

University of Groningen

Supporting medical technology development with the analytic hierarchy process

Hummel, Janna Marchien

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version

Publisher's PDF, also known as Version of record

Publication date:

2001

[Link to publication in University of Groningen/UMCG research database](#)

Citation for published version (APA):

Hummel, J. M. (2001). Supporting medical technology development with the analytic hierarchy process s.n.

Copyright

Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

Take-down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): <http://www.rug.nl/research/portal>. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.

**MEDICAL TECHNOLOGY ASSESSMENT: THE USE OF THE
ANALYTIC HIERARCHY PROCESS AS A TOOL FOR
MULTIDISCIPLINARY EVALUATION OF MEDICAL DEVICES**

HUMMEL JM, ROSSUM W VAN, VERKERKE GJ, RAKHORST G

PUBLISHED IN: INTERNATIONAL JOURNAL OF ARTIFICIAL ORGANS 23(11): 782-787 (2000).

© WICHTIG EDITORE. REPRINTED WITH PERMISSION OF THE PUBLISHER.

Most types of medical technology assessments are performed after the technology has been developed. Consequently, they have only minor effects on changes in clinical practice. Our study introduces a new method of constructive medical technology assessment that can change the development and diffusion of a medical device to improve its later effectiveness in clinical practice. The method, based on Saaty's analytic hierarchy process, quantitatively supports discussions between various parties involved in technological development and diffusion. We applied this method in comparing a new blood pump with two competitors based on technical, medical and social requirements. These discussions changed the evaluators' perspectives, reduced disagreements, and ended in a reliable evaluation of the pump's performance. On the basis of these results, adaptations were derived to improve the design and diffusion of the blood pump. This application shows the adequate potential of our method to steer technological development and diffusion of artificial organs.

7.1 Introduction

To support decision-making, medical technology assessment (MTA) evaluates medical technology based on medical efficacy and other aspects, such as economical, social-cultural, legal, ethical and organizational factors. The most common types of MTA are the efficacy and adequacy studies of a medical technology that has finalized its development stage. In efficacy studies a new technology is generally compared with an existing alternative on medical outcomes. A more broadly diffused medical technology is generally examined in adequacy studies of which the cost-effectiveness studies are well known. In these studies the effects of the implementation of a technology are evaluated on predominantly economical and medical factors. While efficacy studies have a direct influence on clinical decision-making, the effects of adequacy studies on policy and clinical decision-making are limited. In the phase in which adequacy studies are conducted, the technology is already being applied (albeit in specific samples) and has found some influential proponents in the medical profession. Consequently, changing the nature of the technology or influencing its application is difficult at that time (Van Rossum, 1991).

Constructive technology assessment (CTA), the MTA of a technology that is still in its development stage, has been proposed as a remedy for this drawback (Schot and Rip, 1996). By performing a technology assessment in this early stage, CTA aims to provide those involved in technological development and health care with a tool to help steer technological development and diffusion. CTA should analyze a medical technology based on medical, social, economical and social factors relevant to the decision-making of the diverse participants shaping development and diffusion.

CTA is especially relevant in guiding the development of new medical technologies that call for an integration of different forms of medical and technical expertise. An example is the development of artificial organs. In this field mechanical, and electrical engineers co-operate with medical doctors, biologists, biochemists and veterinarians. Having such professionally diverse parties providing information during in-house product testing is essential to medical technology development (Rochford and Rudelius, 1992). This ensures that the technology is sufficiently debugged prior to market or customer testing, such as in clinical trials. In the in-house testing

stage, therefore, a multidisciplinary group setting seems useful to assess a new medical device. The assessment supports the decision to declare a device to be either acceptable or unacceptable to tests involving patients, or that it requires product modifications.

Saaty's mathematical model, the analytic hierarchy process (AHP), can be used to support complex assessment processes. The AHP not only structures group discussions, it also supports quantitative analyses by generating inconsistency ratios, and weighting factors visualized in graphs (Saaty, 1989). It is often used to support strategic decisions, including the notable economic decision on resource allocation to projects, in which technological, economical and socio-political aspects have an important impact on the decision. The AHP has been implemented in a user-friendly group decision support system: Team Expert Choice. This article describes a case study that demonstrates the adequacy of Team Expert Choice to support decision-making in the development and clinical introduction of artificial organs.

7.2 Methods

We applied the group decision support system Team Expert Choice to conduct a CTA of the *pulsatile catheter pump* (PUCA pump). This left ventricular assist device (LVAD) provides temporary support (hours to a week) to the circulatory system (Mihaylov *et al*, 1997). It consists of a membrane pump connected to a valved polyurethane catheter. The tip of the catheter is introduced via the peripheral arteries or open thorax into the left ventricle. Triggered by electrocardiogram, the PUCA pump can aspirate 3L/min blood from the left ventricle and eject it into the ascending aorta (Verkerke *et al*, 1993). A research group of a Dutch University is developing this ventricular assist device in collaboration with industry, other universities and a university hospital. In the current stage of development of the project, the prototype of the PUCA pump is subjected to animal tests.

In our case study, a multidisciplinary group of developers, manufacturers and end-users (*i.e.* cardiologists and thoracic surgeons), as listed in table 1, estimated the effectiveness of the PUCA pump based on clinical, technical, social and economical requirements.

Table 1. Professional backgrounds of the panel members

NO.	PROFESSION	EXPERTISE
U ₁	Cardiologist	Clinical use of IABP, PUCA animal experiments, potential user
T ₁	Mechanical engineer	Development and clinical trials of LVAD's
T ₂	Chemical engineer	Biomaterials science and coating techniques
T ₃	Mechanical engineer	Manufacturer of membrane pumps
T ₄	Electrical engineer	R&D VAD driving systems
U ₂	Surgeon	Animal experiments with LVAD's
U ₃	Veterinarian	Project coordination, LVAD testing
T ₅	Mechanical engineer	Development and testing of the PUCA pump
T ₆	Mechanical engineer	Development and testing of mini-axial blood pumps

Effectiveness was estimated relative to the intra-aortic balloon pump (IABP) and the hemopump, which are two alternative ventricular assist devices at the time of this assessment being applied in clinical practice. The IABP is an alternative LVAD commonly used for temporary support of the failing left ventricle. A disposable polyurethane balloon is located in the descending aorta via the femoral artery. The balloon is pneumatically driven and triggered by the ECG. The balloon is inflated when the heart relaxes, and deflated when the heart contracts. The expansion can increase the coronary flow up to 60% and the diastolic pressure up to 100% (Kantrowitz *et al*, 1995). In contrast to the PUCA pump, the IABP has a very limited pump capacity.

The second LVAD is the hemopump. It consists of a disposable pump catheter with impeller, and an external electromotor controlled by an electrical console. The catheter with impeller can be introduced via the peripheral arteries or through the open thorax. These disposables continuously draw blood from the left ventricle and expel it into the aorta. The hemopump can produce a flow of 5 L/min (Aboul-Hosn and Wampler, 1985).

Based on the comparisons of the three assisting devices, the pump's strengths and weaknesses in the market of ventricular assist devices were analyzed, as well as the possibility for technical improvement of the PUCA pump. These rationales aimed to support the essential go/no-go/modify decision on the PUCA pump before this pump was to be clinically tested.

According to the procedures of Team Expert Choice, the first stage of the assessment was a brainstorm session to define the goal of the assessment, the alternative ventricular assist devices, and a list of requirements considered relevant to this evaluation. The requirements were hierarchically structured into requirements and sub-requirements. Subsequently, the expert panel pairwise compared the importances of the requirements in each category. By using radiographic hand-held keypads, the most important requirement of each pair of requirements was assigned a score from 1-9, of which 1 represents equal importance and 9 extremely higher importance. Likewise, the relative qualities of the alternatives were compared with regard to each sub-requirement. Individual scores were projected on a screen, allowing the members of the panel to discuss the rationales behind their individual scores. Based on geometric averages of the final, possibly revised, scores of the individuals, Team Expert Choice calculated weighting factors representing the importances of the requirements and the priorities reflecting the qualities of the alternatives. In addition, inconsistency ratios were derived to reflect the degree to which each redundant comparison did not accord with the remainder of the pairwise comparisons. See appendix A for a more elaborated overview of the quantitative methodology of the AHP.

The adequacy of the panel discussions ensuing from these procedures was analyzed by comparing the evaluators' weighting factors, inconsistency ratios, and the degree of disagreement between the evaluators' weighting factors, prior to and after the discussions in t-tests with a two-tailed significance level of $p \leq 0.02$. Our data collection concluded with propositions, rated on a 7-point Likert scale, on the adequacy of the support by Team Expert Choice.

7.3 Results

Corresponding to the goal to compare the effectiveness of the PUCA pump with alternative ventricular assist devices that provide short-term support to the failing heart, the IABP and hemopump were considered to be those most relevant to include. In contrast to other short-term support systems, the IABP and the hemopump are trans-arterial pumps that can be applied with minimal invasive surgery, a compelling trend in heart surgery.

The extracted requirements on these devices are in alphabetical order: acceptance by healthcare people, applicability, blood compatibility, coronary flow, de-airing of the device, ease

of introduction, ease of use, medical complications, monitoring functions, necessary introduction facilities, peripheral flow, pump flow, pump performance, replacement time of the device, safety, set-up time, transportability and unloading effect. These data were introduced in the Team Expert Choice program to compose the hierarchical evaluation structure (figure 1).

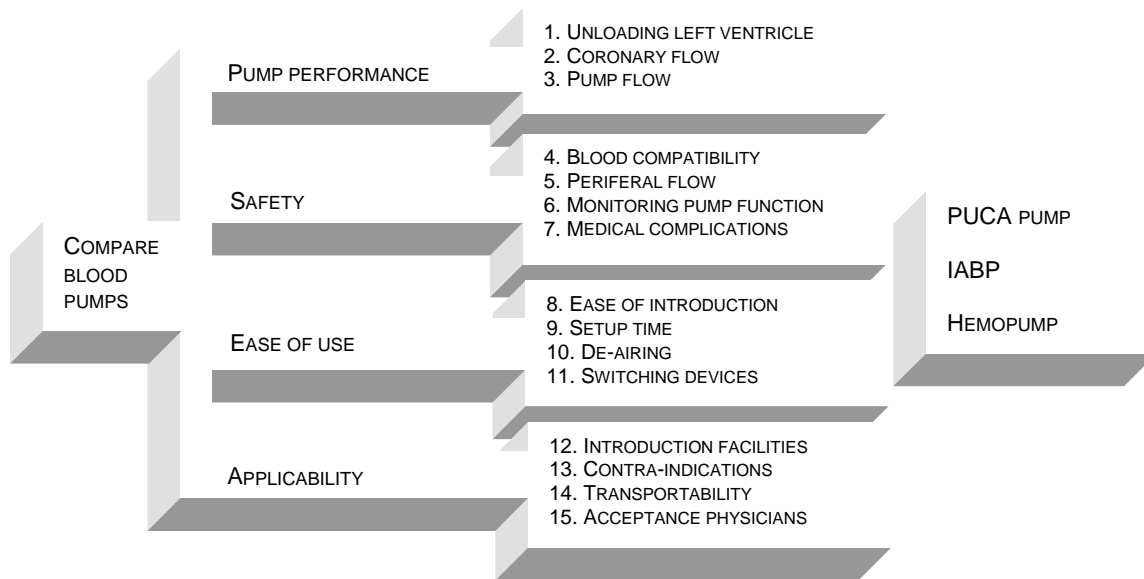


Figure 1. Hierarchical structure of the PUCA-pump assessment

Based on the final scores on the pairwise comparisons, weights and priorities were assigned to the factors in the hierarchical evaluation structure. Table 2 includes the weighting factors of the main and sub-requirements and the overall priorities of the ventricular assist devices. The cells reveal the priorities of the devices with respect to each sub-requirement.

Table 2. Final importances of the requirements (between brackets) and preferences for the alternatives

REQUIREMENTS	PUMP PERFORMANCE (.24)			SAFETY (.60)				EASE OF USE (.10)				APPLICABILITY (.07)			
	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.
	(.28)	(.20)	(.52)	(.36)	(.10)	(.13)	(.41)	(.23)	(.12)	(.58)	(.07)	(.23)	(.21)	(.09)	(.47)
PUCA pump .23	.50	.58	.21	.19	.13	.30	.19	.14	.15	.10	.17	.14	.20	.33	.14
IABP .49	.06	.21	.03	.65	.43	.58	.62	.76	.81	.75	.65	.73	.60	.33	.78
Hemopump .28	.44	.21	.76	.16	.44	.12	.19	.11	.04	.15	.17	.14	.20	.33	.08

Pump flow, weighted 0.52, is considered to be the most important sub-requirement of pump performance; pump performance, which has a weighting factor of 0.26, is the second most important main requirement. With regard to the pump flow, the mini-axial pump was superior to the PUCA pump and the IABP, considering the respective preferences of 0.76, 0.21 and 0.03. The panel had the highest preference for the PUCA pump concerning the pumps' support to the unloading of the left ventricle (0.50) and the coronary flow (0.58).

The calculated overall preference for the IABP is rated beyond the preference for the PUCA pump and the hemopump. In general, both the PUCA pump and hemopump are preferred for their pump performance, yet the IABP scores higher on the remaining main requirements of which safety is deemed most important. The most important sub-requirements influencing safety were considered to be medical complications (infections, bleeding, rupture and dislocation of the device), and blood compatibility (mechanical blood cell trauma, thrombo-embolic events, and immune activation).

Of these final weighting factors, eight significantly differed from the weights assigned by the panel members before the panel discussions (t-test, two-tailed $p = 0.02$). Most significantly, the panel discussions led to the understanding of the utmost importance of blood compatibility, as

shown in the elevation of the corresponding weight from 0.15 to 0.36. Furthermore, a pairwise t-test concluded that the discussions significantly increased the degree of consensus in the panel (two-tailed $p < 0.0005$). On average, the variance between the panel members' weighting factors was reduced by 68 per cent. Reflected by an average score of 6 on a 7-point Likert scale, the panel members rated the degree of consensus attained to be reasonably high. For example, the medical- and technical-skilled subgroup only assigned significantly different weighting factors to the need for introduction facilities, a sub-requirement of ease of use (t-test, two-tailed $p = 0.02$)¹.

In addition, the inconsistency ratio's prior and after the systematic discussions differed. Results from a paired t-test indicate that the reduction in individual inconsistencies is significant ($p < 0.008$). Regression analysis showed that in particular highly inconsistent evaluators considerably reduced their inconsistencies. The overall inconsistency ratio of 0.08 was acceptable according to the guidelines provided by Saaty (4).

The panel judged each proposition about the adequacy of the assessment with an average score of 6 on a 7-point Likert scale. Accordingly, the panel members considered a CTA of the PUCA pump to be important in this stage of the project. They thought it provided an adequate basis for common goal setting until clinical introduction. Furthermore, the support of Team Expert Choice was considered to be adequate. The procedures were thought to be user-friendly, and the participants would be willing to use Team Expert Choice for similar decisions.

7.4 Conclusions and discussion

CTA attempts to provide a broad analysis of a medical technology in its development stage. The results are to be used to support decision making concerning development and diffusion of the technology (Schot and Rip, 1996). In our case study, the group decision support system Team Expert Choice satisfactorily and adequately supported a CTA of the PUCA pump. On the basis of their multidisciplinary expertise, the assessment panel formulated technical, medical and social requirements for the performance of the PUCA pump. These requirements were considered

¹ A graphical oversight of the Euclidean distances between the weighting factors of the individual panel members shows in more detail the differences in judgements within the panel before and after the panel discussions (appendix 7.1).

relevant to a broad patient-group requiring short-term mechanical support of the failing heart. Pairwise comparisons focused on the importances of the requirements, and the relative quality of the alternative ventricular assist devices concerning these requirements. Led by these comparisons, the versatile perspectives of the panel were systematically discussed. The resulting ranking of the PUCA-pump prototype on the different sub-requirements vis-à-vis the two existing competitors facilitated the indication of the required changes in the developmental process of the pump. Involving the actors concerned with the development and diffusion themselves in the consensus-generating discussions directly supported the alignment of their development and diffusion activities.

The results of this assessment helped to ground the go/no-go/modify decision representing the gate to clinical introduction. They showed that with regard to the heterogeneous group of patients that requires short-term cardiac support, the overall effectiveness of the IABP is estimated rather high compared to the effectiveness of the PUCA pump and the hemopump. The IABP is considered to be relatively safe and easy to use since it does not require the introduction of a large bore catheter into a peripheral artery and introduction into the left ventricle, as the PUCA pump and the hemopump do. However, these properties of the latter pumps are inherent to their superior pump function. Such improved pump function is desired in clinical practice as shown by the declining use of the IABP due to its rather poor pump function and the development of novel pharmaceuticals like enoximone. Based on these considerations, the PUCA pump assessment resulted in the decision to modify not predominantly the properties of the PUCA pump but the strategy of diffusion in particular. The PUCA-pump project can adapt its strategy by focusing its diffusion on medical indications for use that attune to its specific pump performance, and the results give clear indications how to adapt effectively.

In contrast to the IABP, the PUCA pump has an active pump function which enables organ perfusion to a greater extent. For example, patients suffering from weaning complications, or low output syndrome benefit from this perfusion. In contrast with the hemopump or a comparable mini-axial pump, the PUCA pump provides a pulsatile flow, which enhances coronary flow. This can avoid further degeneration of myocardial tissue after an ischemic myocardial infarction. Considering these examples, the PUCA pump could provide more adequate support to specific groups of patients due to its active, pulsatile pump function. Clinical

trials of the PUCA pump will give more insight in the most appropriate medical indications for use.

In addition, improving the PUCA pump with respect to the other requirements listed remains beneficial for clinical practice. The outcomes of our application reveal effects on the overall effectiveness of the PUCA pump of potential improvements concerning each requirement. Notably, improvements with respect to safety appear to be essential. In order to guaranty a peripheral flow, cadaver studies started to determine the most appropriate peripheral artery in which to introduce the PUCA pump. In order to reduce the chance of medical complications, the development of a training program on the use of the PUCA pump has been planned. Besides these enhancements aimed at the safety of the PUCA pump, the assessment outcomes have evoked improvements related to the ease of use of the PUCA pump. Making the PUCA pump compatible with the driving system of the IABP and other pneumatic driving systems has facilitated the switch between the application of other devices and the PUCA pump. The ease of introduction of the PUCA pump has been improved by a simplification of the introduction technique. These examples show that in contrast to traditional technology assessments that consider the properties of a technology as given, our assessment extends its influence by evoking changes in the technological development of the PUCA pump. This influence is imperative in the pre-clinical development stages, since at the time a technology has been clinically diffused, MTA studies often fail to evoke adaptations to the medical technology or its use (Van Rossum, 1991).

In essence, our approach steered technology development and diffusion by means of discussions about the effectiveness of the PUCA pump in comparison to its competitors, and on strategy to improve the pump. Step by step, these discussions constructed convincing rationales to modify the PUCA pump and to revise the medical indications for application. It is important to realize that the outcomes of the Team Expert Choice facilitated assessments are influenced by the composition of the expert panel. The medical, social, industrial or technical backgrounds of the panel members influence the factors that are incorporated into the assessment, as well as the corresponding weighting factors. It is therefore necessary that the expert panels be comprised of a representative sample of the various professional groups involved.

Assessment outcomes consist of predictive statements that are based on assumptions derived from good-laboratory-practice studies. Therefore, this CTA does not intend to make *in-*

vitro or *in-vivo* testing redundant. It aims to provide a comprehensive perspective on the clinical performance of the medical device. This insight is essential to determine the technological activities that are relevant to the device's clinical performance. In overall, results of CTA studies should be used for restricted purposes, as defined by the panel. From this Team Expert Choice case study no conclusions can be drawn with regard to the absolute quality of the IABP or hemopump. The pump alternatives were only valuable to position the PUCA pump on its possible future market and to analyze the steps that had to be taken in order to compete with them.

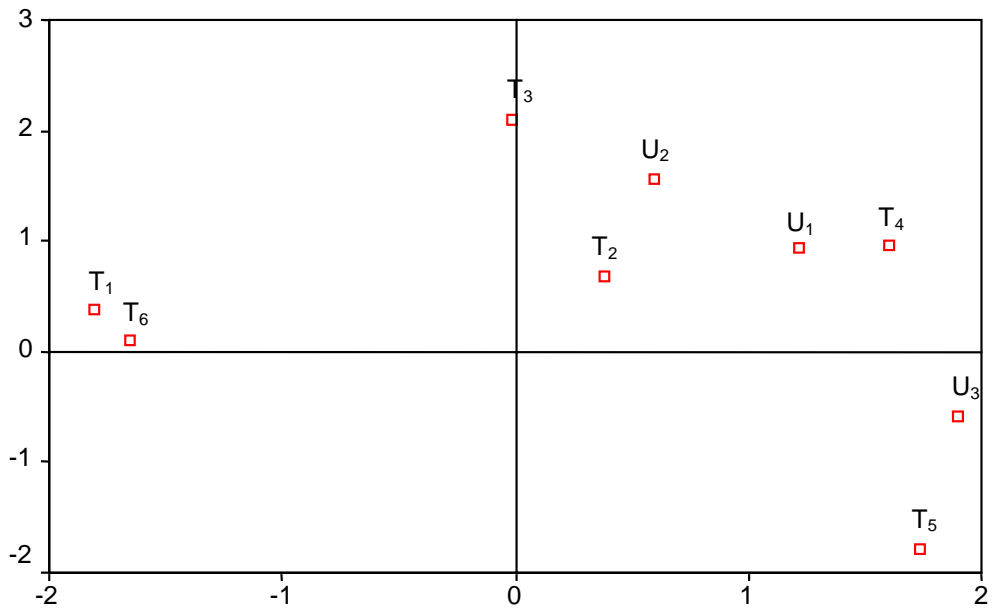
Team Expert Choice structures a heterogeneous CTA into comprehensible sets of pairwise comparisons. Insight on the individual members' judgements focuses the panel members to learn from the diverse expertises and to overcome disagreements, which is eminent in the context of the predominantly multidisciplinary research on artificial organs. This supports a synthesis of the perspectives of the multidisciplinary panel members, resulting in more consistent judgements. The graphic presentation of the quantitative analysis on the requirements and the alternative medical devices enhances insight in the potential market position of the new technology. It encourages technological developers to contemplate on clinically beneficial production modifications as well as on appropriate medical indications for clinical use of the device. These effects benefit strategic decision-making in technological development and diffusion. In our view, this approach of CTA can be adequately applied to a great variety of medical devices due to the wide applicability of Team Expert Choice.

References

1. Aboul-Hosn W, Wampler R. The hemopump: clinical results and future applications. In: Felix Unger, ed. *Assisted Circulation*. Berlin Heidelberg: Springer-Verlag 4: 152-165 (1995).
2. Kantrowitz A, Bridgewater B, Au J. Intra-aortic balloon pumping for assisted circulation: New techniques and new prospects. In: Felix Unger, ed. *Assisted Circulation*. Berlin Heidelberg: Springer-Verlag 4: 12-35 (1995).
3. Mihaylov D, Kik C, Elstrodt J, Verkerke GJ, Blanksma PK, Rakhorst G. Development of a new introduction technique for the pulsatile catheter pump. *Artificial Organs* 21(5): 425–427 1997.
4. Rochford L, Rudelius W. How involving more functional areas within a firm affects the new product process. *Journal of Product Innovation Management* 9: 287-299 (1992).
5. Rossum W van. Decision-making and medical technology assessment: three Dutch cases. *Knowledge and Policy* 4: 1-2 (1991).
6. Saaty TL. Group decision-making and the AHP. In: Golden BL, Wasil EA, Harker PT (eds). *The Analytic Hierarchy Process; Applications and Studies*. Berlin; Springer-Verlag: 59-67 (1989).
7. Schot JW, Rip A. The past and future of constructive technology assessment. *Technological Forecasting and Social Change* 54: 251-268 (1996).
8. Verkerke GJ, Muinck ED de, Rakhorst G, Blanksma PK. The PUCA pump: a left ventricular assist device. *Artificial Organs* 17(5): 365–368 (1993).

Appendix 7.1. Aggregated Euclidean distance model of individual weighting factors before and after the panel discussions (RSQ = 0.80)

A) Distances between individuals' weighting factors before the panel discussions



B) Distances between individuals' weighting factors after the panel discussions

