

Clinical Economics in Clinical Trials: The Measurement of Cost and Outcomes in the Assessment of Clinical Services through Clinical Trials

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Abstract. As the population ages and more expensive high-technology services become available, health care costs continue to spiral upward. Because the financial resources for health care are limited, economic analysis can help to evaluate expenditures and set priorities. Economic analysis of medical technology or medical care evaluates a medical service by comparing its dollar cost with its dollar benefit (cost-benefit), by measuring its dollar cost in relation to its outcomes (cost-effectiveness) as well as in relation to its utility or quality-adjusted outcomes (cost-utility), or simply by tabulating the costs involved (cost-identification). Direct costs are generated as services are provided. In addition, patients' productivity is affected, and these costs can be considered, especially in determining the benefit of a service that decreases morbidity or mortality. Intangible costs are those of pain, suffering, and grief. The point of view, or perspective, of the study determines the costs and benefits that will be measured in the analysis. Sensitivity analysis, which can evaluate the stability of the conclusions to the data used, is an important assessment within economic analysis. Economic analysis of new pharmaceutical therapies is increasingly being incorporated into clinical trials. Although there are some limitations of pharmacoeconomic information in clinical studies of drug safety and efficacy, these trials are often the only opportunity for economic data collection before adoption and reimbursement decisions are made. Validation after the drug has been introduced should complement economic information developed from clinical trials. (Keio J Med 48 (1): 1–11, March 1999)

Key words: clinical economics, pharmacoeconomics, cost-effectiveness analysis, clinical trials

Introduction

As populations age and as the use of expensive high-technology services increases, health care costs have been increasing at rates greater than inflation in most developed countries. For example, with one person in six already older than 65, the challenge of how Japan will support its aging society grows more bedeviling with each passing year.¹ Moreover, in Japan, health

care costs have recently been increasing every year by at least 1 trillion yen (\$8.3 billion),² although the fund of premiums to support the health care system has been relatively decreasing. As a result, copayments by patients, including aged patients, have been increasing in Japan. A consequence of scarce resources available to fund health care services is that it might not be possible to fund every treatment that might have some benefit.

When resources for health care are scarce, allocating

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