

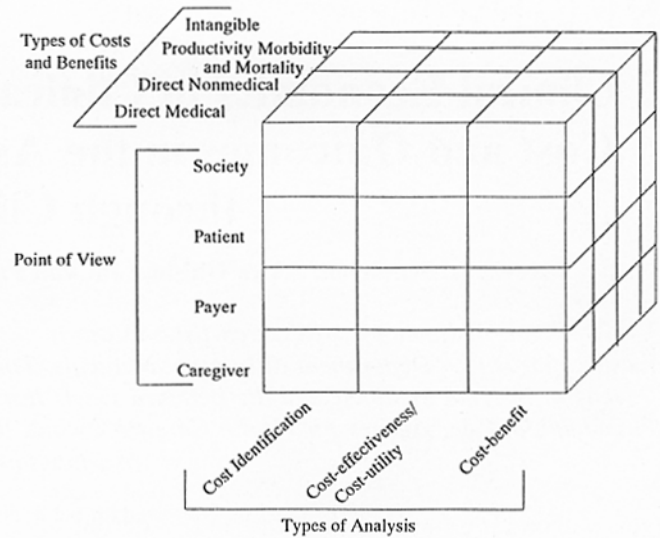
these resources requires careful decision making. In this setting, information with which to make these decisions becomes critical. Asking questions about effectiveness (health benefits in real practice settings rather than efficacy or health benefit derived under ideal conditions), efficiency (the effectiveness of the treatment in actual clinical practice compared with its cost), and cost is important for this purpose. Economic analysis has been introduced as a means to improve information for decision makers facing these allocation decisions. In order to help meet these information demands, the Japanese government established the Institute for Health Economics and Policy, a non-profit organization, in 1993.

Although the importance of economic analysis for purchasing care or for regulation has been stressed,³ clinical uses of economic analysis should not be ignored. For patients themselves, the data from economic analysis may be useful in understanding the outcomes and resource use associated with a treatment. Pharmacoeconomic studies are often designed to meet the different information needs of health care purchasers, regulatory authorities, clinicians, and patients. In recent years, pharmaceutical companies have been submitting pharmacoeconomic data to the government in Japan.⁴ With the increased use of economic data in reimbursement discussions worldwide, the methods of economic evaluation have evolved rapidly. Economic evaluation of pharmaceuticals (pharmacoeconomics) has been implemented in phase III clinical trials in order to improve data for setting priorities and determining whether to provide reimbursement for new pharmaceutical products.⁵ This effect complements previously established modeling methodologies for economic analysis. Thus, economic analysis is becoming increasingly more informative at a time when use of the data it provides is more critical.

In this paper, the methods of economic analysis will be explained and issues related with incorporation of economic analyses into clinical trials will be introduced.

Methods of Clinical Economic Analysis

In considering economic analysis of medical care, there are three different dimensions of analysis, represented by the three axes of the cube in Fig. 1.⁶ Along the horizontal axis there are three different types of economic analysis: cost-identification; cost-effectiveness including its subtype, cost-utility; and cost-benefit. Along the second axis there are four different types of costs and benefits that can be included in economic analysis of medical care: direct medical costs and benefits, direct non-medical costs and benefits, productivity costs and benefits, and intangible costs and benefits. Along the third axis are four points of view, or per-



Adapted from Bombardier and Eisenberg 1985

Fig. 1 Three dimensions of clinical economics.

spectives, that one may take in assessing the costs and benefits of a new medical therapy: society, patient, payer, or provider. Each of these dimensions will be reviewed in the following sections.

Types of Economic Analysis

If two or more alternatives are compared and if both costs and consequences of alternatives are examined, a full economic analysis is being performed.⁷ There are four full economic analyses performed in clinical economics: cost benefit, cost-effectiveness, cost utility, and cost identification analysis.

Cost-benefit analysis: Cost-benefit analysis of medical care compares expenditures in different programs and values all outcomes or health states noticed by the patient⁸ in the same economic units, usually monetary units (e.g. yen). Cost benefit analysis is potentially a broad form of economic evaluation which allows policy analysts to compare the economic impact of newly developed health care technology with other investments in health care or with investments in other fields such as education, construction, or the environment. If properly done, benefit-cost analysis can be of great help to agencies participating in the development of health, environmental, and safety regulations.⁹ In practice, however, the full implementation of this paradigm is often restricted by measurement difficulties caused by the disadvantages of this method.

The major disadvantage of cost benefit analysis of health care is the requirement that human lives and