NEED FOR STANDARDISING RESEARCH METHODS

MMS Ahuja

The Subject is being presented under the following headings:

1. Characteristics of research
2. Definition of standards
3. Present status of research at post graduate and post doctoral level.
4. NIH guidelines for research projects
5. Components of clinical research
6. Pre-requisites
7. Helsinki declaration / who 1992
8. Conclusions

Characteristics of Research

The investigator should have a scientific temper of enquiry, attitude for search and develop the habit of making critical observations.

The research methods followed by a scientist should be reproducible by another scientist using the same technique.

Lastly, the research should lead to an advancement in the existing knowledge as well as be useful for a betterment of human beings.

Definition of standards

This is an attribute, which determines the level or the degree of quality considered appropriate and adequate for a specific purpose. Standards identify excellence in comparison to certain set parameters. Comparison with standards provides the basis for ongoing improvements.

Present status of research at postgraduate and post doctoral level

In most instances, the topic selected for research is a duplication of work already done is not available on the subject Students tend to follow a set paradigm and are unwilling to put forward new concepts which are likely to meet opposition and criticism. [1].

Selection criteria for study subjects for clinical trials are usually biased as they are generally non-randomised and consist of hospital staff or clinic patients recruited due to easy access.

In laboratory work, internal or external quality control methods are not employed and routine laboratory data are included in the studies. There is a tendency to employ 'F' (fudge) factor. In some instances plagiarism is followed and data from other laboratories are utilised as if it is the original contribution of the scientist.

N.I.h. guidelines

N.I.H guidelines [1] are as follows:

A proposed basic research should address a significant fundamental question, incorporate appropriate controls, employ appropriate tests of statistical significance and power, provide adequate characterization of the treatment used, present evidence to human and be based on testable hypotheses.

Besides having similar characteristics a proposed clinical study should address the question of effectiveness and or safety, offer benefits commensurate with the risks involved for patients, allow question of effectiveness to be decided within a predictable time frame and when appropriate include comparison with other medical approaches.

This brings one to consider, in real time, organisation of the components of clinical research project, which are as follows:

Hypothesis

One needs to evolve a process of some original approach to an existing problem and frame 2-3 questions, solutions to which might bring out new information.

Material

In selection of sample for study, randomisation or matching or stratification of age, gender, specific disease, its important prognostic factors should be taken into consideration.

Adequate control group or equivalent subjects on placebo must form part of the study. No other intervention is permitted nor should there be a cross over bias. Confounding factors that may affect prognosis be excluded.

From sitaram Bhatia Institute, New Delhi.

A sound statistical advice at the planning stage of the study is most essential. It should suggest sample size, format and the period of study to give some meaningful results.

Follow-up should have compliance of about 80% of the enrolled subjects to provide data for statistical analysis based on confidence intervals, probability distribution or odds ration, matched against a parallel outcome or a 'gold standard'.

The conclusion should indicate possible utilization of the results of study and be eligible for peer review and worthy of publication in an indexed journal.

Certain pre-requisites that need emphasis include:

i. A pilot study, which involves a trial, run on completeness of data, testing the Performa or clinical studies.

ii. Statistical training of technical personnel in laboratory methodology or for field work.

a) Supervised training of technical personnel in laboratory methodology or for field work.

b) Ensuring resource availability till completion of study e.g. chemicals, regents, assay kits etc.

c) Arrangements for external quality control of laboratory investigations and provision of midcourse review by experts in the field/speciality to take any corrective steps, if necessary.

In the declaration of Helsinki (WHO 1992)[2] it has been stated that in research on man the interest of science and society should never take precedence over considerations related to the well being of the subject.

In any medical study every patient including those of a control group, if any, should be assured of the best proven diagnosis and therapeutic method.

In respect to third world countries [3], it states that the control group should be receiving the best current treatment, not the local one. Also subject be provided protection at least equivalent to that of the sponsoring country.

There is another aspect with a denominator of challenge for biomedicine that states that the present dominant model of disease is biomedical, it should incorporate psychological or behavioural dimensions of illness and new model be on biopsychosocial basis [4].

In conclusion, with premise of promotion sound basis for clinical research, we need to augment the resource availability and provide a respectful status to the investigations currently; those engaged in clinical practice have privileges denied to research workers.

There needs to be recognition of the recent contributions of basis scientists in molecular biology, genetics, cellular immunology epidemiology and their liaison with clinical counterparts for application of such areas for the studies. Research offers new challenges and any new paradigm or findings will meet resistance form colleagues with conventional ideology, but this should not deter one from pursuing new horizons.

REFERENCES:

1. Cassileth B, Jonas W, Cassidy CM et al. Research Methodologies Alternative Medicine Expanding Medical Horisons 017-04-0-537-7. Report to N.I.H. –usa. 1992, P289.

2. World Medical Association. Declaration of Helsinki, Adopted by the 18th World Medical Assembly-1993.

3. International Ethical guidelines for biomedical research-in-volving human subjects, W.H.O. Pub. C1oms, 1993

4. Engel G.I. The need for a new medical model-a challenge for biomedicine. Science, 1977, 196: 129-36.