



Economic Evaluation of Medical Technologies

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Abstract

Innovation in medical science is progressing at a rapid pace. As a result, new medical technologies that offer to improve upon or completely replace existing alternatives are continually appearing. These technologies – which include pharmaceuticals, devices, equipment, supplies, medical and surgical procedures, and administrative and support systems – are changing the way medicine can be practiced and delivered, forcing healthcare providers and policymakers to consistently evaluate and adapt to new treatment options. Meanwhile, society is becoming more demanding of new medical technologies. Emerging medical technology, however, has been viewed as a significant factor in increasing the cost of healthcare. The abundance of new medical alternatives, combined with scarcity of resources, has led to priority setting, rationing and the need for more technology management and assessment. Economic evaluation of medical technologies is a system of analysis used to formally compare the costs and consequences of alternative healthcare interventions. EEMT can be used by many healthcare entities, including national policymakers, manufacturers, payers and providers, as a tool to aid in resource allocation decisions. This paper discusses the four current popular methodologies for EEMT (cost-minimization, cost-benefit, cost-effectiveness and cost-utility), and describes the industry environment that has shaped their development.

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“The value of biomedical innovation to the U.S. equals the value of innovation in all other sectors of the American economy combined.”

Mark McClellan, MD PhD, former U.S. FDA Commissioner

More medical technology = more decisions

Since the recent advances in sophisticated technological development tools and the emergence of bioinformatics as a powerful tool to exploit the current proliferation of basic science information, the pace of innovation of medical technologies is poised to begin accelerating. Rational drug design, for example, a computer-based molecular design tool, has greatly shortened product development cycles [1]. Intense competition in the pharmaceuticals market is forcing drug companies to increase the number, quality and specificity of new products, and also the speed with which these are developed [2]. The pending of accelerated product development is even affecting regulatory fields. For example, the United States Food and Drug Administration recently issued a report, “Improving

Innovation in Medical Technology: Beyond 2002,” that explicitly outlines initiatives for shortening the review process in order to accommodate the accelerated development of new medical technologies [3].

Partly due to medical technology, people are enjoying longer, healthier and more productive lives. From 1975 to 2000, for example, life expectancy at birth increased by 7.3 years in Israel [4] and by approximately 4.6 years in the U.S. [5]. Regarding quality of life, the prevalence of disabilities among the elderly in the U.S. decreased by 20% over the past 20 years. Where productivity is concerned, 75% of patients undergoing lumbar fusion surgery in 2003 were able to return to work, whereas only 27% were able to do so in 1990 [6].

It is possible that modern advances in medical technology will fundamentally alter the way medicine is practiced. Pharmacogenomics, for instance, aims to identify the genetic sensitivity of individuals to pharmaceuticals so as to better predict the effectiveness of therapies. This is called “drug response profiling” and promises to greatly improve the quality, safety and specificity of drug products [7]. In addition, elegant technological solutions such as minimally invasive procedures, telemedicine, and drug/device combinations offer to shift the nature of healthcare toward a more home- and self-care model and towards medical (rather than surgical) management [8]. In the spring of 2004, the United States established the Office of the National Coordinator for Health Information Technology to increase the use of information technology throughout the healthcare industry, with the goal of making electronic health records available to most Americans within the next 10 years [9]. Electronic prescribing alone, according to a 2004 study published in the *British Medical Journal*, could save US\$ 29 billion [10].

It is also possible that new medical technologies will address two major growing healthcare industry concerns – an aging population and quality issues. For example, the adoption of new medical technologies could enable accommodation of the growing aging population, since technological advancements in medical technology often result in an expansion of treatment accessibility (dubbed the “treatment expansion effect”). Regarding quality concerns, the eventual widespread implementation of healthcare information systems offers to greatly improve quality by significantly reducing errors [8].

Thus, because new technologies may begin to emerge at a more

EEMT = economic evaluation of medical technologies

rapid rate, and because of the influential nature of some of the more novel technologies, decisions regarding implementation of new medical technology will become more numerous, more complex and perhaps more consequential.

The widening gap between demand and supply

As the number of technological alternatives continues to increase, the demand for these costly technologies is also growing. First and foremost among factors contributing to high demand for medical technology is the demographic shift towards an older population. Though the relationship between aging and overall healthcare utilization is not a clear and direct one, as the elderly population increases so will the incidence of chronic disease, which could ultimately lead to an increased demand for technology.

The increase in medical information accessible to the public is also an influencing factor with respect to demand. Medical information represents the second largest category of information on the Internet [6]. In addition to obtaining medical information from the Internet, patients are increasingly being exposed to direct-to-consumer advertising. Expenditures by the pharmaceutical industry on DTCA tripled to nearly \$2.5 billion from 1996 to 2000 [12]. One study examining the relationship between DTCA and healthcare demand showed that direct marketing had possibly influenced patient demand for omeprazole and ranitidine [13]. Although research results are mixed as to whether DTCA has influenced the use of healthcare resources, it is clear that the expectations and overall level of awareness of the public has increased.

Since the healthcare market does not behave as a traditional supply and demand market, the growing demand remains unchecked. This is the concept of "healthcare market failure." Firstly, the consumer is not a sophisticated buyer, which is a condition required for market forces to work correctly. Instead, it is clinicians who primarily determine the amount and types of technology used [14]. Moreover, payment for this product is not made fully by the consumer or the physician, but rather by a separate entity. This lack of direct accountability allows for over-consumption or possibly even inappropriate use of healthcare resources and medical technologies. As a result, cost-containment efforts such as clinical practice guidelines, physician monitoring, and reimbursement rules have emerged in recent years.

Evidence of the disparity between demand and supply in healthcare can be found in the large amount of remarkable medical technology that is currently not nearly universally provided. For example, cardiac resynchronization heart failure products (also known as physiologic pacemakers), the most rapidly adopted medical device therapy during 2 years ending in October 2003, were accessible to only 1 in 10 indicated patients. Insulin pumps, whose benefits over conventional insulin shots have been firmly supported by scientific evidence, are only used by 20% of the more than 1 million people in the U.S. who are insulin-dependent [6].

While many social, legal, ethical and political factors affect accessibility to new medical technology, economic considerations

are paramount. Although budgets in the healthcare industry grow each year to accommodate a price increase caused by changes in "technology and treatment patterns" [15], no increase in budget allocation can ultimately match the level of demand. The unique tendency of prices of healthcare technology to increase with new advancements is due partly to the fact that markets for new medical technologies, specifically pharmaceuticals, are highly regulated, via long patents, to protect the intellectual property rights of companies that may have invested hundreds of millions of dollars to develop a safe, effective and innovative product [16]. Moreover, due to great recent advances in basic sciences, the medical product development path is becoming increasingly challenging and costly. The higher cost of product development raises the price of those few investigational products that do pass the clinical trial phase [17]. As a new medical technology emerges, the product is thus protected from price competition and the company can charge extremely high prices relative to the cost of production in order to compensate for huge research and development outlays. Illustrating this, an analysis of 25 common brand-name drugs with generic counterparts shows that generic versions cost, on average, as low as approximately 30% of the name brand [18].

The rising cost of healthcare threatens to have a significant negative impact on national economies. In the case where healthcare is at least partially privately funded, as in the U.S., this burden is ultimately borne by employers and employees [19]. In Britain, the costs of deficits in National Health Service funds, caused by providing more services than is affordable, are ultimately borne by creditors and the whole economy [20]. These economic consequences of healthcare spending will likely be a factor in the continued emergence of EEMT, especially if ever-expanding healthcare budgets continue to threaten to usurp resources from other societal sectors.

Four methodologies for EEMT

Economic evaluation is "the comparative analysis of alternative courses of action in terms of their costs and consequences" [21]. Those alternatives that result in the greatest health or monetary gain relative to the resources they consume suggest that they should be given priority. In order for an economic evaluation to be complete, both inputs and outputs should be considered and there must be comparison of two or more competing alternatives. EEMT is useful when a new technology is introduced that competes with an established technology or when two or more competing technologies are introduced into the market simultaneously. An EEMT focuses on the incremental, or marginal, cost of implementing a new technology and the marginal health-related outcomes that result. The four EEMT methodologies are cost-effectiveness analysis, cost-minimization analysis, cost-benefit analysis, and cost-utility analysis. The methodologies differ primarily in the way that the clinical gain is valued [Table 1],

Cost-effectiveness analysis

Cost-effectiveness analysis attempts to identify healthcare interventions that will result in the greatest clinical improvement in health, as measured by a distinct, quantifiable clinical unit, for the

DTCA = direct-to-consumer advertising

Table 1. The four methodologies for economic evaluation of medical technologies

Methodology	Description	Example
Cost-Effectiveness Analysis	Measures health outcomes in discrete clinical units to provide ratio of cost per clinical outcome	~\$7,000 / repeat revascularization avoided
Cost-Minimization Analysis	Compares only costs of alternative interventions. Measuring of benefits not needed because clinical outcomes are deemed equivalent	\$X vs. \$Y for inpatient surgery vs. outpatient surgery for hernia repair
Cost-Benefit Analysis	Costs and benefits both assessed in monetary terms to determine whether there is a net monetary benefit	Cost to benefit ratio of 1:3.7 for neonatal screening of congenital hypothyroidism
Cost-Utility Analysis	Clinical outcome measure expressed as QALY (quality-adjusted life-year)	Range of acceptable cost-effectiveness: 20,000–30,000 pounds sterling per QALY

least cost. Thus, it seeks to compare the productive efficiency of medical technologies. In only the first half of 2004, many cost-effectiveness analyses were published in a wide-ranging number of fields, including, among others, epidemiology, gastroenterology, plastic surgery, neonatal medicine, telemedicine, radiology, infectious diseases, oncology, and genetics. The main advantage of this type of analysis is that, since the health benefit is kept in terms of a quantifiable clinical unit, no valuation or sophisticated survey techniques are required. A disadvantage, however, is that it is limited to comparing only interventions that result in a single common health effect, be it immediate, such as an improved lab value, or ultimate, such as additional life-years gained.

Recently, the Drug-Eluting Stent Task Force issued its final report and recommendations on the new Cypher sirolimus-eluting stent. Included in this report was a formal cost-effectiveness analysis comparing the cost per repeat revascularization of the drug-eluting stent versus other therapies aimed at preventing repeat revascularization. This analysis showed that implantation of drug-eluting stents has a cost-effectiveness ratio of approximately \$7,000 per repeat revascularization avoided. Since several alternative technologies in the U.S. have been adopted and reimbursed that have a cost-effectiveness ratio of less than \$10,000 per repeat revascularization avoided, it was determined that this new medical technology was relatively “economically attractive” from the societal and healthcare system perspective [22].

Cost-minimization analysis

Cost-minimization is a special case of cost-effectiveness analysis in which the clinical outcome of the competing alternatives is deemed to be equal. Thus, the purpose becomes only to identify the least expensive alternative. An example would be whether to perform a given surgery on an inpatient or outpatient basis, assuming that the surgery is equally successful in each case. All costs are measured for each alternative and the least-cost alternative is revealed.

Cost-minimization is the most simple of the four economic analysis methodologies because it only focuses on the costs of each alternative. It does not require an attempt to measure or place a value on the clinical benefits, which can become very complicated and involve many subjective judgments. However, before under-

taking a cost-minimization analysis, it should be carefully considered whether competing health alternatives are in fact equally effective in achieving the desired clinical outcome.

Cost-benefit analysis

Cost-benefit analysis examines inputs and outputs in monetary terms in order to evaluate whether a given intervention is of net positive monetary value. It determines whether the future cost savings due to health gains offset the costs of the treatment. Since health gains are translated into cost consequences and not left in specific clinical terms, cost-benefit allows comparison of treatments for different health conditions. Thus, this methodology can be of

value in public health policy regarding resource allocation. The main methodologic challenge of cost-benefit analysis, however, is in accurately determining the actual cost savings due to health gains.

In 2000, a cost-benefit analysis showed that, while the cost of neonatal screening for congenital hypothyroidism was 129,175 Chinese yuan, the financial benefits, including money saved in treatment, nursing care, special education and loss of income avoided was 468,457 yuan, resulting in a cost-to-benefit ratio of 1:3.7 and clearly supporting the implementation of the screening program [23]. Interestingly, neonatal screening for hypothyroidism and phenylketonuria are considered to be the only post-intrauterine early detection programs that save money.

Cost-utility analysis

It has become recognized that, depending on quality of life, the value, or utility, of additional life-years is not always equal. For example, years lived in a compromised health state hold a lower value than years lived in perfect health. Cost-utility analysis takes cost-effectiveness analysis (specifically, those cost-effectiveness analyses that use additional life-years gained as the clinical outcome measure) one step further by adjusting additional life-years gained for quality of life. QALY, the Quality-Adjusted Life-Year, is the most popular aggregate measure that takes into account both length of life and quality of life in cost-utility studies. A utility factor, for instance ranging on a scale from 0 to 1, is obtained by ranking given health states via surveys. The number of years gained in a given health state due to an intervention, multiplied by its utility factor, results in the total number of QALYs gained.

A major advantage of using QALY as the outcome measure is that it enables comparison among healthcare interventions for a wide variety of health conditions. However, because of the difficult nature in measuring society's utility preferences regarding quality of life, and the large amount of assumption and subjectivity that is required in these studies, QALY is one of the most controversial of the measures involved in economic analysis of medical technologies. For example, economic analyses using QALYs have been

QALY = Quality-Adjusted Life-Year

charged with discriminating against the elderly and the disabled [24]. In addition, there has been considerable debate about whether the preference-based measure of patients or those of the public should be used to obtain utility measures such as the QALY [25]. The literature contains many examples of significant effort at improving and refining both the QALY and the health policy decision processes that use it.

Conclusion

EEMT continues to evolve and improve, building on the momentum of the last decade. There have been a number of methodologic improvements with respect to carrying out EEMT in practice. For example, economic analyses are increasingly being run alongside clinical trials in order to obtain more relevant cost data, though a number of design issues remain [26]. In addition, considerable discussion has ensued regarding whether future health gains should be discounted to reflect time preference, and if so, at what rate [27–30]. Finally, sophisticated statistical methods are being developed to address uncertainty inherent in economic assumptions [31], and systems for modeling transition through health states using decision sciences are also evolving. A more detailed discussion of methodologic processes is outside the scope of this article.

Currently, there is a myriad of public and private agencies engaging in these types of analyses. Although the majority of involved parties today agree that economic considerations are important in today's healthcare decision-making environment [32], implementation of the results of these studies is still quite limited. Thus, while the literature historically has centered on refining the methodologic processes of economic evaluation, today more effort is focused on improving the usability of these studies through improved credibility, standardization and dissemination in order that their potential to improve the efficiency of strained healthcare systems be realized. While EEMT is currently useful in analyzing value, perhaps its greatest asset is its promotion of a more systematic approach for setting priorities and for defining the most important new medical technologies to be adopted by society.

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