Supporting medical technology development with the analytic hierarchy process

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Methods of medical technology assessment (MTA), including the efficacy and adequacy studies, try to influence clinical practice at the time the technology under assessment has already been introduced into the clinical market (e.g. Banta and Luce, 1993, chapter 2). In contrast to this approach, methods of constructive technology assessment (CTA) attempt to influence clinical practice by steering the development process of medical technologies or products before they have been clinically introduced. This thesis developed a method of CTA to influence decision making about the development and application of a medical technology. During the development stage of the technology, it directly involves the diverse decision-makers that shape the development and application processes. Supported by the analytic hierarchy process (AHP), these actors systematically discuss the pursued and/or attained quality of the medical technology or product relative to a competing one with regard to technical, medical, social, and economical product requirements. Based on the outcomes of these discussions, guidelines are derived to optimise the quality of the technology. The adequacy of this method of CTA is related to the fit of the timing of its application with the dynamics of technological change, the information used in the assessment, the consensus formation about, and the quality of the assessment outcomes.

Successful technology or product development is a dynamic process of mutual adaptive activities between the development team and groups that belong to the environment, including users, external technological researchers, manufacturers, and competitors. Chapter 3 shows that communication between these groups to steer technological change is essential during the start-up, roughly around the temporal midpoint and during the completion stage of a development project. During the start-up of a project, when a core development team has been formed to transform a product idea into a valid product concept, these discussions are essential to new product success. We showed in chapter 3 that development teams in this stage of their project need to match their objectives and planning with the requirements the diverse groups pose upon the new product and with the attainable knowledge, skills and
resources. At this stage, a relative high level of uncertainty exists concerning the user needs, competitive reactions, technological solutions, and the required knowledge, skills and resources. The theory in chapter 3 about radical product development, an extreme example of product development in conditions of high uncertainty, indicates that clear new product objectives are essential even if market and technological information is scarce. Nonetheless, defining new product objectives often does not receive enough systematic attention. Poor new product objectives have become one of the main factors leading to new product failure (e.g. Gupta and Wilemon, 1990, chapter 5). Chapter 5 elaborates an application of our method of CTA in the start-up stage of the development of a liver preservation system. The definition of the pursued quality of the medical technology in comparison with a competing technology represents the new product objectives. In addition, the critical areas of research and the need for additional knowledge, skills and resources were identified to reduce the main market and technological uncertainties. The new product development team was satisfied with the quality of the objectives and the planning, and committed to the implementation.

Chapter 3 indicates that when the team has resolved the main market and technological uncertainties, feels the need for progress, and has enough time to make significant changes in the design of the product, reconsidering the new product objectives and planning can yield ideas for significant design improvements. However, particularly when the project members are affiliated to different organizations, the design activities are often inadequately steered and aligned (e.g. Bruce et al, 1995, chapter 6). This failure may result in products with little market value, withdrawal by one of the partners, increased lead-times and costs. Chapter 6 elaborates a CTA to steer and align the design activities focused on the development of a voice-producing prosthesis, conducted around the temporal midpoint of the development process. This assessment centres on the comparison between the quality of a competing prototype, the attained quality of the team's prototype, and the pursued quality of this prototype. Subsequently, it focused on the determination of the design modifications and the accompanying design activities to bridge the difference between the attained and the pursued quality of the voice-producing prosthesis. The new product development team of the voice-producing prosthesis was satisfied with the quality of the outcomes, and committed to the implementation of the design modifications.

Gersick’s model of new product development described in chapter 3 indicates that an approaching deadline of a project often results in a final burst of activities. Nevertheless, the finally realised quality of the prototype of a medical product or technology is of critical
importance for a successful introduction into the clinical market (e.g. Rochford and Rudelius, 1992, chapter 7). Chapter 7 reports a CTA of a medical heart pump in the completing stage of its development. The prototype of this heart pump was compared to two heart-assisting devices commonly applied in medical practice. The assessment panel was satisfied with the quality of the outcomes of this assessment. These outcomes steered the concluding activities of this development project. The activities focused on the final modifications of the prototype to improve its safety and ease of use, and the determination of the appropriate medical indications for application of the heart pump.

The information discussed during these CTAs is relevant to successful new product development and application. Such as described in chapter 6, a key factor to new product success is to deliver a product that is of higher quality than its competitors in the market. By assessing the quality of the product under development relative to the quality of its most threatening competitor, this competitive aim is explicitly taken into consideration during the technology’s development and application. Moreover, involving the patients, clinicians, technological developers, and manufacturers in the assessment can evoke innovative ideas to improve the quality of the product. Another success factor is to have sufficient managerial, technological and marketing skills and resources. This factor is important to consider in project selection, but during project execution as well. As shown in chapter 3, in technological networks the pool of available skills and resources as well as the need for skills and resources is dynamical. At relevant points of time, the CTAs provide a means to convince the partners with the appropriate skills and resources of the value of their involvement in the development activities. Finally, the assessments of the products’ quality provide the essential foundation to effectively and efficiently plan the development activities.

The CTAs incorporated information about the products’ quality related to a comprehensive range of product requirements. These requirements incorporate the interests of clinicians, patients, technological developers, and manufacturers. Roughly, these requirements were related to the product’s or technology’s safety, function, user friendliness, clinical applicability, and costs. In each of these applications, safety was regarded as the most important consideration, to be followed by the main function of the device. However, the remaining factors are important to take into account as well. For example, the quality of the liver perfusion system is pursued to differ most extensively from its competitor concerning its ease of use. Furthermore, the factors combined provide more comprehensive information about the consequences of design choices. It shows for example that the technical design of
the heart pump that accounts for a relative high pump performance also evokes the pump's low score on ease of use. Furthermore, the design of the voice-producing prosthesis is pursued to minimise the required investments of the manufacturer. Safeguarding this interest of manufacturing is relevant in maintaining industry as a partner in the project. Therefore, a CTA needs to go beyond the technology or product's safety and function, the prime factors of analysis in efficacy studies.

The commercially available group decision support system Team Expert Choice supported the CTAs. This system incorporates the mathematical procedures of the AHP. As described in chapter 5, the AHP seems to be the most suitable technique for multi-criteria decision analysis to quantitatively support the discussions concerned with a CTA regarding the heterogeneous range of product requirements. As described most extensively in chapter 5, they step by step supported the group members to engage in discussions that created awareness of the advantages and disadvantages of the technology under development. The scale, the prioritisation technique, and the group aggregation technique of the AHP are, however, subjected to some criticism as described in chapter 4 and 5. Its imperfections to some extent affect the outcomes concerning the inconsistency ratios, the priorities, and even the rank order of the alternatives. Nonetheless, the AHP provides an overview of the main inconsistencies in the group members’ judgements, and the serious differences in the relevance of the product requirements and the accompanying qualities of the alternatives. This overview is valuable for gaining insight in the attained and pursued quality of the product and the relevant activities to engage in the project. Instead of replacing decision making, the AHP supports the process of making well-deliberated decisions.

The panel members claimed to be satisfied with the support by Team Expert Choice. Chapter 8 indicates that the cognitive influences by Team Expert Choice enhanced the common perspective on the information factors relevant to assess, which included all relevant product requirements. It improved the efficiency and rationality of assessing these factors, the mutual understanding of the group members’ perspectives, and the synergy in the information-sharing processes concerning these factors. The strongest social influences enhanced the drive to contribute, the openness to learning, and the constructive resolution of conflicts. Resultantly, Team Expert Choice convincingly improved the quality of the outcomes of the assessment, and the group members’ satisfaction with the group processes. As suggested by our pilot applications of the AHP in multidisciplinary groups described in chapter 4, its support is relevant for panels concerned with CTA. The cognitive and social
effects helps them to deal with the different perspectives, complementary information, and conflicting judgements the panel members are likely to have due to their diverging professional backgrounds, expertises and interests.

During the CTAs, the panel members need to integrate their information about the context that defines the problem to be solved by the technology, and the performance of possible technological solutions (Clark, 1985, chapter 5). In medical technology development, communication between physicians and technological engineers is pivotal. The physicians often possess in-depth knowledge about the problem to be solved by the technology, as well as the performance of existing technological solutions, while the engineers are more knowledgeable about new technological solutions. However, information sharing is often limited between group members that have a high degree of unshared information and perceive the same information differently. In the majority of the topics discussed in our CTAs, information was shared between the subgroup of physicians and of engineers. As shown in the Euclidean distance models, these discussions evoked both subgroups to revise their judgements. The information-sharing performance is likely to have been enhanced by the multidisciplinary composition of the product development teams. By including members with medical and technical backgrounds in the team, initially more information and perspectives are shared between the team and the external physicians and engineers. For example, the Euclidean distance model of the liver perfusion project shows that the team member with a medical background affiliated at the university the least diverges in judgement from the technological engineers and external physicians. Since the composition of the assessment panel influences the outcomes, it needs to be a well-balanced representation of the groups with relevant, state-of the art knowledge that influence the technological development processes and clinical application.

Mutual understanding of the remaining differences in judgements and forming a critical degree of consensus in this heterogeneous panel is essential for its continuing group and task commitment (Gear et al, 1999, chapter 5). Discussions in the panel may even emphasize some differences in judgements. In our applications however, the discussions resulted in hardly any significant differences between the priorities of the product requirements and quality of the products as assigned by the technological engineering and user group. In overall, each panel significantly reduced disagreements and claimed to be satisfied with the attained degree of consensus. One needs to be aware that groups may reduce differences in given judgements through social pressure instead of persuasive arguments. In
our application no indications were found that social barriers or manipulation by the group members hindered the CTAs. Moreover, the commitment of the panel members to the implementation of the outcomes indicates that at least a critical degree of consensus has been formed.

In general, our method of CTA appears to be an adequate method to influence technological development and clinical application. In contrast to the adequacy studies, the timing of the applications of our method was attuned to the dynamics of technological change. In the recommended periods of time, not only the various actors that shape technological development and application feel more inclined to discuss technological change, these discussions are then critical to successful technological development and clinical application as well. In contrast to the efficacy studies, our method supported the actors to evaluate the quality of a technology based on a more comprehensive set of criteria. Our method inspired the actors to share information about their versatile perspectives on the quality of the technology. By means of the mathematical methodology of the AHP, this information was used to build a quantitative overview of the quality of the new technology. As is often lacking in applications of other methods of CTA, the actors were satisfied with the degree of consensus they attained about the outcomes, and the quality of these outcomes. These outcomes actually guided their decisions to make technological changes to enhance the quality of the technology.

The potential influence of our method of CTA on clinical practice can be illustrated by two new product failures. The first example deals with the Boneloc bone cement as used in total hip replacement. A mantle of bone cement is used to fixate the cup of the hip prosthesis to the hipbone. Boneloc was associated with a poor fixation of the cups (e.g. Ensing et al, forthcoming) and was withdrawn from clinical use in 1995. It had been developed in pursue of having better chemical properties than conventional bone cements. Nevertheless, its inferior performance was mainly caused by its mechanical properties (Thanner et al, 1995). Criticism was uttered that information that was or could have been obtained in laboratory tests had not been adequately applied in making a correct analysis of its overall quality before clinical introduction (Gebuhr et al, 2000). Our method of CTA provides a means to discuss the information related to diverse disciplines such as chemistry and mechanical engineering. It provides a methodology to analyse the various effects of the properties of the new product on its quality. Such a comprehensive assessment of Boneloc’s quality might have led to the decision not to clinically introduce this product as it was designed. This would have prevented
the patients’ sufferings and the high financial expenses involved with the revision operations of the hip prostheses inserted with Boneloc cement.

A more recent example of a new product failure is the silver-coated version of the St Jude mechanical heart valve. Endocarditis, an infection at the inner side of the heart, is an infrequent but life-threatening complication of cardiac valve replacement. In order to prevent this complication, the cuff of the St Jude heart valve was coated with silver. This element is an agent that reduces bacterial colonisation. The seemingly innocent product modification evoked however serious complications. A data safety monitoring board suspended a large-scale clinical trial (Schaff, 1999) because the silver-coated valves evidenced a higher risk of infection, thrombus formation and leakage between the cuff and heart tissue than those without the coating did. As a result, the worldwide clinical inventory of this type of heart valve was recalled in 2000. Our method, such as applied to the voice-producing prosthesis, can support an evaluation of the various effects of product modifications on the quality of the new product. Such an evaluation does however not imply that the evidenced complications could have been predicted. The experiences with the silver-coated valve might be a cautious tale about the unknown uncertainties involved with technological advances. The value of our method lies in the reduction of uncertainties that can be recognised by the diverse relevant experts, such as in the field of the ion beam-assisted coating technology, the toxicity of the coating, or the bio-adhesion to the coating. Even before clinical introduction, it encourages the integration of their knowledge to create a more in-depth and comprehensive awareness of the effects of a product design and product modifications in order to prevent later clinical failure.

Our method of CTA evaluates the performance of a new product relative to competing products. Still, it can be applied to new products with diverging market positions. Two extremes on a market dimension are an innovative new product that solves a new problem, and a new product that offers incremental improvements to existing solutions to a problem. Without adaptations it is not suitable to assess the extreme case of an innovative product with no envisaged competitors. However, it proved to be valuable to assess incremental new products in the case of the heart pump, innovative new products of which a competing prototype has been developed in the case of the voice-producing prosthesis, and even an innovative product of which a competing prototype is likely to be developed in the case of the liver-perfusion system. Two extremes on another market dimension are a new product that is pushed into the market by its technological developers, and a new product that is pulled into
the market by its envisaged users. Most new products, however, are a combination of these scenarios. The heart pump has for example relatively more characteristics of a market-push project, and the liver-perfusion project of a market-pull project. Even though information initially is likely to prevail about the technological solutions in a market-push project, and information about user needs in a market-pull project, the design of these products ultimately has to comply with both technological requirements and user needs. Despite the existence of limited information, the development of new products needs guidance from new product objectives that are based on a comprehensive range of product requirements.

Since these assessments focus on a technology or product’s performance to solve a problem and not on the characteristics of specific solutions themselves, this method can compare even radically new solutions with existing ones. Moreover, it can evaluate product ideas, prototypes and completely developed products. During the transformation of a product idea into a new product, information is collected to support the estimations about the relevance of the product requirements, and the quality of the product on these requirements. Therefore, the outcomes of the assessment should not be treated as a rigid representation of the truth, but as the panel’s perceptions and estimations at that specific point of time in the project. As described in this thesis, it is advisable to reassess the product under development when relevant learning experiences have occurred. In addition, changed external circumstances, such as competitive market introductions or technological advancements may call for an iterated CTA.

This thesis provides the first insights in the adequacy of our method of CTA, and the high applicability of this method. It appears to be a valuable addition to the practice of MTA. Due to practical restrictions, these conclusions are based on a few applications. To overcome these restrictions, the predominant part of the studies on the use of group decision support systems such as Team Expert Choice has used small groups of students, ad hoc assembled for the decision-making experiments (Nour and Yen, 1992, chapter 8). In contrast to new product development teams, the rather homogeneous population of students offers practical advantages that allow conducting multiple comparative experiments with control groups. The access to this population is relative inexpensive and easy, and the relative high homogeneity of the subjects and their experimental environment removes an uncontrolled source of variance between the groups that is bound to exist between existing new product development teams. Yet, also within the groups of students the homogeneity is higher than within the groups composed of actors that influence new product development. Moreover, the ad-hoc
assembled groups of students are likely to experience less task and group commitment than the real-life new product development groups do. The distinctive size, homogeneity, task and group commitment of the groups all influence the nature of the decision-making processes and outcomes (chapter 5). Therefore, the validity of the results derived from the students groups to the larger-sized, multidisciplinary, established decision groups in the context of inter-organizational new product development is troublesome. As a first exploration, we consider our three empirical applications to be valuable to study the support of Team Expert Choice to the decision-making processes and outcomes as shaped by the specific group members in their context of inter-organizational product development. Even though all teams of our applications are co-ordinated by the same university, the high diversity in the personal, professional and organizational backgrounds of the members within the teams defies the pitfall that these teams are too similar to be a representative sample of inter-organizational product development teams.

The results about the adequacy of our method of CTA are in favour of evaluating this method in larger-scale studies. This evaluation is recommended to focus on the timing of the consecutive applications, the quality and the influence of the assessment outcomes. One interesting option is to conduct longitudinal, comparative case studies that focus on the technological changes during the technology’s development as well as clinical application. Considering the high variance between product development projects, it is suggestible to increase the number of projects in the analysis and to reduce the variance between these projects. The reduction of variance can be achieved by analysing multiple projects conducted within a particular network of one or more organizations concerned with technological development and a hospital. This experimental design increases the validity of the comparison between the projects that are facilitated by the multiple applications of our method and the un-intervened ones. The appropriateness of the timing of the assessments can be studied by means of the patterns of technological change of the non-facilitated as well as facilitated projects. The quality of the estimation of the technology’s quality of the CTAs can be evaluated by comparing the outcomes of the CTAs with the outcomes of clinical studies of the technology in combination with additional research on the remaining factors that determine the technology’s quality in clinical practice. The quality of the guidelines derived from this estimation can be studied by analysing its fit with the actual technological changes during the development and application of the technology. The influence of the constructive CTAs can be analysed by comparing the technological changes during their development and
application between the facilitated and the non-facilitated projects. In later instance, the external validity of the outcomes of this study could be tested in field studies using multiple organizational networks. These studies can provide the logical foundation for generalizing the value of our method of CTA for healthcare.

References