



Research Methodology

From recorded history it is obvious that providers of medical services are forever trying to devise better and more efficient medicines, and surgical procedures for healing the sick faster and with greater success. In earlier times a physician would experiment with newer methods of treatment based on trial and error, anecdotes, and information from peers.

Experiments and clinical trials gradually evolved over the centuries. Clinical experiments, controlled trials, randomized studies, field surveys, and developing and trying out of medicines or new surgical techniques etc. constitute medical research which is going on since centuries. However, in the last 50-60 years the way we conduct research is radically changed.

Until the middle of 20th century the patient was taken for granted. He trusted the doctor completely and expected that all the actions of the doctor will be entirely in his interest. Hippocratic dictum of *primum non nocere* is as valid and relevant today as it was 2500 years back. While this was followed to a large extent researchers often gave priority to their research interest over the welfare of the patient even ignoring the harm likely to be caused to the patient involved in research. The Tuskegee study, a clinical research for studying the natural evolution of syphilis in patients to whom all treatment was denied which was conducted in USA for decades since the 1930s is a classic and very sad example of this. But what shook the conscience of the entire world out of its complacency is the cruel experiments conducted by Hitler's physicians on Jew prisoners during the second world war. This resulted in the Nuremberg code in 1948. Subsequently World Medical Association devised Ethical Principles for Medical Research involving human subjects in the form of Helsinki Declaration in June 1964. The Declaration was revised periodically in 1975, 1983, 1989, 1996, 2000, 2002 and 2004. The Indian Council of Medical Research formulated guidelines for Research Scientists in 1980. As a result Ethics Committees have come into existence. All clinical research must be approved by the ethics committee of the institution / hospital. In fact, even research studies on animals need to be approved by the ethics committee to prevent unnecessary suffering of the animals. Besides,

these are the days of empowerment of the patients. Every patient is entitled to make a decision regarding his choice of treatment based on the complete and relevant information provided by his physician. Besides every person, has a total freedom to decide regarding his participation in a clinical trial after obtaining all the requisite information from the researcher. He also has a right to walk out of the research study at any time without his treatment being affected in any way. No research trial can be conducted on any person without providing him full information and obtaining his consent in writing. Empowerment and autonomy of patients under care and of persons participating in any research must be duly respected without any compromise by clinicians and researchers.

Every clinician is expected to practice evidence based medicine. Evidence regarding new treatment comes from correct interpretation of research studies. Such interpretation has to be necessarily based on the touch stone of statistical evaluation, whenever applicable, and not on the researcher's belief or perception. Involvement of a biostatistician right from the stage of planning of the research is an important part of modern research.

The outcome of research studies reaches clinicians through various publications. There are parties interested in the research outcome eg. pharma companies, instrument / equipment manufactures, fund providers etc. Providing information regarding these vested interests to the readers of the research studies is mandatory today. No monetary payment or financial incentive should be paid to any patient or research scientist. Sponsoring of the research personnel for attending conferences to present the research work and giving them gifts also have to be declared as vested interests.

The outcome, positive or negative, of every research study should see the light of the day. Unfortunately, for varying reasons, negative results do not get published. As a result clinical trials whose outcome is known but not published get unnecessarily repeated by others resulting in wastage of funds, facilities, and man power besides causing avoidable inconvenience to research subjects.

Every research study has to be well planned to avoid waste of efforts but still ensure valid answers. The study must have sufficient but optimum number of subjects to give 80 - 90% power to arrive at reliable valid conclusions. Number of subjects should not be more than that required since it amounts to waste of resources like money, researcher's time and skill, and patients' troubles and inconveniences.

Knowledge of these and many other facets of modern methodology of research are very important not only for research workers but also for readers of research studies. Researchers should be aware that no reputed scientific journal would publish their work if they have not followed proper research methodology. It must be added that scientific writing of the paper in good English is equally important in order to convey to the readers clearly and accurately the results of the research. A reader must be knowledgeable about proper research methods so that he can properly judge the merits of what he reads before he considers utilizing new options and information in clinical practice for the benefit of his patient.

The Journal plans to provide research workers and readers information and guidelines on these and other aspects of modern research methodology in installments.

It must be added that since two years the Journal is successfully conducting PICSEP (Program for Inculcating the Culture of Scientific Enquiry and Pursuit) projects in different parts of the country with the help of member societies of the Federation of Obstetric and Gynecological Societies of India. This is sensitising our members too and creating in them an awareness of modern research methodology.

Lastly, as the next step of PICSEP project the journal in collaboration with Dr. P.C. Mohapatra of Association of Obstetricians and Gynecologists of Orissa organised the 1st National Congress on Science of Research in November 2006. The 2nd National Congress on Science of Research will be held in Aurangabad in October 2007.

The Editorial Board Conveys Season's Greetings to all its readers and wishes them A very Happy New Year.

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JOURNAL BEST PAPER PRIZES FOR THE YEAR 2005

is awarded to -

Dr. Muralidhar V. Pai (Manipal) in the Open Category for his paper on 'Placental laterality by ultrasound - a simple yet reliable predictive test for pre-eclampsia'.

Dr. Dipankar Bhattacharya (Kolkatta) in the Junior category for his paper on 'Clinical correlation with biochemical status in polycystic ovarian syndrome'