

ASSESSING MEDICAL TECHNOLOGIES IN DEVELOPMENT

A New Paradigm of Medical Technology Assessment

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Abstract

Objective: Our study aims to provide a practical contribution to the field of medical technology assessment within a new paradigm. This paradigm indicates the need for more comprehensive technology assessments in the development stage of a new technology.

Method: We introduce a method, based on Saaty's Analytic Hierarchy Process, which quantitatively supports discussions between the various actors that shape the technology's development and diffusion. These discussions focus on technical, medical, social, and economical requirements relevant to the design and diffusion of the new technology.

Discussion: In contrast to more traditional technology assessments, our method encompasses the perspectives of the diverse actors in the social context of technology development and diffusion. It influences their decision making on technology design and diffusion in order to improve this technology's later clinical as well as social effectiveness.

Keywords: Healthcare technology assessment, Interinstitutional relations, Equipment design, Decision support techniques

Medical technology assessment (MTA), as it has been developed in the past 15 years,¹ can be divided in two broad categories: assessments of the efficacy of medical technologies and assessments of the adequacy of medical technologies in practice. Efficacy relates to the effects of a technology on clinical outcomes. Adequacy, however, is conceived in different terms. Economic studies consider adequacy in terms of cost-effectiveness or cost utility (9). Studies focusing on the fit between the implementation of medical technologies and medical indications conceive it as appropriateness (6). Other studies relate adequacy to a range of other aspects of the implementation of medical technologies, such as ethical, social, and organizational aspects.

Assessments focused on the adequacy of a technology are generally based on a more versatile range of aspects than the efficacy studies. However, this adequacy is commonly determined when the technology is in an advanced stage of diffusion. At this time, the efficacy of the technology is shown, and the technology is often already well accepted in the medical profession. Consequently, conform to the Collingridge dilemma, the results of the adequacy studies may exert only a limited influence on clinical and policy decisions (7).

In this research note we propose that additional technology assessments should take place in the developmental process of medical technologies before clinical diffusion, and should address more aspects than the efficacy studies do. We developed an adequate approach to support a versatile assessment of a new technology in its development stage. Such

a notion is within the province of constructive technology assessment (CTA). Instead of influencing policy making in health care, CTA attempts to influence the development and diffusion of a new technology (15). This influence is based on technical, medical, social, and economical information provided by the diverse actors that shape development and diffusion.

LIMITATIONS OF THE TRADITIONAL PARADIGM OF TECHNOLOGY ASSESSMENT

As with all technology assessments, MTA can be considered a multifaceted field of science. Different aspects of medical technologies, including medical and surgical interventions, are studied using different disciplinary perspectives. Nevertheless, the basic paradigm from which medical technology is assessed is surprisingly similar. Koch (11) discusses two assumptions of this paradigm:

The paradigm assumes that the scientific and technical content of a medical device is developed in a social and policy vacuum and that social factors only enter the equation at the stage of diffusion. Moreover, it assumes that the diffusion stage of a medical technology is the appropriate place to assess the social factors that play a role in the adoption of medical technologies. (11)

Based on these assumptions, medical technologies are considered to be the “inevitable and inescapable” (5) result of the application of scientific research. This linear model of the innovation process presumes a socially unproblematic technical development process, resulting in new products that can be diffused. Accordingly, there are only two moments relevant to perform technology assessments. The first moment is at the final stage of the developmental process. Only when a prototype is developed is it relevant to assess its efficacy. The second moment is after the diffusion of the technology has started. At that time it is relevant to assess the adequacy of the technology in its context. Technology assessments applied in earlier stages of the developmental process of medical technologies become predictive studies, e.g., early warning systems of emerging medical technologies (see the Special Section of the Fall 1998 issue of this journal).

This linear model of the innovation process has been criticized from three different points of view. First, the social constructivist approach within the sociology of technology (4) conceives technology as an inherently social phenomenon. To adequately represent technological development, it is necessary to include the “seamless web” of social relationships around the technology. In line with this argument, Blume (5) showed for the case of diagnostic imaging instruments that one should pay attention to the social attributes of the specialty of radiology to adequately represent the way in which new imaging instruments, such as computed tomography and magnetic resonance imaging, were developed and introduced. Hence, a technology assessment that ignores such social relationships misrepresents the eventual consequences of the emerging technology.

A second line of criticism focuses on the distinction between the developmental and diffusion stages of technologies. Especially within the field of innovation management (12), empirical research regarding the attributes of innovation processes shows that technologies are still changing during the diffusion stage. Consequently, the implementation of a new technology should be taken as an integral part of the innovation process. In the case of medical technologies, this involves, for instance, the gradual involvement of other indications for which the technology, such as in vitro fertilization in the Netherlands, is being put to use.

A third line of criticism can be formulated from the perspective of evolutionary economics. In their argument, the development of technologies is determined by path-dependent

trajectories (8). These trajectories can be conceived as frames of references indicating the nature of the change to be expected. For example, the development of mainframe computing toward increasingly larger sizes in the 1940s and 1950s was reversed by the subsequent trajectory of developing microcomputing. If such trajectories influence the nature of emerging technologies, they should be taken into account in the assessment of the consequences of the technology.

These lines of criticism help explain limitations in the implementation of the results of MTA in healthcare decision making. Methods of MTA that establish the technologies' efficacy or effectiveness prior to diffusion do not capture the dimensions, including the social relationships around the technology and its technological context. MTAs incorporating a broader range of factors are generally conducted only in an advanced stage of diffusion. At that time, the technology is embedded in its social context and may have found some influential proponents of the technology who consider the initial results to be promising. Resistance to reconsidering the established practices is most likely to hamper the perceived value of the cost-effectiveness studies by the assessment's audiences and, consequently, the implementation of the assessment's conclusions.

TOWARD A NEW PARADIGM OF TECHNOLOGY ASSESSMENT

Considering the limitations of the traditional paradigm of technology assessment, it seems necessary to supplement this paradigm of MTA with a new one. This new paradigm takes into account that decision making on medical technologies, both in the developmental and the diffusion stages, involves technical as well as social choices. These decisions are made by different types of actors and at different levels of decision making. It is only by assessing the interaction of all these decisions that the consequences of the technology can be adequately assessed.

This view harmonizes with the notion of CTA, which takes the dynamics of technological development and social change into account. By assessing a technology in its development stage, a comprehensive range of dimensions, including social factors that influence the eventual consequences of the application of a technology, can be incorporated. CTA asserts that the properties of technology can be assessed and subsequently directed by means of interactions between technology producers, users, and third actors such as governments, unions, and pressure groups. These interactions support decision making in technology development and application.

Existing methods of CTA include technology-forcing programs, platforms, consensus development conferences, social experiments, and dialogue workshops (15). To actually effect changes in development and diffusion, the practices of CTA would benefit from some adjustments. In general, these methods of CTA have been applied at a national macrolevel distant from technology development. Therefore, there has been limited feedback to the technological developers and the outcomes have had little impetus (15). Moreover, technological actors affected by the outcomes often contested the credibility of the outcomes.

It has been suggested that a method for CTA applied close to the technological development activities can overcome these problems (16). If the actors of the technological developments as well as actors within the future user contexts of the technologies themselves would derive an assessment of the technology, technological changes are more likely to occur. In particular, dialogue workshops could offer such an opportunity.

However, current problems of dialogue workshops relate to the perceived value of their outcomes by the affected actors. In dialogue workshops in which actors with diverging backgrounds participate, the actors involved often have contrasting opinions about the relevance of the criteria for technology development. Such divergent perspectives often hinder technological change (13). In addition, the discussions generally focus on the future

social, cultural, and technical context of the technology. This creates awareness by the actors about relevant issues that could concern technology development. Nevertheless, it does not provide practical solutions for technology improvement. These factors impede the perceived value of the assessment by the audiences. In our view, by paying explicit attention to consensus formation and aiming at providing practical guidelines for technology development and diffusion, a method of CTA that can integrate a diverse range of dimensions could effect changes that are more far-reaching than the traditional technology assessments.

A NEW APPROACH OF CONSTRUCTIVE TECHNOLOGY ASSESSMENT

Appropriateness studies, such as the RAND studies, focus on the appropriateness of the use of medical technologies. This approach can, in our view, be extended to include aspects of the development of the technology as well. The appropriateness studies then become a form of CTA; not only decision making on the use of the technology is then at stake, but also the decision making on the development of the technology. To support decision making adequately, the assessment needs to take account of the technical design options, the needs and requirements of the envisaged users, and the social context of the technology in development that affects the emerging technology's eventual consequences (10).

To identify and assess the broad range of requirements posed upon the technology, an expert panel needs diverse actors conducting technology development and diffusion. The team version of Saaty's Analytic Hierarchy Process (AHP) can be used to support the assessment by such an expert panel. This multi-attribute utility technique supports decision-making dialogues with logical foundations (14). These logical foundations concern the quantitative comparison of alternatives, which in the case of technology assessment could be a new technology and alternative technologies. As opposed to more traditional techniques, it can account for both quantitative and nonquantitative impacts, and can integrate them into a single overall score for ranking alternatives. It provides the various actors with a means to reduce the complexity resulting from the heterogeneous requirements facing the emerging technology, as well as from the diverging perspectives of the actors.

AHP structures a complex decision into a hierarchy of factors. An appropriate structure could consist of four hierarchical levels, including the goal, requirements, sub-requirements, and alternative technologies. Weighting factors, reflecting the importance of the sub-requirements and the preferences for the alternatives, are computed based on pairwise comparisons of sets of two subrequirements or alternatives. The relative importance or the preferences are appointed on a 9-point ordinal scale, in which 1 reflects equal importance or preference and 9 is extreme importance or preference. In addition, AHP provides a measure of inconsistency to ensure that each pairwise comparison is consistent with the remainder of the comparisons. When the AHP supports a group of decision makers, it aggregates the individual pairwise comparisons by computing a geometric group average. Moreover, the geometric variance measures how much an individual's sets of judgments differentiate within the group. Accordingly, it supports the discussion to focus on topics that are subject to the highest disagreements. It aids the processes of learning, debating, and revising one's priorities. This creates a dialogue in order to reach consensus among the various judgments representing diverse experience.

The team version of AHP seems to offer a scientific sound approach to integrate requirements of each nature into the assessment. Since the approach is based on experts' estimations instead of clinical results, the technology can be assessed for applications based on a broad set of medical indications. To facilitate the implementation of the results of the assessment, this approach aims to evoke results that are relevant at the level of the technological activities and that reflect the judgments of the accompanying actors. We have affirmed the

actualization of these prospects by three case studies involving the assessment of a new transarterial blood pump, a voice-producing prosthesis, and a liver-perfusion pump.²

DISCUSSION

Constructive technology assessment attempts to provide a broad analysis of a technology in its development stage. Its results are to be integrated into the processes of development and diffusion of the new technology. Thus, in contrast to traditional technology assessments that consider the properties of a technology as given, our approach can extend its influence by evoking changes in the properties of the technology. Moreover, its potential influence is multifaceted due to the possible use of a broad range of requirements. The AHP provides a logical foundation to quantitatively integrate the various requirements involving medical, technical, social, and economical aspects. Consequently, the assessment can take account of the technical design options, the needs and requirements of the envisaged users, and the social context of the technology that affects this technology's later consequences.

One of the basic problems of traditional as well as constructive technology assessment is an unsatisfactory value of the outcomes as perceived by the actors that are affected by these outcomes. Not surprisingly, one can observe problems regarding the policy implementation of, for example, cost-effectiveness studies. One of the present authors found discrepancies between the outcomes of cost-effectiveness studies regarding liver transplantation, heart transplantation, and in vitro fertilization in the Netherlands and the subsequent use of these studies in the policy process (17). Our method for CTA attempts to overcome this obstacle by directly involving the actors concerned with the development and diffusion of the technology. Its explicit focus on consensus formation instigates these actors to broaden their perspectives and to remove sources of misunderstanding. The accordingly facilitated integration of the perspectives enhances the actors' perceived value of the assessment outcomes and thus commitment to the implementation of the outcomes. This promotes the actors to attune their decision making on development and diffusion to improving the technology's later clinical and social effectiveness.

Our approach provides a practical contribution to the field of MTA within the new paradigm. The hierarchic structure of the AHP allows the incorporation of all requirements affecting the effectiveness of the technology into the assessment. The subsequent systematic comparison of the effectiveness of the new technology with alternative technologies gives clear guidelines for improvement of the design or diffusion of the technology in development. The quantification of the comparisons involved helps the actors to deliberate on trade-offs between the heterogeneous requirements. In our view, the approach can be applied to a high variety of medical technologies due to the wide applicability of the AHP. As a supplement to traditional technology assessments, it can support decision making during technology development based on a more comprehensive set of requirements.

NOTES

¹ See the overviews of the development of healthcare technology assessments (1;2;3).

² Requests for copies of the papers elaborating these results should be sent to J. M. Hummel (e-mail: J.M.Hummel@bdk.rug.nl).

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