Health Care Technology Assessment: Implications for Modern Medical Practice.

Part I. Understanding Technology Adoption and Analyses

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Abstract

In the modern era of rapidly rising medical costs, health care technology assessment—multidisciplinary evaluation of clinical and economic aspects of technology—has assumed an increasingly important role in health policy and clinical decision-making. This review examines health care technology adoption, its impact on medical and surgical practice, and recent trends in health care technology assessment. Part I discusses the difficult challenges posed by assessment and provides a guide to the methodologies used.

The cost of providing health care in industrialized nations, particularly the United States, continues to attract the attention of governments, third-party payers, patients, and health care providers. In the United States, health care costs have risen faster than the gross domestic product (GDP) in the majority of years since 1960 and, despite moderation in the mid-1990s, have now returned to inflation rates that outpace GDP growth.[1]

Policy experts and health care researchers have identified numerous factors that may contribute to rising costs, but much analysis over the past several decades has focused on the role of health care technology (HT): the medications, devices, and medical and surgical procedures used in health care, and the organizational and supportive systems within which such care is provided. Although some have argued that the precise contributions of HT to rapidly expanding costs are not clearly defined,[2] nearly every health care management article published over the past 2 decades represents technology acquisition and use as primary drivers of health care costs in the United States. As a result, health care technology assessment (HTA), multidisciplinary evaluation of evidence-based clinical data on efficacy and safety as well as economic aspects of technology acquisition and use,[3-5] has assumed an increasingly important role in the decision making of US health care organizations.[5]

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A Challenge for US Physicians

In a 2004 review article, Heath[6] summarized the practicing physician's perspective on HTA: "In its current incarnation, the processes of HTA … [are] becoming ever more exhaustive and unwieldy, while failing to meet the varied needs of the different stakeholders. However, the potential of HTA to inform decisions by both clinicians and politicians survives." Heath's frustration with HTA is common. HTA remains difficult at theoretical and practical levels, and in the United States little formal infrastructure exists to facilitate collaboration among or commitment by the major players driving technology adoption and use.[5,7-11] These challenges are compounded by the increasingly large amount of HT brought to market each year. Indeed, the task of analyzing HT already in use, the majority of which has not been evaluated to determine related policy and practice implications, is enormous.[12]

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Yet, as Heath[6] and others have noted, HTA continues to hold promise. As new technologies are developed and come to replace old ones, a formal methodology is needed to prevent use of ineffective innovations and to regulate use of those that, though proven effective and safe, are extremely expensive. In the future, such an approach will be necessary to reasonably control costs while sustaining high standards of care.[4,5]

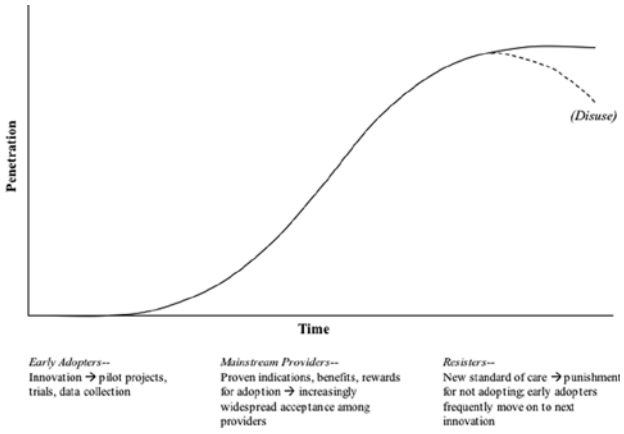

Figure 1. The S-curve model of health technology adoption.

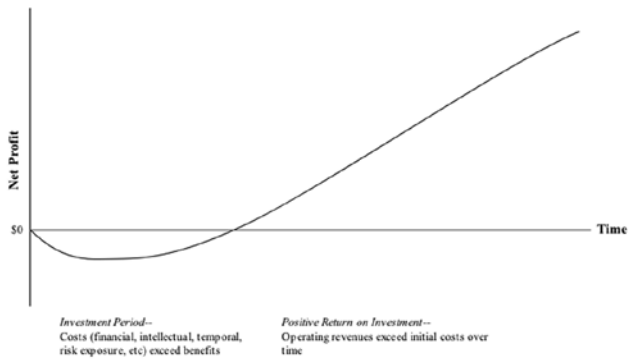

Figure 2. The J-curve model of technology profitability.

This need does not mesh well with the traditional perspective of US physicians. Professional values demand that everything possible be done for patients,[13] who come to their providers expecting the best possible care regardless of cost.[14] Physicians therefore have a moral and legal responsibility that does not relate primarily to economic considerations, such as expense to the health care system or cost-effectiveness of tests and therapies.[13]

On the other hand, policymakers and health care organization managers must contend with cost containment in their attempts to maintain patient access to health care. They often attempt to do so through regulatory actions, evidence-based clinical guidelines, peer review processes, and controlled reimbursement methods, many of which increasingly rely on HTA to establish which tests, treatments, and approaches are most effective and affordable.[5,13]

Not surprisingly, tension frequently arises between physicians and other groups that influence technology assessment and utilization. Disagreement occurs in part because physicians, as a group, remain largely unaware of the processes and goals of HTA, and few providers possess the skills needed to participate in assessment, adoption, and diffusion of HT systematically. In this article, we provide an overview of the relationship between US medicine and technology and highlight the relevance of HTA for practicing clinicians, whose daily work depends on adoption and use of health innovations.

Understanding Technology and Its Adoption

In the broadest sense, medical technologies fall into one of 2 categories. The first is embodied innovation, or technology in the form of physical products such as new medications, surgical lasers, and imaging devices. The second is disembodied technology, or innovations in information about how to best manage disease. Examples include novel surgical approaches using preexisting instrumentation, new algorithms for cancer management, and updated guidelines for postoperative care. Unlike embodied innovation, which involves creation of a "thing" that one can hold in one's hand, disembodied innovation is creation of useful knowledge that resides in one's head.

One of the most commonly cited models describing the development, diffusion, and use of medical technologies proposes a 7-step process[15]:

1. Discovery, through research, of new knowledge, and subsequent correlation with existing knowledge.
2. Use of applied research to translate discovery into new technology.
3. Evaluation of the safety and efficacy of a new technology through clinical trials.
4. Demonstration of feasibility for widespread use.
5. Diffusion, beginning with trials and continuing through increasing acceptance into medical practice.
6. Education of the professional and lay communities in use of the new technology.
7. Skillful, balanced, and widespread application of the technology.

The rate at which a new technology moves through such a model from discovery to widespread use has been studied for many innovations, including intensive care units and cardiac pacemakers.[15] If the extent of adoption (penetration) is plotted against time, an S-shaped curve results (Figure 1). Notably, nearly all innovations involve some initial investment of resources and effort that can be recouped only over time. Graphically, this concept may be captured by plotting return on investment (net profit) against time, which gives a J-shaped curve (Figure 2).

Much HTA research assumes close adherence by researchers, physicians, and technology manufacturers to such models. However, medical discovery and innovation are often unpredictable and not methodologically controlled. Thus, using linear algorithms to capture the relationship between technology and medical practice is frequently unrealistic and uninformative. Rather than attempt to refine such models here, we discuss the various influences on the process of HT evaluation and adoption, which may be more useful for practicing clinicians.

HTA Methodology

Numerous clinical and health economics research methodologies have been used in HTA efforts. As with any research-driven field, the usefulness of conclusions is directly proportional to the quality of research methods and inputs.[16]

Basic and clinical sciences often produce knowledge that leads to medical innovation. Additionally, medical research supports HTA through creation of information that answers important practical questions[3]: Does a given technology work? Is it safe? How does it compare with the gold standard? Is it effective and efficacious? Prospective, randomized controlled trials (RCTs) are considered the best source for high-quality answers to these questions. However, for many technologies, such data are unavailable, as RCTs are not feasible because of cost, ethical considerations, inadequate blinding, or sample size requirements. In addition, RCTs often are not required for formal licensing and marketing of an innovation. As a result, many technologies used by providers have no RCT data supporting them.[17]

When RCTs are not possible, observational studies, such as retrospective reviews and cohort studies, can provide important information about innovations. However, these studies (vs RCTs) are usually handicapped by more bias.[18] Clinical databases and registries can also prove useful in generating and evaluating research hypotheses that have not been studied previously.[19] Finally, epidemiologic and surveillance studies are useful in identifying rare adverse effects of a technology.[16]

When studies are small or offer conflicting data, meta-analysis can be helpful, especially in framing policy recommendations and requests for further research. This approach is successful only when high-quality studies exist, and meta-analysis, like other retrospective approaches, provides useful answers only in hindsight, not in real time.[3]

Health economics evaluations provide another tool for assessing the benefits of existing and new medical technologies. Cost-minimization, cost-effectiveness, cost–utility, and cost–benefit analyses all have useful applications.[20] Cost–utility and cost–benefit studies are particularly helpful in comparing relative values of treatments across disciplines, as outcomes are measured in common utility or monetary units[21] (Table). Economic modeling techniques offer a useful alternative to long, complicated, and expensive clinical trials by simulating future outcomes and incorporating complex variables to reveal which parameters seem to produce the most substantial effects. When combined with sensitivity analyses and backed by strong empirical investigations, these techniques may add important depth and breadth to HTA.[18]

Table. Common Health Economic Analyses

Cost-Minimization Analysis

In cost-minimization analysis, various treatment options that produce equal outcomes are selected. Economic evaluation is performed to determine the cost of each approach, thus revealing the least expensive option.[22]

Cost-Effectiveness Analysis

Cost-effectiveness analysis, in a strict sense, is a form of economic evaluation in which outcomes are measured in physical or natural units, such as life-years gained or number of patients treated successfully. No attempt is made to assign a subjective or preference value to the outcomes. Because value of an outcome is not considered, subjective bias is more easily avoided than in cost–benefit or cost–utility analyses. However, the cost-effectiveness approach is not helpful in choosing between 2 options that may produce different outcomes or when outcomes must be measured differently. In addition, statistically significant benefits under this method may or may not represent clinically significant benefits. Finally, there is no attempt to decide if an expenditure returns true value on an investment; the only consideration is whether one expenditure is as good as another (eg, new technology vs current gold standard).[20,22,23]

Cost–Utility Analysis

In cost–utility analysis, different types of outcomes are expressed in terms of a single utility-based unit of measurement. Utility here is used to describe the subjective level of well-being or value that people experience in different states of health. For purposes of comparison, health outcomes are weighted to produce an index, such as quality-adjusted life-years. This approach is useful when alternative treatments or technologies produce different outcomes or when, for instance, longer survival is bought at the expense of reduced quality of life. The main limitation of this approach is that creating an accurately weighted index is exceedingly difficult, as well-being is largely subjective.[20,22,23]

Cost–Benefit Analysis

Cost–benefit analysis examines costs associated with a particular health-care intervention and assigns a monetary value to outcomes. Health consequences are assigned values by asking health care consumers what they would be willing to pay for services that achieve combinations of particular results. The goal of this approach is to determine whether the value of benefits produced exceeds the values of resources consumed in monetary terms.[22] Thus, only cost–benefit analysis addresses whether too much is spent for a given intervention. Although many people consider cost–benefit analysis to be the most sophisticated and theoretically sound form of economic analysis in health care, accurately assigning monetary values to patient outcomes is often difficult.[20] The advantage is that, when effects of a given technology are multiple, or the nature of outcomes is different, cost–benefit analysis is more useful than other approaches.[23]

HTA in its current manifestation, then, is essentially a hybrid of clinical and economic research. Evaluating existing HT should therefore be straightforward: answer questions about efficacy and safety with clinical studies and add information on cost and policy implications by economic methods. In practice, HTA is less simple. Producing high-quality and clear-cut clinical data is difficult, and economic evaluation in health care relies heavily on assumptions about poorly defined quantities, such as the value of living without a given ailment.

Examining emerging technologies is even more difficult, as data cannot be produced instantly, and information relevant to different questions, such as safety, efficacy, and cost, often emerges at different times. Ideally, the right time for assessment of a new technology comes between the demonstration that it is useful and its subsequent widespread application. This would require that cost-effectiveness evaluations and clinical trials measuring safety and efficacy be conducted simultaneously—something seldom done.[14]

Some researchers have therefore called for a more integrated approach to the scientific basis of HTA—one that would require all HT studies to include variables related to costs. However, full-scale economic evaluation adds considerable expense to most clinical trials, and it would not be feasible to perform such analyses on all new technologies. An alternative suggestion is to perform economic assessment only if technologies are either extremely costly to use or likely to be costly in aggregate because of widespread application.[14] Others have argued that HTA in the United States centers too narrowly on efficacy, safety, and costs and that neglect of the social, ethical, and political dimensions in HTA is untenable, given what is known about the nature of HT and its extensive and often unanticipated effects on society.[3,13]

Although rational priority setting and evidence-based medicine—both high priorities in health policy—would benefit tremendously from rigorous HTA that incorporates economic assessment into every clinical or basic science study, analysis will most likely continue in ad hoc rather than systematic ways. Nonetheless, HTA will surely remain in the policy-making toolkit, as demands for critical evaluation and rational use of HT increase.[4,5,13]

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Part II, Decision Making on Technology Adoption, will appear in the February 2007 issue. It presents the factors that drive the technology choices made—by patients, by individual physicians, by provider groups, and by hospital administrators.

The references and the disclosure statement and acknowledgments appear in Part II.