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Editorial

Influence of Clinical Trials on the Treatment of Diabetes Mellitus

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The shift from empiricism and observational studies to experimental methods as the basis for advancing the treatment of human disease has occurred only recently. The modern age of clinical trials, born with the British Medical Research Council's study of streptomycin treatment of tuberculosis in 1948, has provided the substrate for evidence-based medicine. Clinical trials have been credited with "three of the seven years of increased life expectancy over that time and an average of five additional years of partial or complete relief from the poor quality of life associated with chronic disease". The enormous expansion of clinical trials has paralleled the event of latest therapies. With the massive number of medicine in development and therefore the requirement for controlled clinical trials for approval, the expanding number of clinical trials isn't expected.

Despite the obvious benefits of bringing scientific methods to the evaluation of therapies, the need for clinical trials has recently been challenged. Proponents of epidemiological studies as substitutes for clinical trials have suggested that conclusions from observational studies, including meta-analyses, often give similar answers as clinical trials. Although empirical data may provide useful information regarding established therapies, it should be obvious that they play a very different role from clinical trials.

Diabetes mellitus is the most common chronic endocrine disorder, affecting an estimated 5–10% of the adult population in industrial westernized countries and an increasing fraction of populous countries in Asia, Africa, and Central and South America where agrarian, often subsistence; economies are giving thanks to industrialization. The accompanying shift in life-style to more sedentary activity with higher fat, lower fiber diets and resultant obesity, apparently underlies much of the increased prevalence of type 2 diabetes.

Given the increasing importance of diabetes mellitus, and especially type 2 diabetes, as a public health problem, the recognition of its myriad long-term complications, and the increasing number of potential therapies to treat the metabolic disorder(s) and therefore the attendant complications, it should come as no surprise that clinical trials have played a serious role. Therapies established as effective in clinical trials have had a serious salutary effect on the lifetime and quality of life for persons with diabetes.

Ultimately, the results of clinical trials remain academic unless they're implemented. Several factors can interfere with the translation of interventions demonstrated as effective in clinical trials. To the extent that a study population is very selected and not representative of the non-study disease population, the study results might not be generalizable. In addition, study therapies that can't be implemented within the non-study setting due to their complexity, expense, or other factors are going to be of limited utility. On the opposite hand, if study populations and interventions are carefully chosen, balancing research needs and clinical relevance, effective therapies are often promulgated. The usual routes for disseminating information regarding new effective therapies include publication in peer-reviewed journals, presentation of results at medical meetings, guidelines prepared by professional organizations and governmental agencies, and promotional advertising by the pharmaceutical industry. Investigators often lose control of their study "message" during the bedside translation; however, their participation within the educational outreach programs and formulation of guidelines that always follow large, successful, clinical trials should serve to preserve the scientific and clinical integrity of the study results. Investigators should be encouraged to participate during this important translational phase of clinical research.

Clinical trials have played a critical role in defining effective therapies for DM and for various stages of its myriad complications. Equally as important, ineffective therapies have been discarded on the basis of controlled clinical trials. The net effect of controlled clinical trials has been an expansion of lifetime and an improvement in quality of life for persons afflicted with this chronic disorder. Future studies may provide effective prevention strategies and cures.

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