



Medical Technology Management: Bridging the Gap between Theory and Practice

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Abstract

New medical technologies that offer to improve upon or completely replace existing ones are continuously appearing. These technologies are forcing healthcare policymakers to consistently evaluate new treatment options. However, emerging medical technology 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 further technology management and assessment. Economic evaluation of medical technologies is a system of analysis within the framework of health technology assessment 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. In this paper we discuss the historical evolution and potential of EEMT, the practical limitations hindering more extensive implementation of these types of studies, current efforts at improvement, and the ethical issues influencing ongoing development. The Medical Technologies Administration in Israel's Ministry of Health is given as an example of an entity that has succeeded in practically implementing EEMT to optimize healthcare resource allocation.

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The cost of comprehensive HTA will be high, but the cost of ignorance is even greater

Dr. Alan Maynard, Professor of Health Economics,
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Rapid increases in health expenditure in the United States in the 1960s and economic problems faced by European economies in the 1970s led to the first efforts to evaluate the benefits and adverse impacts of medical technologies [1]. Initially, there was much debate about the ethics of these types of studies. There was also pressure from medical professionals concerned about impingement on their clinical freedom and from powerful industry groups concerned about profit [2]. However, largely out of necessity, growth in health technology assessment, and economic evaluation of medical technology specifically, have been steady and rapid.

Proliferation was particularly intense in the 1990s, during which

there was a rapid rise in spending on economic evaluation of new healthcare products [3]. Beginning in 1987 with the creation of the Swedish Council on Technology Assessment in Health Care, national technology assessment agencies were established in most European Union countries. The Israeli Center for Technology Assessment in Health Care was created in 1998. In 1993, the International Network for Agencies for Health Technology Assessment was formed and has since grown to include 40 member agencies from 21 countries. In the U.S., meanwhile, rapid growth in HTA activities has occurred in the private sector [4,5].

The inclusion of an economic perspective in the evaluation of health and healthcare has become an increasingly accepted component of health policy and planning. The experience of several countries has shown that cost-effectiveness information can be used with other types of information to aid different policy decisions [6]. Australia was the first country in the world to formally use pharmacoeconomics for the process of drug subsidy. As of 1993, a drug proposed for inclusion in the Australian national formulary must be deemed cost-effective. The use of pharmacoeconomics in the listing decision could be characterized as generally supporting, rather than being pivotal to, the decision [7]. Canada, England and Wales, Scotland, Finland, the Netherlands and Portugal have also begun to introduce official procedures for using economic evidence in selected reimbursement decisions [2]. Systems of this kind are known as "fourth hurdles" to market [3], or "cost-effectiveness hurdles" (safety, efficacy and quality being the first three) because, in effect, they require industry to demonstrate cost-effectiveness before they can successfully launch a new product.

Today, EEMT is used by the World Bank to identify disease control priorities [6] and is implemented regularly to inform coverage decisions at the National Institute for Clinical Excellence in the UK. Medical technology suppliers across the globe have recognized the importance of demonstrating that their technologies are cost-effective relative to other competing technologies. Most large multinational European pharmaceutical companies have created pharmacoeconomics units to analyze and demonstrate cost-effectiveness. Economic evaluation studies are increasingly

EEMT = economic evaluation of medical technologies

HTA = health technology assessment

specified in National Institutes of Health and pharmaceutical company research grants [8].

EEMT and its potential

The majority of cost-effectiveness analysis studies to date have focused on technical efficiency and productive efficiency questions. Technical efficiency assesses whether a given output can be achieved by using less of one input while holding all other inputs constant. An example of this is a lower dosage of the same medication producing the same health outcome. The concept of productive efficiency refers to the maximization of health outcome for a given cost, or the minimization of cost for a given outcome. This is a comparison between different interventions for the same health condition. For instance, if a new technology is less or equally costly compared to an existing technology and the health outcomes are equal to or better than those of the existing technology, then the new technology is considered to be productively efficient in relation to the current intervention. Productive efficiency enables assessment of the relative value for money of competing interventions with directly comparable outcomes. Economic evaluation applications thus attempt to focus on local and marginal improvements.

The term allocative efficiency, on the other hand, takes into account not only the productive efficiency with which healthcare resources are used to produce health outcomes, but also the efficiency with which these outcomes are distributed among the community. Thus, allocative efficiency addresses the issue of achieving the right mixture of healthcare programs to maximize the welfare of society [9]. By definition, addressing issues of allocative efficiency in health requires a sectoral approach to evaluation. By sectoral CEA, we mean that all alternative uses of resources are evaluated in a single exercise. Only a few applications of this broader use of CEA can be found. Examples include the World Bank Health Sector Priorities Review project, the Oregon Health Plan, the Harvard Life Saving Project, and the WHO-CHOICE (Choosing Interventions that are Cost-Effective) [6].

Increased implementation of technology analysis holds great potential to improve the quality and effectiveness of healthcare systems. It was previously estimated that the U.S. Congress's Center for Health Technology produces approximately \$200 in savings for every \$1 spent on health technology assessment [10]. EEMT in technology assessment can inform many important policy issues, including budget determination for public health interventions, the optimal balance between private and public funding or between primary and secondary care, optimal healthcare treatment strategies (prevention vs. treatment), priority-setting and the creation of appropriate incentives and reimbursements [2]. In a recent survey, entitled EUROMET, which studied the impact of EEMT on European healthcare decision makers and their attitudes towards EEMT, about 75% of the respondents stated that economic considerations should influence clinical practice at least to some extent [11].

Limitations

In another recent survey, less than half the information users reported that they use formal benefit/cost results [12]. Anecdotal evidence, expert opinion and clinical trial data still dominate much of resource allocation [2]. If there is such widespread consensus that EEMT is important and that the healthcare environment will increasingly require improvements in efficiency, what are the factors limiting the practical influence of EEMT? A review of the literature indicates several concerns affecting the extent of implementation of EEMT study results. Credibility and validity of studies, for example, has been challenged due to concern regarding significant methodologic inconsistencies and shortcomings [6]. In fact, there is still much ambiguity as to which costs and benefits should be included in analysis. Furthermore, it is not yet understood how these input and output measures, if agreed upon, should be best valued. The following methodologic issues remain at least partially unresolved:

- Variability in the large number of assumptions made in economic studies [11] depending on the study perspective
- How to accurately measure direct healthcare costs (whether prices, charges, or reimbursement rates of medical products accurately capture opportunity cost of healthcare interventions). It was recently argued that the true cost of a new technology, in today's restricted environment, is more accurately represented by the value that is forfeited by diverting funds from other healthcare programs [13].
- All estimates of costs and effects are subject to uncertainty. Parameter uncertainty arises due to sample variation around estimates of variables used to calculate a cost-effectiveness ratio. Uncertainty also arises due to disagreement on value judgments required for the analysis (e.g., quantifying health outcomes).
- Insufficient availability of cost data. There is concern that using past clinical trials to obtain cost data is insufficient because the statistical power of these trials is usually set in terms of health outcomes, not costs. In addition, there are significant design issues with regard to running economic analyses alongside clinical trials (such as aligning study perspective, hypothesis testing, sample size estimation, and data collection) [14]. There is also significant concern as to whether economic results extrapolated from clinical trial data can actually apply in real settings [11].
- Discord over whether to discount future health benefits, and if so, at what rate [15–17].
- Timing issues. An economic analysis is often not completed until the product has moved through several development stages, thus rendering the data inaccurate or at best outdated. Illustrating the difficult nature of creating accurate studies in such a timely manner, an appraisal by the National Institute of Clinical Excellence of interferon-beta and other multiple sclerosis drugs that was commissioned in August 1999 was not concluded until 2002 because it required additional modeling [18]. Survey respondents in a 2001/2002 study examining the use of formal economic analyses indicated timeliness as an important factor and that "economic outcomes were rarely available when needed for decision-making" [12].
- Sponsorship bias, as in clinical trials.

CEA = cost-effective analysis

Compounding credibility and validity issues is the fact that decision-makers often have difficulty interpreting research reports. These reports are often studies presented in a format that is inaccessible to them, largely due to their lack of background in health economics [11,19]. A very low percentage of respondents in the EUROMET study had undergone any sort of training in health economics.

Another important factor influencing implementation of EEMT study results is institutional ability to implement findings. The number one barrier cited by decision-makers in the EUROMET survey was "difficulty in moving resources from one sector budget to another."

Even if a study is deemed to be thorough and credible, and a decision-maker is sophisticated and flexible enough to understand and respond to the results, the question remains whether there is appropriate alignment of incentives. In the case of the clinician-patient relationship, for example, the best interest of the patient supercedes societal or economic concerns. Another example of lack of incentive alignment is observable when it comes to preventive care, which can sometimes be the most cost-effective strategy, though it often does not provide benefits until far into the future. Hospital decisions are constricted by shorter-term budget issues. Managed care organizations in the United States are not keen on investing in preventive services because their patient population is constantly changing, and thus the organization never sees the direct future benefits of its investment [20]. This is most likely a universal problem of insurers and healthcare plans. High level healthcare policymakers and legislators are probably the only parties aligned properly with societal concerns. Even so, they can be largely influenced by powerful lobbies and manufacturers. This is a most pressing incentive problem that the medical society should work to prevent.

Linkage between researchers and decision-makers must also improve in order for EEMT to have a more practical influence in healthcare decision-making. An example of the importance of linkage was a 1995 analysis of technology assessment in eight industrialized countries, which showed that technology assessment studies have little or no effect on policy making in the U.S. and France, two countries that have a "limited policy structure for technology management" [21].

Finally, cultural preferences, such as demand for unlimited availability of new technologies and reluctance towards limitations, could play a significant role, especially in the U.S. [22,23], as can little attention given to developing active dissemination strategies and wide variation in evaluation activity in different countries and regions.

Efforts at improvement

Many trends indicate an effort to improve the credibility and level of implementation of EEMT studies. For example, generalized CEA has been developed to meet a number of limitations in the implementation of sectoral CEA discussed above. One of the desired characteristics for sectoral CEA is that it be presented in a way that can be translated across settings to the maximum extent possible so that the results can benefit as many decision-makers as

possible. The approach of generalized CEA, proposed by the WHO Guide to Cost-Effectiveness Analysis, seeks to provide analysts with a method of assessing whether the current mix of interventions is efficient, as well as whether a proposed new technology is appropriate. It also seeks to maximize the generalizability of results across settings. Generalized CEA proposes the evaluation of interventions against the alternative of "doing nothing," thereby providing decision-makers with information on what could be achieved if they could start again to build the health system. This specific feature is not addressed in traditional CEA, which typically evaluates new interventions as compared to the current mix and thus leads to "intervention mix-constrained CEA." Thus generalized CEA can be categorized as a different, more fundamental, type of economic analysis [24].

Although there are many inherent challenges to international comparison, or generalizability, in health technology assessment (including country-specific variations in health risks, use of services, medical practices, resources and personal valuations of health) [13], the push towards international collaboration is very apparent. Factors contributing to this include globalization of the market for medical technologies, a significant amount of duplication of effort (seven European countries have commissioned research to inform policy choices in prostate cancer) [2], and historically slow dissemination of study findings. The WHO-CHOICE project attempts to enable comparison of cost-effectiveness of health interventions across different countries and health systems [6]. The U.S. and Britain are collaborating in health technology assessment through the Commonwealth Fund and the Nuffield Trust, respectively, to identify outmoded, unjustified or underutilized technologies and to jointly engage in horizon scanning [25]. The European Commission recently supported three projects intended to improve international collaboration in medical technology assessment. These were EUR-ASSESS in 1994 (focusing on dissemination, harmonization, priority-setting and linkage); HTA-Europe in 1997 (emerging technologies, internationally coordinated assessments, outcome measures, role of HTA); and the European Collaboration for Assessment of Health Interventions and Technology in 2000 (prevention and health promotion activities, systems for routine exchange of information, identification of possible joint assessments, best practices, HTA education and support networks, linkage) [26].

As international standardization efforts continue, improvement in methodology and usability also continues. For example, Britain's National Health Service's Delivering and Organization program systematically examines issues that obstruct the translation of evidence into practice, including developing 'receptor capacity'. Receptor capacity is the availability of individuals in the policy-making and end-user communities who are capable of understanding information produced by health service researchers [27]. Regarding quality concerns, there has been a call for improvement in the peer review process [28,29]. More sophisticated statistical methods are being developed to address inherent uncertainty in economic assumptions [30]. In order to improve data accuracy and to address timing issues, economic studies are increasingly being run alongside clinical trials, and cost data are being gathered at

earlier stages of product development [3]. Increased transparency should likely address bias concerns. Finally, the role and capacity of governmental agencies, especially in Europe, seems likely to expand [26], thus strengthening linkage among researchers and decision-makers.

Ethics

Ethical considerations are perhaps the most complex and influential in the ongoing development of EEMT. Firstly, it has been argued that it is simply unethical to take costs into account in clinical decision-making or to attempt to value human life/health in monetary terms. For example, economic analyses using wage as a measure to value productivity costs have been charged with "productivity ageism," or discrimination based on the social stature of the patient [31]. Also, clinical guidelines based partly on economic factors have been criticized as impinging upon the clinical autonomy of physicians.

The Quality-Adjusted Life Year, in particular, has been the most controversial and ethically debatable measure. For example, since older people or those with shortened life expectancy will have shorter duration of health benefit due to a given treatment, health interventions for the elderly produce fewer QALYs. Economic analyses using QALYs have thus been charged with "ageism" [31]. The QALY was also criticized for discriminating against those who are disabled or have a diminished capacity to benefit, since their potential numerical health improvement due to treatment is similarly limited [33].

Despite the ethical criticism, healthcare budget constraints have made economic evaluation unavoidable. It has become apparent that in an environment with fixed resources, allocation to one patient means taking away from another. Because of this concept of opportunity cost, it may be unethical not to consider economic factors in medical decisions, and a physician exercising his clinical freedom for the benefit of one patient may actually be less ethically grounded than community-appointed healthcare policy makers who take into account the entire system of patients [34].

Currently, the debate has shifted to whether the values of patients or those of the public should be used to obtain utility measures such as the QALY. Studies have shown a large discrepancy between the values of patients and the public with regard to measuring quality of life [35]. More importantly, however, it is becoming apparent, based on empirical evidence, that the very concept of basing healthcare policy decisions entirely on the concept of maximization of health gains may be out of line with society's inherent moral preferences for healthcare distribution. This is the debate of "justice vs. efficiency," begun in the mid-1990s [31]. Otherwise stated, the very idea that we should allocate our resources based solely on efficiency and health maximization is being challenged. Rather, society may be willing to sacrifice efficiency to accommodate other circumstantial factors. Studies have empirically shown that society deems the following factors, currently not fully accounted for within economic analysis, to be important in distributive decisions:

- Age – favoring the young over the elderly
- Social role – favoring patients with dependants or other social responsibilities
- Lifestyle and prior consumption of healthcare resources – favoring patients who are ill through no fault of their own
- Potential to benefit – equal preference to patients with or without disabilities in allocation of life-saving technologies
- Initial severity of illness – preferences for those who are "worst-off"
- Rule of rescue – general aversion to denying help to those in the face of death
- Distributional preferences – evidence that the public favors keeping some resources for groups who are disfavored by prioritization due to a "maintenance of hope" concept [36] and a preference for general distribution of health gain as opposed to more concentrated distribution to specific cohorts.

Because EEMT has shifted the medical decision-making process away from a physician-based, individually tailored approach towards a more society-oriented approach based on the collective good, it has become more important to incorporate society's moral preferences into policy-making. Some have advocated adding transparent, deliberative democratic processes to cost-effectiveness analysis results [37]. Others have called for increased reliance on market forces. Still others have advocated attempting to quantitatively integrate social values into the QALY framework, examples being Cost Value Analysis, rank-dependent utility theory and other equity-adjusting methods. As expected, the field of empiric ethics, which attempts to quantify society's moral preferences, may rise in importance.

In a March 2003 survey on the handling of ethical issues among members of the International Network for Agencies for Health Technology Assessment, 80% regarded ethical issues as an integral part of assessments. Whether it is decided that ethical analysis be undertaken by separate ethics committee, or included directly in economic analysis, it is clear that ethics will continue to play a critical role in shaping the ongoing development of economic analysis.

Conclusion

It is likely that knowledge of the impact of economic assessment on decision-making will increase in the near future, especially considering the increased government funding of technology assessment [30]. As the methodologies of the studies are refined and harmonized, their credibility solidified and their implementation improved, EEMT has the potential to become a legitimate and powerful tool in informing healthcare resource allocation policy decisions.

As the methodologies for EEMT continue to evolve, however, their initial purpose should not be forgotten – namely, to identify, among competing healthcare alternatives, those that result in the greatest clinical effectiveness relative to the cost. There is no doubt that, theoretically, capturing societal values in economic analyses is very desirable, such as those regarding ethics, non-health benefits and equity. The question remains, however, whether doing so is possible, and if so, practical in today's health policy environments

QALY = Quality-Adjusted Life Year

with the attendant time and resource constraints. Would healthcare systems be better served by implementing formal, standardized methods of economic analyses that minimize assumptions and subjectivity? In this scenario, EEMT would become a solid, credible and valuable tool to be used as one component of a much more comprehensive and complex healthcare decision. After all, medicine, by its nature, has always been as much of an art as it is a science.

Israel is one example of a country that has bridged the gap between theory and practice by pro-actively integrating rational technology management and assessment into its health policy framework. In the unique, systematic Israeli model, the Medical Technologies Administration of the Ministry of Health assesses and prioritizes the candidate health technologies for inclusion, presenting their appraisals to a public committee appointed by the Minister of Health. This process evolved on the platform of evidence-based medicine, scrutinizing measures of safety, efficacy and effectiveness, and elaborating on needs assessment. The scope of the methodology encompasses medical, epidemiologic, ethical, social, legal, political and economic perspectives [38]. The success of this model of formalized technology assessment is support for our belief that, above all, medical technology should be managed logically – combining a systematic and scientific process with skillful judgment.

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