



EDITORIAL

THE VALUE OF PARTICIPATING IN CLINICAL RESEARCH

Clinical researchers in South Africa face many challenges at present, partly because of financial pressures on academic institutions, where the majority of independent clinical research takes place. It would seem timely to affirm the value of participating in international and local clinical research so as to uphold the role of research in medicine, and to urge that clinical researchers fully utilise those opportunities for clinical research that do exist.

The environment in which clinical research is conducted has changed in recent years, so that research is now seen in a more positive light. A better-informed general public has a clearer appreciation of both the achievements and limitations of medicine. The ethical codes that govern the conduct of clinical research, in addition to having important protective functions for patients, nowadays place increased emphasis on the benefits of research to society.

There is a greater spirit of inclusiveness in research. Lobby groups for patients with specific diseases such as HIV infection, or breast and prostate cancer, encourage their members to be part of clinical studies and promote studies of their diseases of interest. Underrepresentation of minority groups in studies in the industrialised world is regarded as a cause for concern and this representation is now frequently audited in clinical studies. Collaborative research groups are enlarging globally in order to increase the numbers of patients entered into studies. This can be of benefit to both collaborative groups and participants.

The obvious direct benefit of clinical research is an increase in scientific knowledge, and thereby an improvement in the health of future patients. Scientific knowledge reaches across national boundaries, but is applied differently in different countries and communities. Clinicians involved in the research may develop a deep understanding of results so that they can contribute to the interpretation of the findings and implement them with a full knowledge of local conditions.

In addition, there are significant indirect benefits from clinical research. Important lessons have carried over from the conduct of clinical trials into clinical practice. These include the adherence to written treatment protocols, so that administered treatments are consistent and do not follow transient inclinations. The use of a common terminology, for example the assessment of tumour response to treatment or the grading of complications in oncology, facilitates the ability of physicians to assess clinical findings and maintain continuity of care between clinicians. The process of medical audit and the institution of

quality assurance programmes owe much to the developments from clinical trials.

Clinical research assists in the maintenance of standards of medicine. The most objective evaluation of a therapy is by means of prospective randomised trials. Ethical codes, such as the Declaration of Helsinki, require that the control arm in such studies should be the 'best proven diagnostic or therapeutic method'.

This might not always be attainable outside of trials, as all medicine is subject to cost considerations. However, we need to retain awareness of proven standards of therapy and have insight into their cost-effectiveness. Funding organisations, such as governmental health authorities or medical aid societies, should be held accountable to these findings. Moreover, the insistence on a high standard of care within research, irrespective of the financial background of the patient, is a strong challenge to the disparities in service medicine provided to different communities. The total amount of money spent on clinical research is a small fraction of the total amount spent on health care.

All societies grow and develop, and clinical research should be integrated into this process. The individual is the basic unit of development and needs to be empowered intellectually and socially. Ethical clinical research emphasises the autonomy of patients, particularly in the process of informed consent. This rightfully acknowledges each patient's sense of self worth.

Clinical research should be maintained and expanded. It enables us to address important scientific questions and also has indirect beneficial effects on the practice of medicine and the community at large.

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