Health Technology Assessment

Evaluation of Biomedical Innovative Technologies

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This article describes health technology assessment (HTA) as an evaluation tool that applies systematic methods of inquiry to the generation and use of health technologies and new products. The focus of this article is on the contributions of HTA to the management of the new product development effort in the biomedical organization. Critical success factors (CSFs) are listed, and their role in assessing success is defined and explained. One of the conclusions of this article is that HTA is a powerful tool for managers in the biomedical sector, allowing them to better manage their innovation effort in their continuing struggle for competitiveness and survival.

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Innovation in Biomedical Technologies: Definitions and Classifications

In the last few years, breakthroughs in the health-care sector have yielded many advances that improved medical delivery, patient access, and health outcomes. Technological innovations have produced remarkable results. New procedures, equipment, and processes, including new medical and surgical procedures (e.g., angioplasty and joint replacements), drugs (e.g., biologic agents), medical devices [e.g., computed tomography (CT) scanners and implantable defibrillators], and new support systems (e.g., electronic medical records and telemedicine) by which medical care is now delivered, have heralded a new era for health-care provision.

Biomedical engineering and its resulting technological innovations have played a very important role in these developments. It is generally defined as the use of principles and techniques of engineering to solve problems in biology and medicine [1]. As such, biomedical engineering provides tools and the means to improve health-care delivery in both diagnosis and treatment of diseases. These tools include instrumentation, medical imaging, and medical devices such as cardiac pacemakers, artificial limbs, artificial vision, devices for the hearing impaired, and dialysis instrumentation.

The term biomedical technology is usually meant to include engineering and various sciences such as biology, mechanical engineering, and materials science. The terms biotechnology and medical devices have blurred boundaries. There are many health-care products that are the result of various disciplines. The complexity of the health-care delivery system requires the use of multiple engineering and sciences to arrive at useful

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products and processes in the diagnosis and therapeutic aspects of treating patients. "Health (Biomedical) Technology" shows the categories of the biomedical technology universe.

Biomedical technologies can be classified by the type of technology or its function in the delivery of health care. Figure 1 shows the four levels with diagnostics and therapeutics as the main categories.

These technologies yield medical devices and instruments that are used in a broad range of medical procedures: from prevention to screening, diagnosis, treatment, and rehabilitation. Because these devices and instruments become more ubiquitous and more effective in clinical use, their importance as key contributors to medical care tends to increase. The fusion of technology and medical science thus produces significant innovations that greatly contribute to human health and to the quality of life of the population.

Medical robotics is an illustration of a key technology with far-reaching contributions to vastly improved clinical care. There are six products and systems in medical robotics that are predicted to experience rapid development in the near future. First, smart medical capsules are used largely as diagnostics of tumors and other internal abnormalities. Second, intelligent prosthetics with smart functionalities that rely on information technologies will replace the current prosthetics. Third, robotized patient monitoring systems will be used in both hospitals and home care. Other technologies are robotized motor coordination analysis and therapy and robot-assisted mental and cognitive therapy targeted at elderly patients. The last technology, perhaps the most promising, is robotized surgery.

These technological developments exemplify the current and future successful applications of biomedical engineering research and development. Almost every aspect of medical care will soon be dramatically changed because of products and systems generated by biomedical engineers and the biomedical and biotechnology industries. The practice of medicine increasingly relies on technologies that monitor the human body with advanced imaging, interact with patients, conduct diagnoses, and assist in the provision of treatments. The future of medical care is anchored in the flow of technological innovations.

The Cost of Health-Care Technological Innovations

The particularly rapid development in health technologies has increased the health-care expenditures. In the last decade, the biomedical industry has been the fastest growing sector of the U.S. economy, and new medical technologies have been one of the drivers for the rise in health-care costs. Since 1970, in the United States, health-care spending has grown at an average annual rate of 9.8%, about 2.5% points faster than the economy, as measured by the nominal gross domestic product (GDP). Annual spending on health care increased from US$75 billion in 1970 to US$2.2 trillion in 2007, and it is estimated to reach US$4.3 trillion in 2018. As a share of the economy, health care has more than doubled over the past 35 years, rising from 7.2% of GDP in 1970 to 16.2% of GDP in 2007, and

Health (Biomedical) Technology

Technology is the practical application of knowledge. Broad categories of health technology (2) include the following:

- *Drugs*: e.g., aspirin, beta-blockers, and antibiotics.
- *Biologics*: e.g., vaccines, blood products, and cellular and gene therapies.
- *Devices, Equipment, and Supplies*: e.g., cardiac pacemakers, CT scanners, surgical gloves, and diagnostic test kits.
- *Medical and Surgical Procedures*: e.g., psychotherapy, coronary angiography, and gall bladder removal.
- *Support Systems*: e.g., electronic patient record systems, telemedicine systems, drug formularies, and blood banks.
- *Organizational and Managerial Systems*: e.g., prospective payment using diagnosis-related groups, alternative health-care delivery configurations, and clinical pathways.

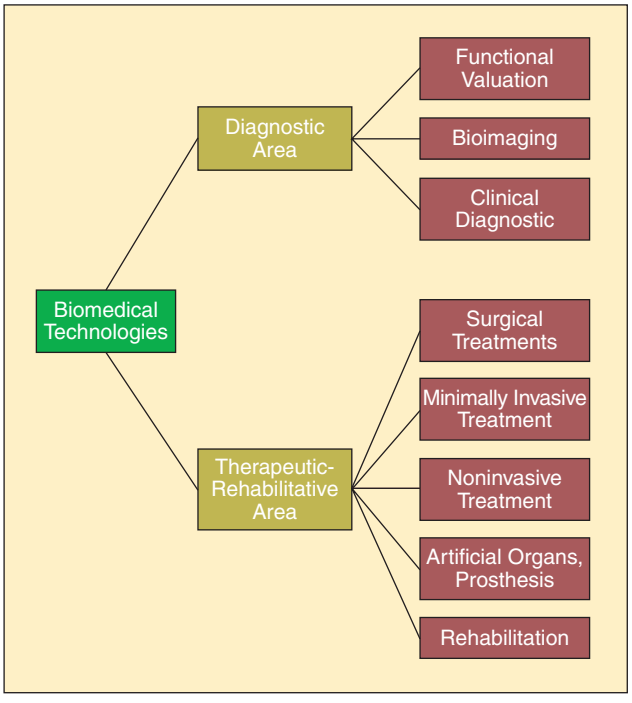

Fig. 1. Classification of biomedical technologies.

it is projected to be 20.3% of GDP in 2018. Health-care spending per capita increased from US$356 in 1970 to US$7,421 in 2007, and it is projected to rise to US$13,100 in 2018 [3].

There are several reasons why new medical technologies are so expensive. First, most new medical products and systems contain added functions and contribute to improvements in quality, safety, and clinical performance. These technologies are developed by complex processes of testing and approval by regulatory bodies. Thus, the costs of development and adoption of these technologies by clinical providers are high. The more ubiquitous these technologies are in clinical practice, the more the providers will spend to acquire them and utilize them in the pursuit of improved quality, safety, and performance of care.

A growing body of literature has shown that even when some technological innovations have contributed to reduced costs of certain health-care providers, this is the exception, not the rule. In an aggregate, a positive correlation exists between the adoption of new medical technologies and increased overall health-care costs. The main reason for this relationship seems to be the impact of new technologies on the level of demand for health-care services and procedures.

As new medical technologies (such as imaging, minimally invasive surgeries, and transplantations) are widely used and adopted, the results are improved clinical outcomes, reduced mortality and morbidity rates, and the corresponding increase in life expectancy. More patients live longer and are thus treated for age-related and expensive illnesses such as diabetes, cancers, and cardiac and respiratory diseases [4].

Ginsburg [5] reviewed the literature in search of the factors that drive the cost of health-care delivery. He concluded that medical technology is a more powerful driver of costs than administrative costs or the growth of personal income. Table 1 shows the various cost drivers identified by Ginsburg.

In a previous study, Geisler and Heller [6] concluded that, among the cost drivers of health-care delivery such as hospital expenditures or physicians' incomes, medical technology accounts for about 18% of the rise in the cost of the delivery of care.

Table 1. A comparative study on cost drivers.

Studies Estimating Contributions of Selected Drivers			
Drivers of Cost Trend	**Smith et al. (25)**	**Cutler (26)**	**Newhouse (27)**
Aging of the population	2%	2%	2%[a]
Changes in third-party payment	10	13	10[b]
Personal income growth	11–18	5	<23
Prices in the health-care service	11–22	19	*
Administrative costs	3–10	13	*
Defensive medicine and supplier-induced demand	0	*	0
Technology-related changes in medical practice	36–62	49	>65

Notes: Amounts in the table represent the estimated percentage share of long-term growth that each factor accounts for.
[a]Represents data for 1950–1987.
[b]Represents data for 1960–1980.
*Not estimated.
Source: Congressional Budget Office, 2008 based on Smith et al., Cutler, and Newhouse.

The increasing level of health-care costs—partly driven by medical technologies—could lead to economic unsustainability of the health-care delivery system and therefore to the rationing of care and cuts in expenditures and investments in the system. In this forthcoming scenario, there will be growing pressures to develop and adopt medical technologies that are more cost effective. The focus will be increasingly on the appropriate use of technologies in clinical practice and in the administration of health-care delivery organizations [7].

Therefore, the role of screening and evaluation of medical technologies will become a crucial component of the decision process to acquire, implement, and adopt these technologies. HTA will become the mechanism by which the resources will be allocated by health-care decision makers to future medical technologies [8].

HTA: Needs, Origins, and Its Role in Health-Care Delivery

In recent years, there has been an increasing demand for a better understanding of the processes by which medical technologies are marketed, regulated, paid for, and utilized [9], [10]. This demand comes from every constituent of health-care delivery system. Makers of medical devices, clinicians, hospital administrators, payers, and regulators are all supporting the effort to gather more information about the performance of medical technologies. This has led to the generation of HTA field of research and adoption by health-care organizations.

HTA had emerged from technology assessment (TA) as a discipline that aims to establish clinical, economic, and managerial/behavioral methods to assess the alternatives offered by medical technologies for new diagnostics and therapeutic opportunities [7]. Coates and Jarratt [11] defined TA as a category of policy studies, aimed at supplying policy makers with the information they need to make good decisions. Banta and Luce [12] added the notion of providing decision makers with policy alternatives.

When TA is applied in health-care policy and management, the definition of this evaluative tool becomes more specific to medicine. The Institute of Medicine [9] offered the following definition of HTA: to denote any process of examining and reporting properties of a medical technology used in health care, such as safety, efficacy, feasibility, and indications for use, cost, and cost effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended.

A Framework of HTA

On the basis of the review of literature, we propose three criteria for HTA and four methods to evaluate these technologies. The criteria for this evaluation are as follows:

1) What is the nature of health technology?
2) What is the function of health technology?
3) What are the inherent attributes or characteristics of health technology?

The classification of the nature of health technologies is composed of the following:

1) systems and general hardware, equipment, and instruments
2) software and other embedded knowledge in these systems
3) procedures, standards, norms, benchmarks, and other workflows

The biomedical industry has been the fastest growing sector of the U.S. economy, and the new medical technologies have been one of the drivers for the rise in health-care costs.

4) items related to or embedded in people: skills, personal knowledge, and personal experience.

The criteria of the function of technology include items on what the technology aims to achieve:

1) goals and objectives of the individual or unit employing the technology and answering the following questions:
   - Do we really need the technology?
   - How can the technology help to meet our goals and objectives?
   - Can the technology help to improve clinical quality, diagnostics, therapeutics, safety, performance, cost savings, and prestige?
2) engendering innovation
3) replacing outdated technology.

The criteria of the inherent attributes of the technology include the following characteristics:

1) degree of newness: evolutionary versus revolutionary
2) degree of complexity: simple versus complex
3) ease of installation, adoption, adaptation, and utilization
4) need for complementary resources for implementation and adoption/utilization
5) ease of integration into existing technologies and organizations
6) economics/cost of purchase, adoption, implementation, updating, and replacement
7) degree of impacts/outputs and contributions
8) degree of competitiveness and ability to protect against competition
9) degree of uniqueness and level of difficulty in imitation or substitution by another technology.

The methods we propose are as follows:

1) *Economic and Financial Evaluation*: This method consists of the analysis and assessment of the economic impacts of the technology on the health-care delivery organization. The method utilizes techniques such as return on investment (ROI), return on assets, contributions to revenue, and the trends in the costs of technology. To accomplish this analysis, we need data on investments/expenditures on the technology and economic outputs of the organization. Investments include the cost of the technology and costs for setup, training, adaptation and peripheral equipment, and maintenance and updating (Figure 2).
2) *Organizational and Structural Evaluation*: This method consists of the analysis and assessment of the implementation of technologies in the health-care delivery organization. The analysis includes structural factors acting as barriers and facilitators to implementation such as degrees of decentralization, formalization, bureaucratization, and interdepartmental rivalries. Other factors assessed in this method include the CSFs the organization employs to evaluate the technology it acquires and implements.
3) *Managerial and Behavioral Evaluation*: This method considers the adoption and adaptation of the technology, including the resistance to change exhibited by the clinical and administrative staffs. Other factors in this method include the level of managerial support for the technology and the perceived impacts of the technology by stakeholders.
4) *Technical Evaluation*: This method includes the analysis and assessment of factors such as quality and standards of use. Other factors in this evaluation are barriers and facilitators to the use of technology. Examples are ease of operation, integration with existing technologies and systems, ease of maintenance, and connectivity.

This framework of criteria and methods allows for a comprehensive evaluation of the key stages in the process of acquiring, implementing, and adopting health technologies. The breadth of assessments criteria and methods thus engenders a solid basis for inputs to decisions by health policy makers.

The Role of HTA in Health-Care Delivery

In addition to providing inputs to health policy makers, the role of HTA is to facilitate the appropriate introduction and use of new health technologies [13], [14]. HTA contributes to the encouragement and sustainability of medical innovations, because it provides evidence of the generation of positive outcomes from these innovations and the justification for the investments made in medical technologies research and development.

HTA is a structural analysis of health technology and is predicated on the functions of knowledge generation and

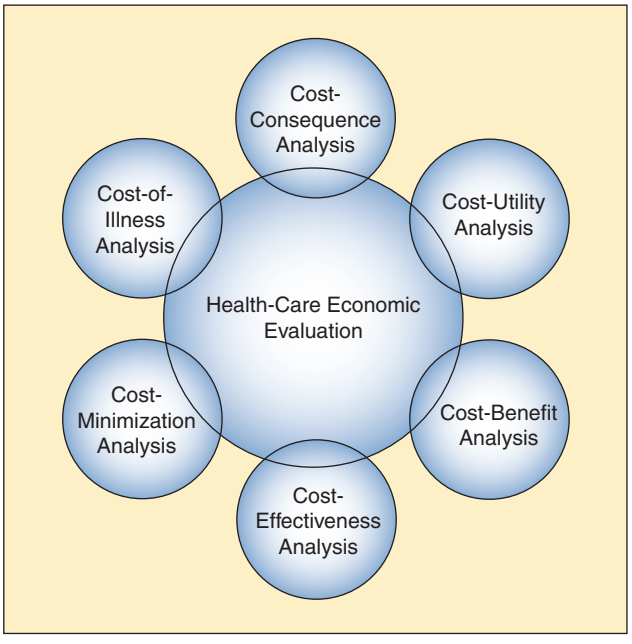

Fig. 2. Some approaches to economic evaluation of health technologies.

knowledge. These functions create a platform upon which health policy makers can make judgments based on evidence.

The knowledge-generation functions of HTA may include the following:

- identifying evidence or lack of evidence on the benefits and costs of health-care interventions
- synthesizing health research findings about the effectiveness of different health interventions
- evaluating the economic implications and analyzing cost and cost effectiveness
- appraising social and ethical implications of the diffusion and use of health technologies as well as their organizational implications.

The knowledge utilization functions of HTA may include the following:

- dissemination of information to policy makers, providers, and patients
- facilitating practice change through various policy instruments
- researching service, organization, and development structures, and their effects on the behavior of providers
- tracking, monitoring, and policing of knowledge use.

Health technologies have to be assessed from the developmental stage to the final stage, and they are different depending on the technology as follows:

- *new*: sometimes in a conceptual stage or in the earliest stages of development, more often over the clinical investigation but not yet in a routine use
- *emerging*: in the applied research stage, about the time of initial clinical investigation, i.e., experimental, like in the case of robot-assisted surgery
- *consolidated*: already diffused into general use and considered by providers and patientlike standard approaches
- *obsolete*: replaceable by another technology and/or nearly ineffective or harmful.

Often, these stages are not clearly delineated. Many technologies undergo multiple incremental innovations after their initial acceptance into general practice [8], [15]. A technology that was once considered obsolete may return to consolidated use for a better-defined or entirely different clinical purpose. A prominent example is thalidomide, whose use as a sedative during pregnancy was halted more than 40 years ago when it was found to induce severe fetal malformation, but which is now used to treat such conditions as leprosy, advanced multiple myeloma, and certain complications of human immunodeficiency virus (HIV) infections [16].

The Biomedical Product Development Process

The biomedical product development process is shown in Figure 3. This process, which generates biomedical innovations, is more complex than the innovation continuum in other industries [2].

The main reasons for the complexity of this process include the presence of multiple interested parties, the interface of several scientific disciplines, the need for coordination between technology and clinical use, and the strong ethical implications of innovations.

Every stage in this process is subject to a different combination of these factors and to the pressures from different constituencies and stakeholders. The regulatory involvement starts very early in the life of the biomedical process. This creates an even greater need for continuous analysis and data generation by means of evaluation and audits.

In this process, there is an accentuated need for feedback and exchanges between the various stages. Results from clinical trials, for example, are critical to previous stages, before the process continues toward commercialization and ultimate clinical use. This interdependency among stages is much stronger than in other industries—such as chemicals or consumer products—because of the sensitivity of each stage to external factors of regulatory, social, ethical, and medical constraints.

HTA in Biomedical Product Innovation

HTA in the biomedical innovation process has a dual role. First, it generates evaluations for each phase of the process as well as comprehensive assessment of the product development continuum. By doing so, HTA creates content for the continuing feedback given to managers throughout the process. Such content is the knowledge the managers need to make reasoned decisions on whether to continue the development process and what needs to be corrected at each phase.

Second, HTA serves as a gatekeeper for the new product development process. The knowledge produced by HTA provides inputs at each phase for decisions on the success or failure of each phase of the process. As shown in Figure 3, HTA generates an assessment of a very complex and multidisciplinary flow of phases. The road from concept to prototype and then to trial and commercialization includes a variety of disciplines and skills so that the degrees of specialization and disciplinary zeal tend to obfuscate a proper internal evaluation. The need arises for an effective assessment by an external perspective [13], [17]–[19].

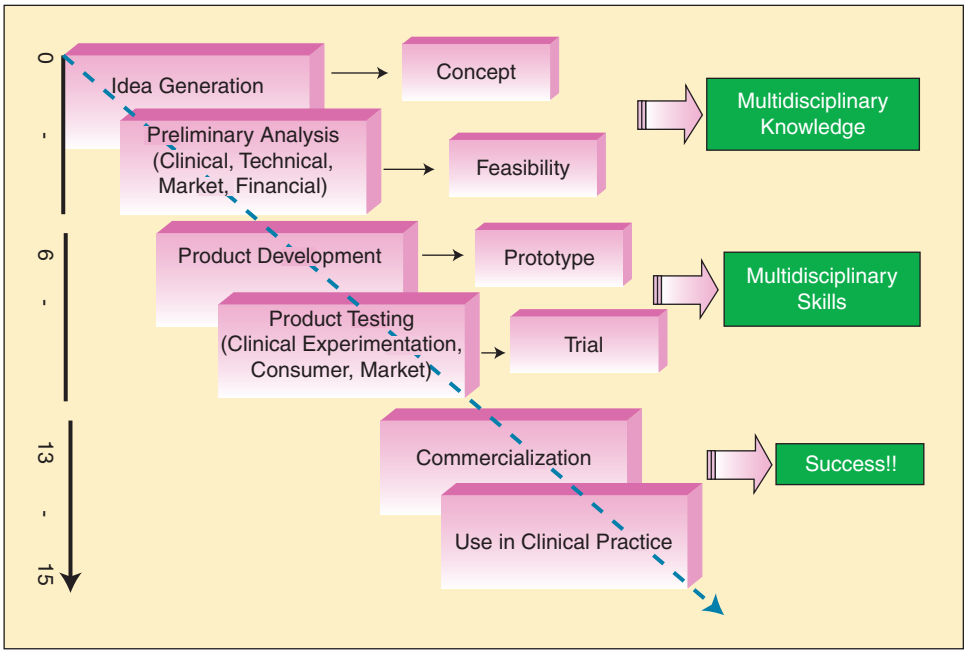

Fig. 3. Biomedical product development process.

The long-standing experience and scholarship in the evaluation of new product development in a variety of industrial settings allow for much desired lessons for the biomedical context of new product development. The flow of phases from idea generation to commercialization and utilization has been extensively studied [20], [21]. The differences between other sectors and the biomedical industry are in the added complexity of the process and its scientific content as well as in the downstream applications in medical practice. This latter distinction generates a special case in the utilization of the new product because of the highly regulated aspect of the industry and the Web of interfaces and interdependencies of each new product with existing frameworks, products, and systems in clinical use [6], [7], [10], [22].

Table 2. CSFs of the biomedical product development process.

CSFs	Illustrative Indicators
Economic factors	• ROI • Cost-effectiveness analysis • Cost-benefit analysis
Organizational factors	• Contribution to the R&D portfolio of the organization • Organizational/structural barriers to the process • Enhanced organizational competitiveness • Ratio of successful projects
Technology factors	• Ease of use • Ease of integration in the product • Newness of the technology
Marketing factors	• Attractiveness to potential users • Degree of competitiveness • Ease of market penetration and potential/actual sales
Innovation factors	• Newness of the approach • Newness of the product • Comparison with similar innovation
Clinical factors	• Contributions to clinical use and applications: quality, safety, efficacy, etc. • Integration with existing clinical practices

What and How We Evaluate in the Biomedical New Product Development Process

Consistent with the proven methodologies of industrial new product development processes, the focus of the evaluation in the biomedical sector is on the process itself, the outcomes from the process, and the CSFs. The key element of the evaluation is the technology being developed. The four methods discussed in "HTA: Needs, Origins, and Its Role in Health-Care Delivery" section are aimed at the assessment of innovative aspects of the new product being developed.

In the process itself, evaluation aims at the development of the technology from the idea to the final product that can be commercialized and utilized. The evaluation elicits the value being created for the organization as the process moves downstream, with the final product being the innovative product in which the technology is now embedded [23]. Since this process in the biomedical sector is similar to any other new product development process, the methods used in this sector need not be totally tailored to the biomedical industry. Rather, adjustments can be made to accommodate the unique characteristics of the biomedical new product development framework.

The outcomes from the process are another focus of the evaluation. These are the measurable results from each phase of the process. As the prototype is developed, the evaluation follows its betterment and changes in its functionality and utility until the new product enters the phase of commercialization. HTA is designed to elicit knowledge about the ways in which these outcomes have met the expectations of the new product developers and the medical community. The evaluation also assesses the degree to which the technology embedded in the new product has contributed to the innovativeness of the biomedical product.

The results from the phases of commercialization and utilization are of primary importance. These outcomes provide a justification for the process (if successful) and offer a mechanism to compare the new product and its technology with other products developed by the organization as well as by competitors [1], [2], [7], [14]. The ability to compare the new product with similar products in the market offers policy and decision makers in the biomedical industry a valuable managerial and marketing tool for the discharge of their fiduciary and organizational responsibilities.

Finally, the CSFs are a set of factors used by managers to determine whether a project, process, or unit have been successful. These factors are the building blocks of the evaluation effort. They are generated by the HTA as milestones and objectives of the successful completion of each phase and the success of the entire process. Table 2 shows the various CSFs and some of their indicators in the biomedical sector.

The set of six categories of CSFs and their diverse indicators can be used as components in the assessment of the success of the biomedical new product development process. In the application of HTA, the choice of factors and indicators depends on the policies of the organization and the preferences of its managers. This choice is also strongly influenced by the market conditions under which the biomedical organization operates and the pressures imposed upon it by the highly competitive nature of its environment. The need to produce biomedical innovations within a given time frame tends to generate undue constraints on the biomedical organizations. There emerges a rush to innovate, thus, to vigorously attempt to maintain a competitive stance in the market and to survive [17], [23].

The implementation of HTA within the biomedical sector greatly contributes to the sound management of these organizations. Executive decisions can be consistently based on hard data and cogent analytical schemes. Unlike other industrial models for the assessment of new technologies, HTA provides the much-needed link between biomedical processes and health-care delivery.

Conclusions

In the present global climate of concerns about the funding of health-care delivery and the harsh limits imposed on public

and private budgets, there is a strong need to find appropriate uses for health-care resources. Technology and innovations in medicine are a crucial component of the rationalization of health-care resources and the incessant effort to improve the quality, accessibility, and affordability of care.

In this scenario, HTA is an essential tool for the support of decision makers at the levels of health policy strategy and operations. For the biomedical sector, HTA offers a unique instrument that allows for an evaluation of process and outcomes, leading to improved effectiveness of the biomedical new product development process and to better positioning and competitiveness of biomedical organizations.

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