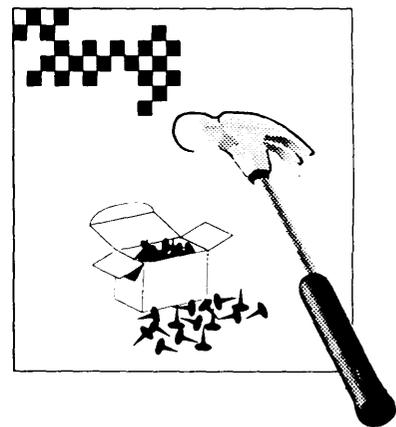


Introduction

Scientific developments often occur alongside changes in the cultural and political environment, and this has certainly been true in recent years for the evaluation of health care technologies. New methods of research and evaluation have been developed, and new adaptations of existing methods are being applied. At the same time, the American health care system has undergone radical changes. The enormous expansion in managed care, the movement of many highly complex and sophisticated medical services into nonhospital settings, and the increasing willingness of physicians and patients to question the effectiveness of common procedures all bear witness to the tumultuous past decade in health care. And along with these changes has come an eager market for information on the value of existing medical technologies and the research methods that can supply this information.

Each of the five background papers contained in this volume describe new methods or new adaptations of existing methods to evaluate which health technologies work best. * These examples by no means describe the universe of changes in evaluative techniques. They do, however, demonstrate the great variety of areas in which methodological developments have been taking place.

The first of the five papers deals with one of the most basic questions in any health research endeavor: how to measure the outcomes associated with whatever is being studied. The devel-



¹ Summaries of these five papers, and a discussion of the methods in the broader policy context of the evaluation of medical technologies, appear in the Office of Technology Assessment report, "Identifying Health Technologies That Work: Searching for Evidence," OTA-H-608 (Washington, DC:U.S. Government Printing Office, September 1994).

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opment of reliable techniques to measure health outcomes through *patients' reports* of how they feel represents not only a new research method but a subtle philosophical shift regarding which outcomes are important to measure.

The second and third of these papers deal with two methods of investigating the question: of two competing medical technologies, which is more effective? Both methods—the *analysis of large administrative databases*, and *large, simple randomized trials*—have been promoted as affordable, generalizable alternatives to the more costly, complex, and limited traditional randomized controlled trial. In fact, these two newly adapted techniques are not really substitutes for each other and fill somewhat different niches. They also differ in the amount of attention they have received by the U.S. research establishment. Large database analysis has gained prominence in the United States, as a method emphasized in the federal government's medical effectiveness initiative. In contrast, large, simple trials are a European development that has many potential applications but has so far seen relatively little use in this country.

Where previous studies of a technology's effectiveness already exist, medical technology assessors must sift through the often obscure and sometimes contradictory literature on the topic. The

fourth background paper in this volume describes the formal technique of *meta-analysis*, which structures a literature review by identifying relevant studies in a systematic, explicit fashion and combining the results quantitatively. Although many topics do not lend themselves to a quantitative meta-analysis, the systematic approach used to identify and evaluate studies is applicable to almost any review of the medical literature.

Along with the health system's new interest in documenting the value of existing medical technologies and practices has come a new, very pragmatic interest in techniques to determine the relative cost-effectiveness of competing technologies. The technique described in the fifth background *paper-clinical-economic trials*—is an increasingly popular method for analyzing a technology's cost-effectiveness early in its life cycle, at the same time that the technology's clinical effectiveness is being tested.

Few of the techniques described in this volume are fundamentally new. All are being applied with a new vigor and new twists, however, in the current drive to evaluate the worth of existing medical interventions. Understanding these techniques—their applications, their strengths, and their limitations—is a worthwhile endeavor for evaluators and policymakers alike.