we leave it for the persons engaged in clinical research to evolve a case taking form suitable to their needs.

Once the standardised case taking is achieved it requires to be analysed properly and submitted to the process of repertorisation, Importance of repertorisation is so well known that it will be a sheer wastage of time to discuss it here.

Here it will not be out of tune to mention that once a standardised case taking system is evolved, the persons who are engaged in clinical research or wish to do so, must get extensive training in the art of case taking and repertorisation so as to do justice with the job.

(3) *Observation and Collection of Data* : The next important stage of clinical research is "Observation". By meticulous observation we gather data in the form of symptoms. The entire fate of a clinical study depends on data which accumulates as a result of observation during the course of study. It is then imperative that once the drug is employed on a sick person and the stage of observation is in effect, every change, may it seem to be irrelevant at that time, in the condition of the sick is to be recorded in complete, so that there is no possibility of missing anything. Such changes may be put to critical evaluation at the time of analysis of data. They are only to be discarded as irrelevant if they do not prove their validity through confirmation in other subjects. Observation-Data analysis-Conclusion, the three important stages of a clinical study are inter-related and the latter dependant on the preceding-one. A good clinical research must pass through all these stages or it loses its credibility. As observation is closely related with analysis of data, it is discussed further with illustration under that

heading.

(4) *Data Analysis and Conclusion* : Once the data is collected as a result of observation, it requires to be analysed properly in order to arrive at valid conclusions. This process requires very careful interpretations. In Homoeopathy clinical data is constituted of symptoms observed to disappear or appear in one or more subjects after employment of a drug. To draw right inferences from data, it requires great skill, for correct interpretation is the goal. Various possible sources of the symptoms observed, other than the drug itself, should be taken into critical consideration and subjected to confirmation in other subjects before they are accepted as genuine. To cite an example; A subject who requires Thuja Occidentalis for his complaints feel worse after he eats onion but is not aware of this. He, during the course of study, takes onion without knowing what it would do to him and develops undesirable complaints. Now it is left for the wise experimenter to draw inference after careful interrogation, that the symptoms are due to onion and will disappear soon if intake of the onion is checked. The fool who is not careful enough to observe this fact will attribute it to the action of Thuja. In like manner a wise experimenter has to observe every significant or seemingly insignificant changes meticulously during the study, and subject it to the test of confirmation in order to achieve his goal, that is valid conclusion.

(5) *Communication* : Last but not the least important is "Communication of results to the profession". Complete and prompt reporting of research is highly appreciated. The delay in reporting may lead to duplication of work by other thus wasting time and money which could have been well spent on other useful research. Moreover a research made public in time may lead to another discovery contributing to the progress of science, Scientific communication should contain all the details related to material, method, surroundings and circumstances under which study was conducted, so that nothing is missed from the reviewer who may like to confirm the results. It should be in such a form that it is both complete and concise, at the same time and is easily comprehensible to the reviewer.

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