

highly variable clinical course and an evolving pattern of clinical expression and occurrence. These features help demonstrate that a careful assessment of a disease can be as important to the evaluation of technology as is a comprehensive understanding of the technology itself.

Our selection of cimetidine emerged gradually. Initially, we wanted to use an assessment of peptic ulcer disease as a backdrop for reviewing the costs and benefits of a number of diagnostic tests and therapeutic interventions such as those listed in table 1. (In addition to these contemporary interventions, the variety of clinical approaches to ulcer disease over the past century constitutes a rich history for anyone interested in the progress and byways of medical science (85).) It soon became evident that we could either review several interventions superficially

or analyze one in detail. We elected the latter course, believing it would produce a more coherent exposition of the general model.

We selected cimetidine for several reasons. First, it is a recent innovation that was disseminated rapidly. Second, as a chemical entity, the drug cimetidine does not evolve technically (unlike, for example, endoscopy) and its effects are relatively independent of the skill of the clinician (unlike, for example, surgery's). Since there are fewer such complications related to the technology, we can appreciate more readily the complexity introduced by features of the disease. Finally, the clinical effects of cimetidine have been studied extensively, and its costs and benefits have been and continue to be formally assessed.

The body of this case study is organized into three main parts. First, we present a brief description of a general benefit-and-cost model for evaluating medical interventions. Second, we describe pertinent clinical and epidemiologic features of peptic ulcer disease, and summarize several cost-of-illness studies of the disease. Third, we review the development, dissemination, health benefits, and resource costs of cimetidine. As a framework for the analysis of cimetidine, we use the general benefit-and-cost model for evaluating medical interventions and a set of questions provided in a section of this case study entitled "Guidelines for Review of Health Care Benefit-and-Cost Analyses." We offer a critique of one major analysis of cimetidine's costs and benefits and end with suggestions for further research.

Table 1.—Selected Contemporary Interventions Used in Peptic Ulcer Disease^a

Diagnostic interventions	
Imaging	
• Air-barium, double-contrast radiographic studies	
• Fiberoptic endoscopy	
Physiologic function tests	
• Gastric secretory testing	
Therapeutic interventions	
Medical	
• Antacids	
• Anticholinergics	
• Cimetidine	
Surgical	
• Partial gastrectomy	
• Truncal vagotomy, with antrectomy or drainage procedure	
• Highly selective vagotomy	

^aDescriptions of some of these interventions are provided later in this study.

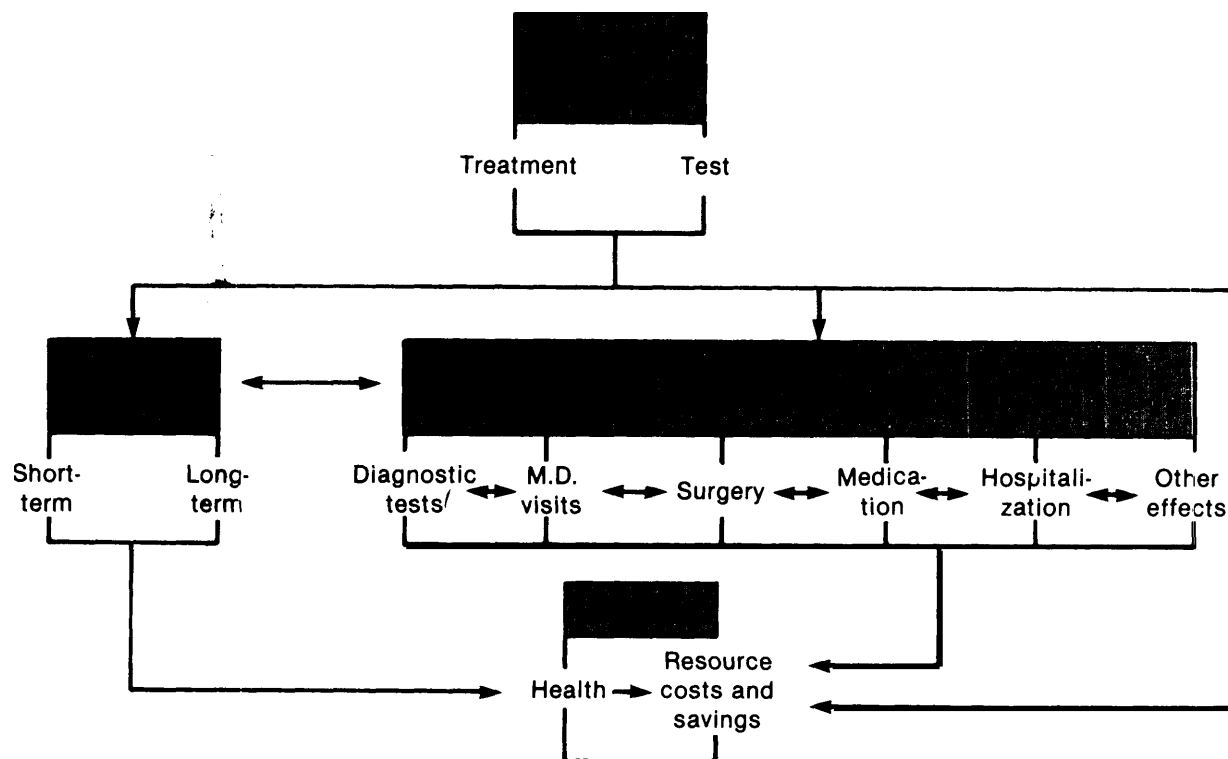
THE BENEFIT-AND-COST MODEL FOR MEDICAL INTERVENTIONS

Every assessment of the benefits and costs of medical care should apply to an identifiable patient population and a specific health intervention. The ultimate objective of a benefit-and-cost assessment is to measure the effects that a specific intervention has on the health outcome of those patients and on resource consumption. Implicit in this objective is a societal perspective. The health and resource outcomes result from the intervention's direct and induced ef-

fects on the clinical well-being of patients and on other components of the health system. These relations and interactions are summarized in the benefit-and-cost model shown in figure 1.

The principal components of the model are as follows: 1) population, 2) intervention, 3) clinical effects, 4) health system effects, and 5) outcome. The population may be delineated in terms of a particular diagnosis or pathologic en-

Figure 1.—Benefit-and-Cost Model for Medical Interventions



tity (e.g., peptic ulcer), a risk factor (e.g., cigarette smoking), a clinical sign or symptom (e.g., dyspepsia), or a complication of disease (e.g., gastrointestinal hemorrhage). Interventions are of two broad types: tests, which are meant to produce information about the clinical status of the patient; and treatments, which are intended to alter the development or course of disease.² Clinical effects include any physical or psychological changes that may alter the health status of the patient; these effects may be short or long term. Health system effects include all changes in the methods and means of medical care that are consequent to the initial intervention. The health outcome is reflected in mortality and morbidity, i.e., in the length and quality of life. The resource outcome, resource costs and savings, pertains to net effects on social resource consumption.

²The distinction between tests and treatments is useful analytically, but not absolute, since, albeit rarely, a therapeutic trial may also have a diagnostic intent.

The general framework of the model applies to any intervention and patient population. The detailed components under clinical and health system effects, however, will vary with the particular disease and intervention being considered. Thus, for example, if we were analyzing an intervention that might affect chronic disease in the elderly (e.g., a prevention or treatment for senile dementia), we would want to consider nursing home use explicitly under health system effects. In general, the components identified for clinical effects and for health system effects should be: pertinent to the disease and intervention; complete, in that all important effects are considered; and mutually exclusive, so that a single effect is not counted twice. They should also be components for which readily available and accurate measures can be obtained. The validity and feasibility of a cost-effectiveness or a benefit-cost evaluation depend on the extent to which the analytic components conform to these criteria.

According to the model, an intervention itself may alter a patient's clinical status, effect changes in the health system, and consume resources. Clinical effects include both the advantages and risks of care. The direct clinical effects of a test are typically limited to side effects and complications, but a test can also alter clinical status by inducing changes in the health system, primarily by altering the choice of therapy. A treatment is intended to have direct clinical effects, but can also alter subsequent use of diagnostic procedures (a health system effect) by changing the course of the disease.

Clinical effects and health system effects can interact in both directions. As illustrated in the model, interactions among the various health system components may also occur. Changes in a patient's clinical status are likely to alter the future course of medical care for the patient; and shifts in the medication, hospitalization, surgery, or other care given to the patient are likely to affect clinical status.

Although the model is premised on the application of a particular intervention for a particular disease, health system effects may not be limited to the target disease entity. For example, if an intervention reduces the number of physician visits for a particular disease, it could alter the number of diagnostic tests and amount of medication employed for other disease problems.

Health outcome typically includes mortality measures, such as number of deaths, age-adjusted death rates, or years of life lost. It also includes morbidity measures, such as quality-of-life or health-status indexes. Morbidity and mortality may also be combined into a unitary measure, such as quality-adjusted life years (152) or another multiattribute utility scale (87). As indicated in the model, morbidity and mortality also have direct implications for productivity and hence for social resource consumption.

The benefit-and-cost model for a particular population and intervention suggests the complexity of undertaking a comprehensive assessment of either all uses of a single intervention or all interventions for a particular population.

Consider two interventions, endoscopy and cimetidine, and the population of patients with duodenal ulcer. Both interventions are used in some patients with duodenal ulcer; each is used independently of the other in some patients with duodenal ulcer; and both interventions are also used, singly or together, in some patients without duodenal ulcer. Moreover, neither intervention is used in some patients with duodenal ulcer. Compound these partial overlaps with additional interventions, add variations in the particular populations for which data are available, and the magnitude of the problem begins to become apparent.

The benefit-and-cost framework outlined here is applicable to both BCA, or cost-benefit analysis (CBA), and CEA. A BCA assesses the net value of an intervention by summing all effects on a common scale. Typically, both resource expenditures and health outcome effects are assigned monetary values. A variety of means to measure the resource value of health benefits have been proposed; the most widely used is expected productivity loss based on discounted future earnings at the age of death or disability (31,89). Thus, a BCA converts decreased deaths and disabilities into increases in productivity, and treats them as the indirect benefits of a health intervention. These indirect benefits are added to any direct savings in health resource consumption (the direct benefits) to yield a net value.

In the cost-effectiveness approach, the aim is to measure the efficiency with which an intervention achieves health benefits. The questions addressed in CEA are: 1) What is the most efficient way to achieve a particular health benefit? or 2) Given specified available resources, what intervention strategy offers the greatest gain in health benefit? Answering these questions requires the commensuration of different types of benefits, such as morbidity and mortality, but permits benefits to be measured in their own, nonmonetary terms. A cost-effectiveness approach is more likely than a benefit-cost approach to preserve a sense of intangible health care benefits, which in the latter are typically noted and left unassessed. Although CEA may be more suitable for comparing alternative in-