### **REDUCING INTER-ORGANIZATIONAL BARRIERS IN THE MEDICAL SECTOR WITH SIMULATION**

Mark D. Hermans Joost M. Sluijs

Incontrol Business Engineers Planetenbaan 21 3606 AK Maarssen, THE NETHERLANDS

#### ABSTRACT

This paper describes how a simulation model is successfully being used as a communication tool following the introduction of a new law on research projects involving humans. The law caused some resistance at the local medical ethical research boards, mainly because of their uncertainty about imposed changes. The challenge was to communicate the changes to a large number of organizations. An animation model that explained the communication procedures between local medical ethical boards and the central agency was presented at a workshop attended by representatives of all the local boards. The model proved to be a powerful method of providing the audience with a lot of information in a short time, establishing a joint problem definition, and focusing discussions on the important issues. The animation model was a useful instrument in providing a smooth implementation of the law.

# **1 INTRODUCTION**

In the Netherlands, every medical research project involving humans has to be approved by a local medical ethical board consisting of ethical, juridical and medical experts. Approval is given to research projects that do not conflict with current ethical norms and values. For example, tests of medicines on patients are subject to approval. There are more than a hundred local medical ethical boards within the Netherlands. These boards are usually located at hospitals and other medical institutions. A new law on medical research projects has resulted in the creation of a central medical ethical committee, called 'Ceco'.

The paper will describe how a simulation model is used to communicate changes to a large number of organizations and to create acceptance of new interorganizational procedures following the establishment of Ceco. The local medical ethical boards, spread around the country, now have to communicate with the new Hannie Aartsen

Health Council of the Netherlands P.O. Box 1236, 2280 CE Rijswijk, THE NETHERLANDS

committee. Existing procedures both within and between organizations will change. At the local boards, there was some resistance against the law, partly because there was uncertainly about its implementation and the role of the Ceco.

An animation model showing the new communication procedures in a dynamic way was presented at a workshop to communicate the foreseen changes. The model had to convince the local boards to accept the newly introduced procedures and to show the benefits of the Ceco. The model had to appeal to a skeptical public, comprised mainly of non-technical people from a wide range of backgrounds. Furthermore, the model had to go beyond the boundaries of the Ceco and cover inter-organizational communication procedures.

Simulation and animation models have been used before for inter-organizational issues, such as in the logistics field (Wierda, 1991) (Babeliowsky, 1997). This paper is about simulation being successfully used as a communication tool for 'soft' policy matters in the medical sector, without much technical complexity involved. The challenge, however, was to effectively eliminate uncertainty about the new policy, to direct a decisionmaking process to the important issues, and to communicate with more than a hundred organizations spread around the country.

In section 2, the policy context of the introduction of the law on medical research projects is described. Section 3 answers why communication is a useful instrument in policy implementation. Section 4 explains why animation is a powerful communication tool in an inter-organizational context. In section 5, several aspects of our approach are described in detail, followed by a description of the workshop in which the animation model was used. This paper ends with results and conclusions of using simulation in reducing inter-organizational barriers in the medical sector.

# 2 BACKGROUND

Annually approximately 2,500 medical research projects involving humans are conducted in the Netherlands. All projects are subject to approval by a medical ethical board (see ICH Topic E 6, 1996). The main purpose of the new law on medical research projects is to formalize and standardize procedures at the local medical boards to insure a high quality of medical ethical control (Upper House of States General, 1997).

In practice, the local boards already execute most of the procedures proposed in the new law. Essentially, the law will formalize what is already being done. The law has already been passed by parliament, but has not yet been put into effect. Therefore, within the juridical limits of the law a number of practical and operational aspects are still open for interpretation.

The newly introduced Ceco will operate as an independent agency and will monitor the activities of the local boards. The Ceco's specific functions include:

- 1. licensing local boards. This gives them the official authority to approve medical research projects.
- 2. centrally archiving abstracts of research proposals and all decisions made by the local boards.
- 3. serving as a board of appeal for disputes arising from local boards rulings.
- 4. judging medical research projects involving specific designated subjects, such as gene therapy. Local boards are not authorized to judge these types of projects.

In order to insure a high standard of ethical control, the local boards have to meet certain quantitative and qualitative standards before obtaining a license from the Ceco. It was expected that a number of the local boards would not meet these standards, which caused some hidden turmoil within the local boards. Furthermore, there were some rumors about the execution of the newly introduced law, even before the Ceco's information campaign had started.

A multi disciplinary task force was consequently set up to ensure a smooth implementation of the law. The task force consisted of members of the local boards, the Ministry of Health, members of the Association of Local Boards, and representatives of the Dutch Health Council, which is responsible for the operational launching of the Ceco. The main task of the group was to prepare the implementation of the law and address the parts of the law still open for interpretation.

Incontrol Business Engineers is responsible for implementing the Ceco's information system. The local boards will frequently exchange documents with the Ceco. Therefore, it is necessary that the communication procedures and document formats are explained to the local boards to ensure an efficient system of administrative document processing.

In summary, there was a dynamic, complex network consisting of a large number of independent organizations that were quite reluctant to accept the Ceco. There still was uncertainty about the interpretation of the law and the policy. Both the Ceco and its communication procedures had to not only be explained to the local boards, but preferably also be accepted. The challenge was to find a way to successfully launch the new law.

### 3 COMMUNICATION AS A POLICY INSTRUMENT

### 3.1 Influencing the External Environment

In today's world, both private and public organizations are aware that the external environment influences organizational performance. Each organization must align its policies and actions to the external world to be successful (Meinsma, 1997). Decision-making has become more difficult, as a result of different perceptions and interpretations, and incomplete or fragmented information. As described in the previous section, this is also applicable to the situation of the Ceco.

It is difficult to influence the behavior of the external environment. Old policy instruments, such as pressure or hierarchy, often do not work, because there are no hierarchical relations in a network of independent organizations. Forcing organizations to do something can result in counter productive reactions. However, laws or new policies still need to be implemented, accepted, and adhered to. In these situations, an alternative approach is required.

Organizations can adapt internally to the external environment. For the Ceco, this would involve processing a wide variety of document formats and procedures. This adaptation would either lead to chaos, or require a large administrative staff and budget to manage the process.

Another approach is to adapt the external world to the internal business processes. For the Ceco, this would involve adapting communication procedures with the local boards to the internal administrative operations. The local boards would provide reports in a standardized format, thereby using standardized procedures. For example, filling out reports on disk enables electronic archiving of reports. Eventually this will lead to efficient administrative procedures at the Ceco office and, more importantly, a better execution and implementation of the law. However, this requires a convincing initial effort to make the local boards truly accept the Ceco and its procedures. Therefore, a pro-active approach from the policymakers is crucial. To make external organizations aware of a certain idea, solution, or proposal, communication is the magic word.

### 3.2 Communication

Communication has long been used as a policy instrument to make people or organizations change their behavior (De Bruin, 1991). Often it is used in combination with other policy instruments, such as laws.

In order to effectively communicate, it is important to get the target audience in contact with both the medium (e.g. TV, brochures, advertisement, workshop), and the message. Once that is achieved, the message must be formulated and presented in such a way that the audience understands and accepts it. The final step is for the audience to actually change its behavior as a result of the communication process (Algemene Rekenkamer, 1991).

One major objective of communication in interorganizational issues is the achievement of co-operation (Meinsma, 1997). Wierda (1991) conducted four case studies in the area of inter-organizational information systems. Two findings from the case studies are: (1) conflict and misunderstanding between organizations are the results of disagreement about the problems perceived and (2) willingness for co-operation of an organization is not self-evident because of the unwillingness to affect the autonomous position of the organization.

Therefore, it is important to explain the situation thoroughly and understandably to all the stakeholders, so that everyone perceives the problem in the same way. The objective is to give direction to the stakeholders way of thinking and problem perception. Communication should first result in a joint problem definition, which serves as an excellent basis for further, and more focussed, discussions. Particularly in a network of independent, multiform organizations, it is important that all organizations talk the same 'language'. People must first understand the situation and talk in the same terms before starting discussions about issues that are still open for interpretation.

One of the benefits of using communication as a policy instrument is that stakeholders are involved in the decision-making process. It gives all stakeholders the opportunity to voice their opinions. Communication is not a one-way process. It also involves receiving reactions and setting up a dialogue. For the policy- maker, it is also important to try to use this feedback to make a policy more feasible and acceptable. Adapting it to the external environment ensures a more successful implementation.

Another benefit of communication is that it provides the policy-maker with an understanding of the external environment. A lot of information about the external world is generated during a communication process. Therefore, communication also serves as a 'detector' and provides the policy-maker with useful information crucial for strategic decision-making.

In co-operation with the local boards, the Ceco can determine how this freedom of interpretation will be addressed. This will increase the feasibility and acceptance of the law. The challenge was to find a way of communication to ensure a successful implementation.

### 3.3 Workshop as a Means of Communication

In order to create a smooth implementation of the new law and gain support for the Ceco, the Ceco task force launched a publicity campaign. Amongst other communication instruments, such as brochures, a one-day workshop was organized for representatives of all the local boards to inform them about the changes imposed. The task force had actively been searching for opportunities to get the right audience together.

There were several objectives of the workshop:

- Reduce and eliminate uncertainties: Some rumors had resulted in turmoil among the local boards. The license requirements for being authorized as an official local medical ethical board were considered unclear and caused some resistance. As mentioned in the previous section, the independence of an organization is always considered important to stakeholders. Some local boards feared losing some of their power to the Ceco. Therefore, during the workshop, it was important to stress that their independence would be respected.
- Explain the new procedures: The new communication procedures and their purpose had to be explained to the local boards. Though there would be a number of procedural changes, most of the processes would remain as before. For the internal administrative processes at the Ceco, it was important that the new communication procedures were understood and accepted.
- Involve the local boards in the change process: The contents of the new law on medical research projects can no longer be changed. However, within the boundaries of the law there still was some freedom of operation. The Ceco taskforce interpreted the law in such a way that it would mainly formalize existing operations at the local boards. In the workshop, the representatives of the local boards had to be involved in the thinking process of the imposed changes. The margins and opportunities within the law had to be explored. Participation was welcome, since not all procedures had yet been determined, and possible omissions could be detected. It also gave the local boards the opportunity to voice opinions.

- Create acceptance of the Ceco.: The purpose, the reason for being created, and the functions of the Ceco had to be explained. It was also important to create confidence in the Ceco and make a good and solid impression. The Ceco should be recognized as a reliable partner in dealing with proposed medical research projects.
- Prevent and adapt to opportunistic behavior: As mentioned in section 3.2, communication also generates useful information about the external world. There were rumors that the local boards would 'go their own way' and find ways to get around the Ceco. During the workshop, it was essential to prevent the local boards from doing this, and in case it would be unavoidable, also adapt to this behavior.

In order to achieve all these objectives, an effective communication tool was needed.

# 4 ANIMATION AS A COMMUNICATION TOOL

During preparation of the workshop, it was decided that animation would be an appropriate method to explain the new communication procedures between the local boards and the Ceco (see figure 1). Because of the complex nature of the procedures a special approach was necessary. A lot had to be explained within a short time frame. Since the complexity of the law could easily distract workshop participants, it was important to focus discussions on the important issues.

The main goal of an animation model is to visualize the relevant aspects of an object system in such a way what it supports and simplifies the communication between the parties involved (Pegden, 1990) (Verbraeck, 1993). Animation was chosen as a communication tool for a number of reasons:

- Improve communication: Animation improves the communication process. An animation model provides a frame of reference for discussions. Participants will focus on the model and talk about the issues addressed in the model.
- Improve conceptualization of a problem: In section 3, it was explained that disagreements about the problems perceived is one of the major causes of interorganizational conflicts. Animation provides a good method to prevent confusion and differences in problem perception.
- Stimulate participation in problem solving process: Since an animation model is easy to understand and easily accessible, participants can easily relate it to

their own situation. As a result, they tend to participate more actively in the discussions.

- Intuitive verification and validation: Visualization provides a good opportunity to verify and validate a system. This is particularly relevant for checking the communication procedures for inconsistencies and omissions.
- Insight into dynamic aspects: Many of the communication procedures to be explained, were quite complex and contained a lot of dynamic elements. Consequently, it seemed to be impossible to explain it in one afternoon without using animation. The logistic complexity of the procedures demanded a communication method that prevented the appearance of different interpretations of the procedures.
- Professional presentation: An animation model, if built properly, improves the professional presentation of the agency using the model.

The question is how to build an animation model that can serve the purposes as mentioned above.

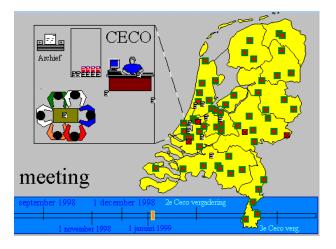


Figure 1: Sample of the Ceco Animation Model

# 5 APPROACH

Communicating using animation involves more than just building a model. Many aspects, both procedural and technical are relevant to successfully create and use an animation model. This section explains how the animation model was built and how the workshop was prepared.

#### 5.1 Procedural Aspects

It is important to create the right atmosphere and circumstances to ensure a good start of the model building process.

- Multi-disciplinary team: As already mentioned in the introduction, a multi-disciplinary task force was created to organize the workshop. The task force represented different points of view, which provided good input for the animation model.
- Actor analysis: Before building the animation model, an actor analysis was preformed. An actor analysis consists of the characteristics, number, and interests of the actors involved. This analysis leads to useful insights and can be used as a starting point for the model building process.
- Flowcharts: At an earlier stage, flowcharts of the proposed procedures both within the Ceco and between the Ceco and the local boards were already made. While the flowcharts were mainly for the design of Ceco's information system, they proved to be useful while designing the animation. It was an easy change from the static flows to dynamic interactions. However, the complexity of the communication procedures proved once again that it would be impossible to explain the procedures in a static slide show. Dynamic insight using animation was required.
- Close interaction with the client: Crucial during the modeling process was communication with the client. In contrast to logistic processes, policy-making processes can be unpredictable and many changes occur along the way. During the modeling phase, there was close contact between the task force and the model builders. The model had to be changed frequently to fit the actual interpretations.
- 'Dress rehearsal': A few weeks before the final workshop, a prototype of the animation model was presented to the multi-disciplinary task force. This revealed vital information, not only of procedural matters, but also of practical matters, such as the choice of symbols and background colors. Furthermore, the strategy for the workshop was agreed upon, as was the agenda, and 'sensitive' matters that needed special attention.

# 5.2 Technical Model Building Aspects

Building the animation model is technically not a complicated process. However, a number of aspects must be considered to successfully use the model. Based on the actor analysis and the flowcharts, a rough sketch of the animation layout was made, and also the level of detail was chosen. All together, approximately twelve communication procedures, with several variants had to be built. The model was built using ARENA simulation software, which provides extensive animation possibilities.

- Logistic focus: Even though the model should support the implementation of a law, the model was built from a logistic point of view. The model focused on document flows between the Ceco and the local boards. Logistic issues, such as locations of stock points of floppies were addressed in the model.
- Modeling conventions and symbols: At an early stage, modeling conventions were also made. Both the static and dynamic symbols were chosen. Static symbols are elements that do not move, like the background. Dynamic elements are symbols that move, like people, documents, disks, etc. The audience consisted of nontechnical people, mainly medical and juridical experts, who had to be convinced within a short time frame. Therefore, the choice of symbols was important. The participants should be able to recognize their own situation in the model.

For example, red always symbolized denial, or refusal. Traffic lights appeared to be useful to symbolize the result of a decision (see Figure 2). Furthermore, since all local boards were spread around the country, a map of the Netherlands was used so nearly everyone could find their own medical institution.

It was challenging to find the right symbols to replace medical and juridical terminology, which avoided usage of jargon and diminished the chance of confusion about definitions and terms.

- Generic structure of the models: During the modeling process, it is important to have a generic logic of the simulation model. As mentioned before, policy-making is a dynamic process and interpretations change, which can have a significant impact on an animation. New developments in the policy-making process required frequent changes to the model. Consequently, the model used had a flexible structure.
- Professional look: One of the goals of the workshop was to present Ceco in a positive light. The model had to look professional in order to gain credibility from Ceco.

# 5.3 Lessons Learnt During the Modeling Process

During the modeling process, several valuable insights were learnt:

• 'What you think is not always what you get': There were several good ideas for the background and setting of the animation model. It was thought that these settings would do well in the animation model to explain the message. However, once modeled, it did

not look as nice as was initially envisioned. By trial and error, clear and understandable visualizations of procedures were designed.

For example, it was first intended to show both the old and new communication procedures in one model. This appeared not to be as useful as was initially envisioned. There were too many moving objects on the screen at the same time, which made it difficult for the audience to get a clear overview. It was important to focus on the basic message that explained the new procedures.

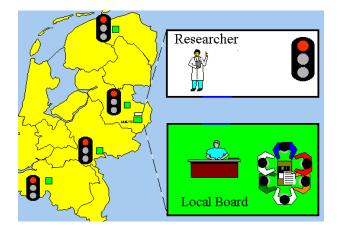


Figure 2: Usage of Symbols, such as Traffic Lights.

- Removal of details: It was soon recognized that a lot of details could be removed from the animation model. This had two advantages. The message would be clearer for the audience, since there would be less interference from details. Second, the amount of time needed to build the basic model would decrease, which created more time for other procedures to be included.
- Revealing inconsistencies within procedures: Since most of the procedures were designed from scratch, they never really had been tested before. Even though they seemed to be documented well in the flowcharts, some inconsistencies and redundancies were discovered by using the animation model.

For example, the local boards were required to use floppies and send them to the Ceco. Yet, no one thought about how to supply accurate and up-to-date floppies to the boards. This sending procedure was designed as a result of the animation model.

Redesign and verification of the communication procedures was performed which increased the quality of the procedures. The animation model served as a tool to verify and design administrative procedures. This purpose was, however, initially not intended in the original assignment.

• Revealing inconsistencies of the law: The animation model revealed that the law included some unpractical procedures. For example, literal interpretation of the law implied that newly established local boards could not be licensed by the Ceco. The inconsistencies could not be changed on short notice, since the law had already been approved by parliament. At the same time, it is expected that some of these inconsistencies will be removed by the time the law is revised.

# 5.4 Conducting the Workshop

Conducting a workshop involves more than merely presenting an animation model. It is important to (1) get the right audience together, (2) create an open, stimulating atmosphere, and (3) to schedule the presentations and contents in a coordinated, balanced, and structured way.

Representatives of all the local boards attended the workshop, which took place over the course of one day. In the morning, a representative of the Ministry of Health explained the history, background, and contents of the new law to the participants. Next, a member of the Ceco task force responsible for the operational launching of the law, explained the contents and the operational consequences of the law. This provided a good introduction for explaining all procedures and communication processes.

In the afternoon, the participants were divided into two groups and instructed about the imposed changes. In smaller groups, it was easier to create participation in the discussions. The Ceco task force presented itself as a coherent front. Incontrol coordinated with the Ceco task force on the contents and design of the slide show and the animation model. This was important as Incontrol presented the animation model on behalf of the Ceco task force. An expert was available to answer any juridical questions.

During the presentation, two animation models were presented. The first model showed an overview of the Netherlands, in which all the local boards were depicted. This was very recognizable for the participants and was therefore directly understood. This served as a good introduction for an in depth presentation of the new procedures. The second model focussed on one local board and the communication procedures between this board and the Ceco.

While presenting the animation model, it was also important to explain the setting and events depicted in the animation. Verbal explanation of the animation model focused the attention to the right elements and improved the understanding of the models.

The reactions on the animation models during the two sessions were quite different. Unexpected questions were asked. Although the models covered nearly all possible and feasible situations, the audience sometimes came up with new situations. This proved that the audience was thinking in logistic terms about the procedural aspects of the implementation of the law. The models immediately got the attention sought and indeed stimulated participation in discussions. The types of questions that were asked indicated that the audience participated in the thinking process about the procedural changes.

Participants tended to reflect the procedures as presented in the animation model to their own situation. This proved that the model was easily recognizable. Since the audience comprised of people from a wide range of backgrounds, the models were interpreted from different points of view. Participants focussed on their own situation, however, within the boundaries of the animation model. In this way, the animation model directed the audiences thought process.

Despite the endless issues raised during the workshop, the model controlled the decision-making process and made participants focus on the relevant subjects. This enabled a lot of information to be successfully transferred to the audience.

The model also highlighted that the independent position of the local boards remained unaffected, once the Ceco had acknowledged the local boards. It was clarified that procedural aspects would change, but the local board would remain autonomous.

Overall, the workshop was received positively. The Ceco task force recognized the animation model added value to the communication process with the local boards. In addition, the reactions from participants were positive. It was said that the dynamics and color of the animation model generally appealed more to the audience than static slide shows. For example, it is easier to identify with a doctor who walks to a local board, than reading a text about a 'medical official' on a slide.

#### 6 **RESULTS AND CONCLUSIONS**

The animation model added value to achieve a clear communication process of foreseen policy changes to a large number of organizations. Although not all workshop participants agreed with the changes and procedures, they understood the message conveyed. The animation model streamlined, directed, and focussed the discussions. This enabled the transfer of a large amount of information within a relatively short time frame.

Though the model was initially built for the workshop, it appeared to be useful for other internal and external purposes as well. The models also extracted useful insights, which have been used to verify and improve the internal business procedures at the Ceco. The models have also been used as a means to instruct the administrative staff at the Ceco and the Health Council about the changed procedures. Furthermore, the models will be presented to other associations in the medical sector to explain the law and its contents.

A logistic focus is useful, even in soft policy environments, such as the implementation of a law on medical research. The logistic focus helps analyze, validate, and communicate procedures as proposed in a policy.

Animation proved to be successful in establishing and directing a communicating process between different organizations, resulting in an improved and joint problem perception. An unambiguous problem definition serves as a good basis to break down barriers between different organizations, such as rumors, distrust, and uncertainty. Reducing these barriers will lead to establishing cooperation more easily.

Currently, the Ceco is preparing to start operations in January 1999.

# REFERENCES

- Algemene Rekenkamer, 'Voorlichtingcampagnes van het Rijk', Tweede Kamer 1990-1991, 22 152, nrs 1-2, The Hague, The Netherlands, 1991 (in Dutch).
- Babeliowsky, M.N.F., 'Designing Interorganizational Logistics Networks', Doctoral dissertation, Delft University of Technology, Delft, The Netherlands, 1997.
- Bruin, J.A. de, and E.F. ten Heuvelhof, 'Sturingsinstrumenten voor de overheid - Over complexe netwerken en een tweede generatie sturinginstrumenten', Stenfert Kroese, Leiden, The Netherlands, 1991 (in Dutch).
- ICH Topic E 6, 'Guideline for Good Clinical Practice', The European Agency for the Evaluation of Medicinal Products, Human Medicines Evaluation Unit, London, United Kingdom, 1996.
- Meinsma, R.R., 'Decision Support in Business Environments', Doctoral dissertation, Delft University of Technology, Delft, The Netherlands, 1997.
- Pegden, C.D., R.E. Shannon and R.P. Sadowski, 'Introduction to Simulation Using Siman, McGraw-Hill, New Jersey, USA, 1990.
- Upper House of the States General, 'Regulations on Medical Research Involving Human Subjects (Medical Research Involving Human Subjects Act)', parliamentary year 1997-1998, 22 588, No. 18, The Hague, The Netherlands, 1997.
- Verbraeck, A. and G.J. de Vreede, 'Animation as a Communication Vehicle in Simulation Studies', in: Modeling and Simulation ESM 1993, A. Pave (ed.), Society for Computer Simulation, San Diego, USA, 1993.
- Wierda, F.W., 'Developing Interorganizational Information Systems', Doctoral Dissertation, Delft University of Technology, Delft, The Netherlands, 1991.

# **AUTHOR BIOGRAFIES**

**HANNIE AARTSEN** is a senior scientific staff member at the Health Council of the Netherlands. She is mainly concerned with issues of health law and health ethics. She is temporarily assigned as the secretary of the Ceco. She received her law degree from the Erasmus University of Rotterdam.

**MARK D. HERMANS** is a Business Engineer at Incontrol Business Engineers, a consulting firm specializing in improving businesses by using quantitative methods. He is specifically interested in issues that transcend the boundaries of organizations, such as supply chain management and intermodal transportation. He holds an MSc from the School of Systems Engineering, Policy Analysis, and Management at Delft University of Technology.

**JOOST M. SLUIJS** is a Senior Business Engineer at Incontrol Business Engineers, a consulting firm specializing in improving businesses by using quantitative methods. He has experience in the design of logistics systems, the implementation of IT systems, and managing organizational change. He holds an MSc Technical Mathematics from Delft University of Technology and an MTD Logistics Control Systems from Eindhoven University of Technology.