Funding Clinical Research Leads to Improved Health and Long-Term Financial Savings

Johnston SC, Rootenberg JD, Katrak S, et al. Effect of a US National Institutes of Health programme of clinical trials on public health and costs. Lancet 2006;367:1319–27.

Study Overview

Objective. To estimate the costs of grant support for clinical trials and the benefits of such trials to society.

Design. Cost-effectiveness analysis.

Setting and participants. All phase III randomized trials funded by the National Institute of Neurologic Disorders and Stroke (NINDS) for which funding was completed by 1 January 2000 were included. Data collected included the cost of funding each trial, the effectiveness of the intervention tested by each trial, the cost-effectiveness of each intervention, and the change in utilization of each intervention before versus after the trial's main publication. Data sources included NINDS (trial costs), the published literature (effectiveness, cost-effectiveness, and utilization), and—for cost and utilization data not available in the published literature—the pharmaceutical industry, manufacturers, and disease-based nonprofit organizations.

Main outcome measures. Total trial costs; total cost-effectiveness of the trial interventions as measured by total intervention costs and total quality-adjusted life years (QALYs) gained, each multiplied by total utilization and projected over 10 years; and total cost-effectiveness of the trials as a group.

Main results. 28 trials were included, with total costs of $335 million. Data on effectiveness, cost-effectiveness, and utilization were available for 8 of the trials. The other 20 trials contributed trial cost data to the analysis but were assumed to have no benefits or harms for society. The 8 trials with data were projected to add 470,339 QALYs to society over 10 years at an additional cost of approximately $3.3 billion for implementing the interventions. This was equal to an incremental cost-effectiveness ratio of $7713 per QALY. Assuming that a QALY is worth the same as the per-head gross domestic product ($40,310), the group of trials resulted in a net savings of $15.5 billion over 10 years.

Conclusion. Public funding of clinical trials yields substantial returns to society in terms of improved health.

Commentary

Few studies have attempted to quantify the value of medical research to society. Johnston and colleagues estimated the value to society of all phase III randomized trials funded by the NINDS before 1 January 2000. They conducted a cost-effectiveness analysis and found that several NINDS-funded trials resulted in interventions that diffused into practice and improved health outcomes to such a large extent that the cumulative health benefits projected over 10 years vastly exceeded the combined costs of the trials and of implementing their interventions.

Johnston et al's study has several strengths. The authors estimated the cost-effectiveness of a contained body of research (phase III randomized trials of a single institute at the National Institutes of Health [NIH]), thereby including studies that found significant effects of interventions and studies that found no effect. The methodology was rigorous, comprehensive, and fairly transparent. Several conservative assumptions were made: (1) clinical trials with missing data for effectiveness were assumed to have no health effects or utilization, and (2) a relatively low estimate [1] for the value of a QALY was used.

Several limitations are worth noting. Johnston and colleagues assumed that the effectiveness of an intervention was the same as its efficacy, an assumption that is likely to overestimate the truth [2]. The authors also assumed that utilization changed over time in a linear fashion, which may not be true. Further, NINDS funded the study, generated the research question, reviewed the initial study plan, and reviewed a draft of the manuscript; this represents a potential conflict of interest. Finally, the study results may not be generalizable to other divisions within the NIH or to other types of medical research (eg, basic science, epidemiology, or health services research).

Applications for Clinical Practice

Despite its limitations, this study makes an important contribution by being among the first to quantify the cost-effectiveness of clinical research [3]. Quantifying the value of clinical research is especially important now because the federal budget for fiscal year 2007 is expected to include the first budget reduction—adjusting for inflation—in NIH funding

since 1970 [4]. Johnston et al's study should stimulate similar efforts to quantify the value of clinical trials in other fields and the value of other types of medical research.

—Review by Lisa M. Kern, MD, MPH

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