intangible costs may be incorporated into the outcome by measuring utility values for health states, as in quality-adjusted life years.

Perspective of Analysis

The third axis in Fig. 1 shows the perspective of an economic analysis of medical care. Costs, outcomes, and benefits might be calculated differently from different points of view, such as society, the patient, the payer, and/or provider. A study's perspective determines how costs and benefits are measured, and the economic impact of an intervention will be reported differently depending upon the perspective taken.

For example, the cost of hospitalization from the perspective of the patient is the amount paid out-of-pocket, or the portion not covered by insurance and the other costs that might be incurred because of illness or treatment, including time missed from work. The cost of hospitalization from the perspective of the provider, such as a hospital, is the cost of providing the service which includes labor costs, the costs of the buildings in which the services are provided, and other overhead costs. The cost of hospitalization from the perspective of the payer, such as Employees' Health Insurance, National Health Insurance, or health insurance for the elderly in Japan, is the amount of money that the payer pays to the hospital under the coverage plan for the individual who is hospitalized. The cost of hospitalization from the perspective of society as a whole is the total net cost of all of the different components of society, including the patient's lost productivity due to the illness as well as the resources consumed in giving and receiving medical care.[10]

Because the broad nature of the health care cost problem suggests that the perspective should be equally broad, the preferred perspective in economic analysis for government authorities or decision makers is societal. A societal perspective seeks to determine the net costs of the treatment or intervention to all payers for all persons. Other perspectives can also be important components of an overall economic assessment and may be of greatest interest to other decision makers.

Economic Evaluation of New Clinical Therapies

The cost of drugs includes not only their purchase price but also the accompanying costs of preparation, administration, monitoring for and treating side effects, and the economic consequences of successful disease treatment, all of which are influenced by clinical and pharmacologic characteristics of pharmaceuticals. Thus, in addition to differences in efficacy and safety, differences in efficiency are pivotal in distinguishing drugs from each other.[37]

Research Methods of Clinical Economics

There are several methods to evaluate efficiency of clinical therapies, e.g. prospective and retrospective analysis of clinical trials, retrospective analysis of specific patient populations, analysis of administrative data bases that describe the experience of a specific patient population defined by the type of health care payer, and decision-analytic models that predict the effectiveness of therapies using existing clinical data.[38] Here, we principally discuss prospective economic analysis of clinical trials.

Prospective Analysis of Clinical Trials

Prospective economic studies of clinical trials are designed specifically to measure the costs and benefits of new pharmaceutical therapies. Although generalizability is an issue in early clinical trials, prospective economic evaluation within phase III clinical trials is a must if systematic decision-making is to be performed prior to making a reimbursement decision for a new product.

Prospective study design has been considered to be needed especially for expensive drugs such as recombinant drugs (e.g. recombinant human erythropoietin and interferons), drugs that are likely to be prescribed in high volume (e.g. antihypertensive drugs), or new and innovative drugs that may be more effective than existing therapy (e.g. HMG Co-A reductase inhibitors).[39] In fact, over the last few years, the number of prospective economic evaluations of new pharmaceutical products has grown rapidly,[5,37,40,41] as these expensive drugs of great importance have been developed despite limited health care resources. Pharmacoeconomic data have become increasingly important for reimbursement decisions by national health programs and private healthcare organizations in the United States and other developed countries.[5] Such economic evaluations aim to compare the costs and benefits associated with a new drug with the current therapy.

Randomized controlled clinical trials are recognized as the best source of data on the efficacy of new interventions and are the preferred approach for evaluating health care technologies. Since clinical trials often precede reimbursement decision-making (phase III clinical trials), they provide an opportunity to collect economic data for reimbursement decision-making.[39] In fact, Australia and Denmark have implemented and Canada is considering a set of national guidelines that would mandate the presentation of pharmacoeconomic data at the time of product registration for pharmaceuticals to qualify for reimbursement through the national health insurance systems.[42,43] In many European countries, submission of economic data is encouraged, although