Articulating user needs in collaborative design: Towards an activity-theoretical approach

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Abstract

This paper analyses the collaborative design of a high-technology product, a neuromagnetometer used in the analysis of the activity of the human cortex. The producer, Neuromag Company is trying to transform the device from a basic research instrument into a means of clinical practice. This transition is analyzed as a simultaneous evolution of the product, producer-user network and user activities. The network is analyzed as a network of activity systems. Each activity has a historically formed object and a motive of its own, as well as a system of cultural means and expertise. We use these to explain and understand the interests and points of view of the actors in relation to the product and the contradictions of the producer-user network. It is suggested that the emerging user needs of collective actors must be analyzed at three levels. At the first level, the use value of the product, its capacity of solving the vital problems and challenges of developing user activities, is characterized. The second-level analysis concerns the creation and development of the necessary complementary tools and services that make the implementation and use of the product possible. This task presupposes collaboration between several communities of the innovation network. The third level is the situated practical use of the product. In our experience, it is advantageous that researchers contribute with their data to a dialogue in which the user needs are articulated.

1 Introduction

We will analyze the collaborative design of a new medical device in transition. The device has been implemented in basic research. The challenge of the producers is to transform it into a tool of clinical practice and create a clinical market. This kind of transition from design to user activity is a critical phase in an innovation process during which it will be resolved whether the artifact is going to be established as a tool in user activity.

It has been suggested that developers often have considerable difficulties in identifying the user's problems or the complex organizational conditions of the implementation of new technology into medical practices (Green, 1992; Den Hertog & al., 1996). Economics of innovation (Freeman, 1991; Rothwell, 1992), sociology of technology (Latour 1987; Pinch &

Bijker, 1987) and organization theory (Powell, 1990; Powell & al., 1996) have all stressed the significance of networking and user involvement for the success of an innovation process. Economics of innovations has underlined the significance of producer-user relationships for the innovation (Lundvall, 1988; von Hippel, 1988). Von Hippel showed that users had a significant, or even leading role, in the development of such high-tech products as scientific instruments and electronic subassemblies (von Hippel, 1976 and 1988). In sociology, actor network theory has raised the challenge of studying the innovation process as a co-construction of the product and a network of actors connected to it (Latour, 1987). Recently Powell and his colleagues have suggested that the locus of an innovation is rather a network of learning than an individual firm (Powell & al., 1996).

Neither the economics of innovation nor actor network theory have provided a satisfactory conceptualization of the co-evolution of the product, network and user activities. The economic analyses of the innovation-related networks often remain formal in focusing on official forms of collaboration and not on design work or network interaction (Freeman, 1991; Powell & al., 1996). Actor network theory focuses on enrollment of allies and largely neglects the analysis of cultural resources of the participants and of learning in networks (Miettinen 1999). In this paper, we will use cultural historical activity theory to study the simultaneous transformation of an artifact, a local network related to it and user activities.

In activity theory, the unit of analysis is an activity system, a community of practitioners having a common object and a common outcome (Engeström, 1987; Cole & Engeström, 1993). Activity is mediated by cultural means, tools and symbols (Vygotsky, 1979). It is also mediated socially: division of labor and rules regulate the relationships between individuals of the community. In our study, a surgical team of a hospital, a research team at a university or a small company constitute collective activities each having its own object and outcome (e.g., surgical treatment of epilepsy patients) and its historically developed array of tools and know-how (knowledge of the human brain, diagnostic apparata and methods etc.). We will use the activity-theoretical approach in two ways: to reinterpret the concept of user needs, and to study the development and contradictions of a network of activity systems related to the innovation process.

We will study the innovation network and the producer-user network as a network of activity systems.² The nodes of the network consist of local activities (Engeström & Escalante, 1996; Miettinen, 1998). We are using the analysis of the historically evolving objects and systems of tools of the participants to explain their interests and points of view in relation to the product under construction (Miettinen, 1998). We further suppose that the transformation of the network is not accomplished without conflicts or tensions, when different motives, world views and expertise of the actors meet. Again, we will analyze the contradictions in the evolving network by using the historically formed motives and cultural resources of the activities as an explanatory resource.

The analysis of user needs formerly provided a standard starting point for the treatment of the design, development and marketing activities in management literature (Kotler, 1991). This

² These terms are complementary. By innovation network we understand the network of various activities that participate in the construction of an artifact. The term producer-user network (in singular) used by economists of innovation is slightly misleading in the sense that often there are several producers and users involved in the design process. For instance, in our case there are three basic types of users of Neuromag forming an interactive network: a measurement laboratory, surgeon groups and patients.

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¹ The activity theoretical approach has been used to study various work practices focusing on different aspects of activity. For a review, see Engeström, Miettinen & Punamäki 1999. For the application of activity theory in studies on human computer-interaction, see Kuutti 1996 and Nardi 1996.

approach, however, has several limitations. First, user needs were taken as something given or pre-existing that can be recognized and met. This is not compatible with the logic of innovation. The user cannot have an articulated need of something that differs radically from their present practice and knowledge (Lindell, 1991; Vicario & Troilo, 1998). Second, user needs are mainly analyzed as individual preferences and opinions on product characteristics (Heiskanen & Niva, 1996). This is a limited view, especially when the users are firms, work communities or other collective actors. In this paper, we take a step towards developing conceptual and practical tools for articulating the needs of collective actors in the process of collaborative design and implementation of a new product.

The idea of a contextual analysis of the usability and human-computer interaction developed in design literature takes a step to that direction (Adler & Winograd, 1990; Nardi, 1996; Beyer & Holzblatt, 1998). We think that activity theory can be used to develop and structure such a contextual analysis, as proposed by Nardi (1996, p. 95). The analysis of usability either experimentally, or only as a situated human-machine interaction, is too narrow an approach. User needs should be understood both historically and as something to be constructed collaboratively in the course of the design and implementation process. The use value of the product in solving the historically evolving vital problems and challenges of an activity is the starting point for construction. On the other hand, the conditions of the use are related to all the elements of the activity: systems of means, division of labor, qualifications of the subjects. It is also, of course, related to the physical layout of the work environment and the qualities of the product. The construction of the need presupposes analysis and articulation at all these levels. We propose a three-level analysis to capture the multidimensionality of the constructing of the user needs: (1) the analysis of use value in a historical perspective, (2) the complementary means (software, standard data, scientific verification) needed for the implementation and use of the product, and (3) the analysis of the situated use of the product.

The central data analyzed in this paper are the discourses in the user seminar that we organized together with the key actor in our study, the Neuromag Company. Although the seminar takes place within the tradition of sociological studies of innovation, it can also be seen as a parallel to develop forms of participative methods in product design studies. In the 1980s, Von Hippel developed a lead user method as an integrated means of marketing research and product design (v. Hippel, 1986; Hearstatt & v. Hippel, 1992). The user-centered and co-developmental design methods have been developed in the planning of computer software systems (Brun-Cotton & Wall, 1995) and industrial automation systems (Corbett & al., 1991). We will elaborate upon a dialogical and interventionist approach, in which the research objects actively participate in the construction of interpretations (see also Miettinen, 1993). The multiple voices of the participants are retained in the analysis. The researcher has his or her own voice and means of contribution. The researcher can bring novel concepts, pieces of data and results as means of influencing the innovation process and of helping the key participants reconstruct their mutual relationships.

We will first introduce the neuromagnetometer device and the emerging local network of producers and users connected to its development. Second, we will discuss the concept of user need and how it was applied in a user seminar organized jointly by the researchers and Neuromag Company. To further elaborate on the concept, we will analyze the points of view presented by two surgeon groups in the user seminar. Third, we will analyze the central contradiction in the producer-user network: the inability of the three producers to meet the expectations of the clinical users. Finally, we will present our conclusions on the dynamics of transition in the producer-user relationships, on the concept of the user need and on the participation of the researchers in the innovation process.

2 Neuromag and the MEG device

The object of our study is the development of a neuromagnetic measuring device for brain research and diagnostics. It is called neuromagnetometer, and its use in studying brains is called magnetoencephalography (MEG). The device was originally developed at the Low Temperature Laboratory of the Helsinki University of Technology during the 1970s and 1980s. Neuromag Company was established in 1989 to commercialize this innovation developed by the physicists and engineers at the Laboratory. The personnel of the company came from the Low Temperature Laboratory, and there still is a continuous and close collaboration going on between Neuromag and the Laboratory. The R&D contract between them, for instance, stipulates that a prototype of the next product version will be installed at the Low Temperature Laboratory.

Magnetoencephelography (MEG) is the measurement of extracranial magnetic fields produced by electrical currents within the brain (Hari & Lounasmaa, 1989; Hämäläinen & al., 1993). In MEG recordings, weak magnetic fields outside the head are detected with an array of sensors, and on the basis of the measured signals, the underlying cerebral currents are estimated. Since cerebral magnetic fields are extremely weak when compared, for example, with the Earth's magnetic field, special devices are needed to measure them. Development of sensitive SQUID (Superconducting Quantum Interference Device) sensors allows the detection of small changes in the magnetic fields. The sensors can function only at low temperatures, and they are located within a container filled with liquid helium at low temperatures, -269 degrees Celsius. With a multi-channel instrument, the data can be collected simultaneously from several points on the head, which shortens considerably the time needed to map the entire field distribution. To reduce the effect of environmental noise sufficiently, measurements are performed in a magnetically shielded room. State-of-the-art electronics and computer systems are also needed to reconstruct the images (Fig. 1). Additional programs used in analyzing and modeling the measurement data are also an essential part of the Neuromag system.

INSERT FIG. 1 HERE

Figure 1. Measurement setting and overview of the MEG system.

The prototype version of the first whole-head neuromagnetometer on the market was built by Neuromag in 1992. Industrial R&D funding for the development of the device was granded for several years by the Technology Development Center of Finland (Tekes), the Finnish National Fund for Research and Development (Sitra) and the Instrumentarium Corporation. The cost of the system is about 2 million US dollars. The device is installed in Finland, in the Low Temperature Laboratory of the Helsinki University of Technology and in the Biomag Laboratory of the Helsinki University Central Hospital. In addition, the company has sold several installations to Japan, to Germany and to the United States. In addition to Neuromag, there are two other MEG suppliers, one in Canada and one in the United States.

3 Local network in transition³

The first MEG models were used primarily in basic research on neuromagnetism and in studying the functions of the human brain. The Brain Research Unit of the Low Temperature Laboratory was founded in the 1980s. It used MEG in research of the functional location of brain activities and in the study of human auditory, visual, somatosensory, and motor systems (Hari & Lounasmaa, 1989). For the most part, MEG has been used to measure healthy adults. Based on this research, the Brain Research Unit and the Cognitive Brain Research Unit of the University of Helsinki have published scientific papers containing novel information about the activity of the brain.

A new phase in applying MEG began in Finland when the MEG device was installed at the Helsinki University Central Hospital, in 1994. The BioMag Laboratory was founded by the Helsinki University of Technology (HUT), the University of Helsinki and the Helsinki University Central Hospital. It was organized as a separate research laboratory that was not affiliated with any hospital clinic. In spite of the hospital setting, however, the tradition of using MEG in basic research was reflected in the ways the measurements were organized and conducted in the laboratory. Most of the users were doctoral students collecting data for their dissertations. With the exception of one nurse, there was no permanent staff for the maintenance of the device or for the measurements services. The doctoral students helped the senior researchers and medical doctors who came to perform measurements to the laboratory. Thus far, MEG has been used predominantly as a scientific instrument in the BioMag Laboratory.

Only a few clinical users have been active in trying to use the MEG measuments in their work. Two of them were the epilepsy surgery team at the Kuopio University Hospital and the brain tumor surgery team at the Helsinki University Central Hospital. The epilepsy surgery team was studying whether the MEG can be used as a tool for presurgical localization of epileptic foci. The team expressed the need for more accurate methods to develop and expand epilepsy surgery for more demanding cases. While the team was put together of practitioners of various hospital departments, it seems to form a community of actors with regular meetings and collective decision making. The coming together of the brain tumor surgery team at the Helsinki University Central Hospital was also based on collaboration between the hospital clinics.

When we started our study in 1996, the managing director of the company underlined the necessity of acquiring new markets for MEG. In a marketing plan made in 1995 the company regarded the basic research market as too limited for maintaining the production of MEG, in the long run. On the other hand, the company anticipated a rapid growth of the clinical market. The owners of the company also stressed the necessity of acquiring new markets. This transition, however, would require further development of the device, services related to it and changes in the structure and collaboration of the producer-user network.

As the company was looking for a breakthrough in clinical markets, we focused our analysis on potential clinical users only. The basic-research groups using MEG were omitted. The selection of the Finnish clinical user communities was based on several sources of data, among them the measurement diary of the Biomag Laboratory and interviews with the Laboratory personnel and the users. In January 1997, we organized a user seminar jointly with

³We concentrate on the analysis of the national Finnish network, omitting the relationships with the institutions using MEG in Europe, Japan and the United States.

Neuromag. We invited to the seminar the four clinical users, performing or planning at that time to start, MEG registrations in their clinical practice.

For the analysis, we have chosen data on two potential user communities: the epilepsy surgery team at the Kuopio University Hospital and the brain tumor surgery team at the Helsinki University Central Hospital. These two communities are the emerging clinical users. Epilepsy surgery and brain tumor surgery are also considered by MEG literature to be the most promising clinical applications of MEG (Lounasmaa & al., 1996; Lewine & al., 1995).

INSERT FIG. 2 HERE

Figure 2. Product and network in transition: the Finnish network of producers and users

Figure 2 presents the local network relevant to the development of the clinical use of MEG. We are considering the three activity systems in the middle of Figure 2 - Neuromag, the BioMag Laboratory and the Low Temperature Laboratory - the producers and developers of MEG. Their contribution is necessary for solving problems related to the development of the clinical use of the device. The Kuopio epilepsy surgery team and the Helsinki brain tumor surgery team, represent the clinical users. We suggest that the analysis of these five activity systems will sufficiently cover the essential challenges and problems related to the transition from the basic research use of MEG to its clinical use.

4 User seminar as an intervention in the research process

Our research project on the development of MEG started in collaboration with Neuromag. The managing director of the company was interested in the research problem, the producer-user network, and immediately realized its relevance to the major challenge of the company: the construction of clinical markets. It was agreed that the results would be discussed with the company as soon as possible and sensible. However, the manner, form and time of this discussion was not planned or decided beforehand.

In spring 1996, the main participants of the innovation network were interviewed. An ethnographic observation was conducted in the BioMag Laboratory, and measurement situations were videotaped. After identifying the main clinical users, the researcher started to interview them in order to make an analysis of their activity and needs in relation to the use of MEG. In late autumn in 1996, an idea emerged in the discussion between the researchers and the company that the time might be right to organize a user seminar, where all the appropriate clinical users could present, in an organized way, their conceptions of the need and usability of MEG. The model of the "lead user" seminar, reported by von Hippel (1986), inspired this decision. All the clinical users showed an interest in the seminar, and so did the developers of MEG. This was the first time all the appropriate actors would gather together to discuss the development of the clinical use of MEG. The user seminar "MEG in Clinical Use" was organized in January 1997 by the researchers and Neuromag. The presentations and discussions in the seminar were videotaped and form a valuable source of the data used here to analyze the transition of the innovation network.

⁴We didn't use von Hippel's method of analyzing the customer field for defining the lead users. There were no clear clinical lead users in Finland.

When planning the seminar, we pondered the question of how the collective, contextual and diffuse nature of needs could be analyzed? The term *need* is mostly used in economic and marketing literature without any clear definition.⁵ It often refers – almost as if it were a psycho-biological concept - to "intrinsic needs", a state of driving unrest or deficiency of a biological organism. One of the Russian architects of activity theory, A.N. Leont'ev suggested that this kind of need state cannot explain the direction of the activity. A *need* turns into a motive, a directing force, only when an agent is able to find, or define, an object for him or herself and the means of obtaining it (Leont'ev 1978). This transition from a need state into orienting towards an explicit object is a complex process presupposing analysis of the environment, the present activity and its critical problems. Definition of a need state in the case of a firm or a collective activity system is unclear. Activity theorists (Engeström, 1987), historians of technological systems (Constant, 1984; Hughes, 1987) and sociologists (Weingart, 1984) suggest that it could be understood as an internal tension, critical problem or a contradiction in the system manifesting itself in many ways.

Howell (1997, 1211) – like also the representatives of contextual design - suggests that the needs should be derived from the existing patterns of use (see Beyer & Holzblatt 1996, 9). Understanding the user activities is, of course, essential. However, user activities change, and there are no established patterns of use for a radically new product or process. Often this product is integrated to the development of user activities as potentially complementary (not alternative) to the existing range of means. In such a case, it is necessary to analyze the user activity broadly, independent of the particular innovation, in order to understand its key challenges. As Norman and Ramírez fittingly propose (1994, 62): "Instead of being concerned to identify and fulfil customers needs it is more helpful, and strategically more relevant, for the supplier to focus on identifying and offering activities which complement its customer's activity processes."

For the seminar, we proposed that a user need should be analyzed at two levels: on the level of the development of user activities and on the level of the situated use of the artifact. A need for a new product necessarily involves some kind of a hypothesis of the use value of the product, its anticipated capacity of solving the emerging problems and challenges of the user activities in new ways. On the other hand, the suitability of the product, its compatibility with the existing system of tools and established forms of work and collaboration is important. This usability becomes visible and analyzable in the practical use of the artifact.

The concrete actions of using of an artifact take place, necessarily, in a certain place, time and community, that is, situationally. A situation, however, can be theoretically understood and analyzed in a variety of ways. Activity theory does not focus, primarily, on the regular patterns of use, but rather on the problems and disturbances of these patterns, which are, then, interpreted in the light of the history of the activity. These disturbances reflect the historically formed systemic contradictions of the activity. Accordingly, the disturbances in the tool use and communication are seen as a developmental opportunity. It has been shown in the studies on the implementation of complex artifacts that disturbances and ruptures are not only something to be eliminated, but also an important source of development (Engeström & Escalante, 1996; Toikka & Kuivanen, 1993). They are the realistic "critical points" providing, through their resolution by innovative measures, a perspective for further developmental

use value of the product can be expected. It has to be constructed in cooperation with the users (Green, 1992).

⁵In innovation studies, the concept of need was connected to the theory of market demand. Several authors have shown that the concept of need in this connection is "shapeless and elusive" (Mowery and Rosenberg, 1979, 140). Especially in the case of innovations, of radically new products, no articulated demand or concept of the

work. The activity theoretical approach adopts these critical points as its starting point for development, instead of such external normative goals as effectiveness, or job satisfaction, that are not derived from the analysis of the activity itself.⁶

Therefore, in the letter sent to the participants, we asked the users to assess their position in relation to MEG, using the following two-level scheme:

- 1. ANALYZING THE USE VALUE OF THE ARTIFACT FOR THE USER ACTIVITY IN HISTORICAL PERSPECTIVE
- 1.1 What kind of evolving problem or contradiction in the activity does the device and method solve and why?
 - a) potentially, in the long run
 - b) in a shorter perspective
- 1.2 Compatibility with other devices and methods used
- 2. ANALYZING THE SITUATED USE OF THE ARTIFACT
- 2.1 Availability and feasibility the measurements (usability, instrumental disturbances and problems during the measurements)
- 2.2 The support for use and collaboration in the measurement (disturbances in communication and collaboration)
- 2.3 The availability and usability of the analyses and the usability of the software

Each of the clinical users gave a presentation in the seminar. All were free to comment immediately. After the presentations the producers and developers gave their comments.

Different actors of the innovation network have different points of view, interests and goals in relation to the artifact. According to the constructivist sociology of technology (see e.g. Pinch & Bijker, 1987), an artifact is constructed through negotiation, by trying to reconcile the different and often contradictory goals of the actors, translating them first into specifications of the artifact and finally into technical solutions. The analysis of the interests or viewpoints of the actors is, hence, important for understanding the innovation process. In our analysis, however, this is not enough. By analyzing the viewpoints of the actors, we expect to find tensions and contradictions between the activity systems calling for solutions. These contradictions emerge from the historically formed objects, means and rules of the participating activities. These contradictions, or critical problems, manifest themselves as differences in points of view, disturbances in communication and barriers to new forms of collaboration.

The definition of a critical problem or a contradiction orientates the participants of the network to finding ways to solve it. This can happen by changing the forms and rules of collaboration or by developing a new conception or a new technical solution. The historians of technological systems understood the nature of the development of technology in an analogous way: finding and defining the problems of an evolving system and then, finding solutions to them (Hughes, 1987). Accordingly, we start from the analysis of the users' points

⁶ About the activity theoretical interpretation of situatedness, see Cole & Engeström, 1993 and Engeström & Cole, 1997. The disturbances of the situated use of the neuromagnetometer, based on the data of the MEG measurements in a hospital laboratory, are also analyzed (Hasu & Engeström, 2000).

of view, then study how the producers react to them and finally proceed to an analysis of the basic tensions in the network.

5 The points of view of the clinical users

We suggested that the user needs of a new technology could be understood as newly emergent and having several dimensions. These needs are related to the major challenges of the user activities, collaboration with other activities, and to the existing tools and organization of the tool use. In this section, we strive to gain further understanding of these different dimensions by analyzing how the representatives of the two surgical teams articulated the various conditions of the possible use of MEG as a diagnostic tool for brain surgery. Analyzing these views, we intend to construct a more comprehensive picture of the different dimensions of user needs and the conditions of the emerging use of MEG. We will show the interdependencies between the dimensions and evaluate the two-level scheme formed for the seminar. Identifying and defining the conditions of the emerging tool use, we simultaneously recognize the areas where measures should be taken to secure the progress of the innovation process itself.

Five members of the *Kuopio Epilepsy Surgery Team* (from the Kuopio University Hospital KUH) participated in the seminar by giving a presentation. The comments included five different points of view concerning the use of MEG in their activity. The second clinical entity having a voice in this paper is the *Brain Tumor Surgery Team at the Helsinki University Central Hospital* (HUCH), by the strength of the two members of the group, a senior neurologist and a doctoral student. We analyzed the presentations and pinpointed the main arguments or points of view.

We categorized the statements into five *categories* (A-E). Then we analyzed how the categories were compatible with the hypothesis we had about the two *levels* of analysis (the use value of the artifact for an activity in a historical perspective and situated use of the artifact). We discovered that a new level was needed, in addition: the theoretical and practical tools of clinical decision-making. The categories were then placed on the levels: A and B to level 1 (use value), C and D to level 2 (the tools of clinical decision making) and E to level 3 (the situated use of the artifact). The results of the analysis are resumed in Table 1. In the following, the viewpoints of the two user activities are presented in the line of the three levels thus formed. We have underlined the key expressions of the statements to facilitate reading.

Level 1. Use value of MEG

The four viewpoints included in category A characterize the problems of brain surgery that may be more readily resolved with the information obtained by MEG. All these problems refer to the potential use-value of the method. However, MEG was mentioned only as one possible source of information in solving these problems.

Viewpoint 1. MEG is needed - in addition to other methods - to increase the understanding of the conditions and consequences of surgical operations

"It seems that we have managed to do the epileptic localization with the methods available at the moment. But the patients still have certain problems after surgery, for instance various neurophysiological and neuropsychological problems such as severe depression, psychosis etc., which we don't know the cause of. Therefore, we still need more neurophysiological information before surgery. MEG is one of the methods we are evaluating to be used for this purpose." (A professor, a neurosurgeon, KUH)

Viewpoint 2. MEG is needed in planning the brain tumor operations to avoid complications - not in diagnosis

"In the diagnostics of brain tumors we definitely don't need neurophysiological methods, but we need them when we start to plan to remove the tumor. Then we have <u>certain problems: can we operate in a certain area, will the patient have a paralysis etc.</u>? This is a practical question for us and the cases are very complicated." (A neurologist specialized in brain tumors, HUCH)

Viewpoint 3. MEG will be needed to gain more information about patients with complications and others who have already been operated on

"We have patients who have not been operated on (because of the location of the tumor /R.M. & M.H.). We also have several patients who have been operated on, and we are trying to decide whether to operate on them again. And not all of our patients have been in MEG registration yet." (A neurologist specialized in brain tumors, HUCH)

Because not much is known about the effects of the use of MEG, the conceptions of its significance are hypotheses that need further studies. One of the members of the Kuopio team expressed this very clearly by suggesting decreasing invasive measurements.

Viewpoint 4. The use of MEG in reducing invasive (putting electrodes inside the skull) registrations

"What particularly motivates us is the <u>wish to reduce invasive registrations.</u> (...) At this moment we can't give any solid opinion about the accuracy or usefulness of MEG in the localization of epileptic seizures compared to other methods we use." (A clinical neurophysiologist, MD, Ph.D., KUH)

Category B involves a vision of a potential use that would significantly change the diagnostic practice in epilepsy surgery: the making of measurements during the epileptic seizure.

Viewpoint 5. A major possibility for epileptic surgery: MEG registration during the epileptic seizure (ictal registration)

"If the technology could be developed to the extent that it would be possible to perform registrations over several days in order to gather information during an epileptic seizure, then I would say that MEG would be a notable method for replacing invasive registrations. It would probably mean the development of a new technology which would fit into the space of a helmet and would let the patient move during the registration." (A neurologist, KUH)

This aim, however, would require the patient to wear the device without a break for a long time. This, in turn, would require "a mobile MEG device", some kind of a helmet. The present device is massive because the superconductivity in SQUID (superconducting quantum interference device) sensors require a rather large container of liquid helium (with a temperature of -269 °C). A mobile device would demand a major change in the basic technology, a leap from low temperature to high temperature materials. This shift is considered "a mission impossible" among the physicists, at the moment. It is hard to imagine a SQUID functioning at a room temperature.

Level 2. Theoretical and practical tools of clinical decision-making

Category C lists the viewpoints related to the method and the interpretation of the measurement results. The "basic problem for all of us" - the relation between interictal and ictal information - is an open and scientifically challenging question calling for systematic research and theoretical work. However, once clarified, it will decisively contribute to the definition of the usability of MEG in epilepsy diagnostics. This shows, how theoretically demanding the task of defining the "user need" can be. The interest in brain tumor diagnosis raised the question of combining MEG with another method, the magnetic resonance imaging (MRI).

Viewpoint 6. The need for understanding the significance of interictal data for epilepsy diagnosis

"I think the <u>basic problem for all of us is the relation between interictal</u> (between main seizures) - which is the information we actually can get from MEG - <u>and ictal (during a seizure) information</u>. Do we have any procedures to establish whether, for instance, a manipulated interictal finding is enough to give notable additional information for epilepsy diagnostics?" (A clinical neurophysiologist, MD, Ph.D., responsible for the MEG measurements and analysis of the Kuopio team)

Viewpoint 7. Combining MRI and MEG for the planning of operations

"The surgeons have stressed the <u>need for this kind of three-dimensional MRI reconstructions</u> of the brain with the MEG dipole location before the operation." (A radiologist, working on a doctoral study about the integration of MEG and MRI, HUCH).

Category D consists of a tool needed in the clinical decision making: the standardized control data. Availability of such information forms the basis for the development of the method and the interpretation of results in clinical decision making. The significance of MEG results being obtained from a particular patient stems, partially, from their availability for comparison with the corresponding results from the "normal" population. As the neurologist of the Kuopio epilepsy surgery team stated, a database and related network should be established. The problem is the deciding of who should organize and maintain such a database.

Viewpoint 8. Reliable control data is needed – under whose responsibility?

"The second problem is the shortage of reference and control data. (...) The question is where this kind of database would exist, who would be responsible for up-dating it and how this kind of network would emerge? (A clinical neurophysiologist, MD, Ph.D., responsible for the MEG measurements and analysis of the Kuopio team)

Viewpoint 9. The need for reliable research results to convince the clinicians

"As a clinician it seems to me that these studies need to be <u>well documented and published and</u> <u>in this way demonstrate their usefulness in practice</u>." (A neurologist specialized in brain tumors, HUCH)

Level 3. Situated use of MEG: organizing measurement and analysis services

Category E is related to measurement and analysis services. Both the clinical users mentioned the necessity of reliable, feasible measurement and analysis services for clinical use. This kind of development of services requires, among other things, solid neurological knowledge, usable analysis software, the feasibility of the device itself and efficient organizing of the measurements at the measurement site, as well as electronic transmission of the results to the users. The creation of routine services is, therefore, a fairly complex collaborative enterprise.

Viewpoint 10. The need for qualified services in data analysis

"In practice the most important issue for us is the data analysis. The analysis is really a problem for us, it is <u>laborious</u> and time consuming. In order to accomplish the analysis on the whole, there should be either a competent person doing it here in Helsinki or an electronic connection from Kuopio to some workstation, which is located in Helsinki and would have the relevant programs. Without one of these two arrangements this work will be all too difficult and it is hard to say whether it (MEG) would be useful in the final analysis or not." (A clinical neurophysiologist, MD, Ph.D., responsible for the MEG measurements and analysis of the Kuopio team)

Viewpoint 11. The need for a routinely maintained service for the localization within the motor cortex

"I believe that surgeons would send the tumor patients to MEG registration routinely - if such a registration service existed. I also hope that tumor patients from other central hospitals will be able to register in Helsinki." (A neurologist specialized in brain tumors, HUCH)

| Level | Category | Kuopio epilepsy surgery team | Helsinki brain tumor surgery team |
|---|---|--|--|
| Use value of MEG | A. Brain surgery problems requiring more information - MEG can probably help | Pre-surgical planning (1) Reduction of invasive registrations (4) | Pre-surgical planning (2) Patients with complications and those already operated on (3) |
| | B. New use requiring change of the technology | Ictal (during seizure) registrations (5) | |
| Theoretical and practical tools of clinical Decision- making | C. Problems related to the use of MEG requiring more research and understanding | Significance of interictal (between seizures) data (6) | Combining MEG and MRI (7) |
| | D. Problems of collecting reference and control data | Reference and control data – who is responsible? (8) | Published studies to demonstrate the usefulness of MEG (9) |
| Situated use of MEG | E. Problem of organizing measurements and analysis services | Data analysis - need for competent personnel and electronic connections (10) | Need for routine registrations (11) |

Table 1. Problem categories presented in the statements of the epilepsy surgery team and the representatives of the brain tumor surgery team concerning the clinical use of MEG in historical perspective (the numbers after statements refer to the quotations in the text).

There is an interdependence between the issues included in the categories presented in Table 1. The potential use value of MEG to solve problems related to epilepsy and brain tumor surgery (category A) requires a better understanding of the significance of the MEG results in relation to them (category C). This, in turn, requires organized research and development. The collection and comparison of standardized data is a precondition for this type of research and development work (category D). The feasibility and standardization of measurements and analysis services (category E) is a minimum condition for the production of such data. It is also a precondition for the users to start a more systematic utilization of the device and the method.

The concerns presented by the users revealed the complexity of the conditions influencing the implementation of new technologies. They illustrate the key idea of activity theory: object and subject constitute each other in the same process. MEG, as a clinical tool, will emerge when surgeon groups learn to use it as a diagnostic instrument, and hospitals are able to organize the measurement and analysis services. The creation of mediating artifacts is needed in the process. The second level of user need, the need for theoretical understanding of MEG measurements, the need for reference data as well as the need for combining MEG with other imaging technologies, exceeds the horizon and possibilities of a single activity or customer, calling for extensive collaboration between several organizations. Collaboration between several key actors is indispensable to make MEG into an established clinical tool.

A major contradiction in the transition process: the inability of the network of producers and developers to meet the user expectations of services

The users participating in the seminar presented several types of conditions for the effective implementation of MEG as a clinical tool for surgery. In this section, we shall analyze how the local network of producers (see Figure 2) copes with these expectancies, especially the most obvious and urgent one, that of the availability of routine measurement and analysis services. It will be argued, that the network fails to meet these expectations efficiently, owing to the orientation and patterns of collaboration which were formed to serve basic brain research. We will analyze, how this historically formed orientation persisted and resisted transition towards the clinical use, thus constituting the major contradiction in the transition.

We will apply the cultural-historical concept of activity to the analysis of the motives of participation and the expertise of the producers of the local network. Accordingly, we will ask three questions. First, what are the objects and motives of activity, the agenda of each of these activity systems? Second, what kind of know-how and resources do the activity system have to be able to meet the expectations? Third, what kind of collaboration do they engage in, and need to engage in, for developing the product? The analysis of these questions is based on the historical data and on the statements of the producers that were presented in the user seminar. The results of the analysis of the first two questions - concerning the motives and expertise of the developers - are presented in Table 2.

| PRODUCER | OBJECTS AND MOTIVES OF ACTIVITY | EDUCATION AND EXPERTISE OF PERSONNEL | |
|---|--|---|--|
| BioMag Laboratory at the Helsinki University Central Hospital | Providing registration time and workstation time for researchers and clinicians Development of technology by integrating MEG to other imaging technologies Organizing graduate school of Functional Imaging in Medicine Clinical probing to find out the possibilities of MEG | A technical physicist, head of the laboratory (Ph.D. in neuromagnetism) and a nurse (background in EEG- nursing) Graduate students with different backgrounds (for instance technical physics, cognitive psychology, neurology) working with their Ph.D. studies | |
| Low Temperature Laboratory at the Helsinki University of Technology | Studying the functioning of the brain by using MEG Organizing graduate studies and producing scientific publications Clinical probing to find out the possibilities of MEG | A senior clinical neurophysiologist, head of the Brain Research Unit (MD, Ph.D.), several post-doctoral researchers and graduate students with different backgrounds (also medical doctors) Recently hired nurse (background in EEGnursing) | |
| Neuromag Company Design and development of commercially competitive device | | President of the company and several product developers: background in technical physics (low temperature physics and neuromagnetism), a marketing manager (background in software engineering), after sales manager (background in technical physics) and production manager (electric engineering background) | |

Table 2. Objects of activity and expertise of the personnel of the Biomag Laboratory, Neuromag and Low Temperature Laboratory in January 1997.

The BioMag Laboratory is led by a physicist. One of the interests of the laboratory is the idea of combining the MEG method with other methods of diagnosis (for instance MRI). The BioMag Laboratory had also an interest in developing its own research on the possibilities of the use of MEG. To a certain extent, it has a research program competing with the research being done at the Low Temperature Laboratory. The research-oriented approach is evident in the organization of the laboratory. The basic unit of organizing the measurements is the research project. The laboratory manager expressed this orientation in his comment on the user laboratory:

"When the BioMag Lab was established, the principle was accepted that the MEG research would be free of charge and different groups would be able to perform research freely according to their interests. (...) The strategy that has been chosen is that we have both clinical research and basic research at the Lab. Then we have areas in between, measuring various patient groups and probing various clinical options. (...) It is not our intention to create a lab such as the one in Albuquerque, which performs mainly routine clinical studies (...) We find it also important to integrate MEG to other technologies such as MRI. (...) I believe that we will have the money needed to start the clinical work this year."

The graduate students contribute by helping with measurements and by preparing the device for measurements in the Laboratory. This organizational arrangement - typical in basic research - does not make routine measurements possible for clinical users. There is no neurological expertise or analysis service available at the Laboratory. Without such expertise, the development of the analysis services is impossible. Therefore, with the present personnel and organization of measurements, the BioMag Laboratory is unable to develop the services pointed out by the users as an essential first step towards the development of clinical use.

Neuromag is oriented to the design and supply of a commercially successful device. Since the designers are technical physicists from the Helsinki University of Technology, they have focused on the technical possibilities of the device. The central line of development and a method of securing the competitiveness of the device (as compared to the competing American and a Canadian MEG devices), is increasing the number of SQUID sensors which makes larger brain areas detectable. Information about a new generation model of the MEG device was published in late 1996. The two major features of the version were the increased number of SQUIDS (306 instead of the 122 of the preceding model) and the possibility of a reclaining instead of upright position of the patient. On the other hand, owing to the pressure coming from the owners, the management of Neuromag knows very well that it is necessary to create clinical applications and access to clinical markets. In the words of the managing director of Neuromag (a technical physicist, Ph.D.) in the user seminar:

"We have to understand the plain truth that MEG is a difficult and demanding technology and method. To develop MEG to a very simple routine use is, in my mind, nearly impossible. It will always need interaction with a competent person who understands both the method and the patient. But to survive, MEG needs some clinical application, that is obvious. The fact that various ambitious research groups make use of it is not enough for its survival and flourishing. So we will need some clinical application which will help clinicians in their everyday problems and which doesn't make things more difficult, but, instead, helps the work of neurologists and neurophysiologists."

The clinical use requires not only the development of the device but, first of all, the development of services related to it: measurement, analysis, interpretation of results and validation of data. Because of the expertise of the personnel (in physics and engineering), Neuromag is unable to develop and supply such services alone. In addition, its network and client relations were formed through the scientific connections of the Low Temperature Laboratory. The firm has no direct collaboration with clinical users. The knowledge of clinical use has been transmitted through the Low Temperature Laboratory and the laboratories in which the device has been installed.

The Low Temperature Laboratory Brain Research Unit has a strong tradition of neurological and neurophysiological basic research. The group continuously trains graduate students, including medical doctors, from the Helsinki district. The laboratory has evidently the best theoretical knowledge of the possibilities of MEG in researching brain functions as well as in clinical use. However, the Laboratory is first of all interested in publishing scientific papers and organizing graduate studies ("Our outputs are scientific articles"). Consequently, it is not interested in making the large-scale validation studies needed for reliable clinical use of MEG, or in organizing routine clinical services. These tasks would be impossible also because the Laboratory and the Brain Research Unit are located in a technological university. The comment of the head of the Brain Research Unit at the Low Temperature Laboratory (a senior clinical neurophysiologist, MD, Ph.D) stressed the significance of neuroclinical expertise as a precondition for developing reliable clinical analysis services:

"In order to work with MEG successfully, you have to know something about the magnetic fields, quite a lot about the method, but the most important thing is to know a great deal about the brain. Knowing only about the method isn't enough. (...) The danger of bad training is 'overdiagnostics' and quasi-accuracy in analysis. I have seen this kind of material coming from different places. (...) I am saying that MEG is not an object of study for physicists anymore, it is an object for neuroscientifical study. (...) Is it really possible for a clinical unit to operate so that the doors are open to everybody: come and measure your own patient? Who will guarantee the reliability of the analysis and the interpretation? In my opinion, a clinical unit should not operate in this way. There should be permanent, trained personnel responsible for the measurements and analysis. Basic research should be done elsewhere."

There is a trap hidden in the established relationships between the producers and developers of the MEG method in the Finnish network. Because of their motives and capabilities and because of the established division of labor between them, nobody takes responsibility for developing the analysis services and validation necessary for the clinical use of MEG. This structure reflects the preceding phase of the MEG development, in which the network developed MEG as a tool for basic research of the brain. It does not support or stimulate the transition to clinical use of MEG. The transition, therefore, requires new kinds of collaborative relationships in the network. The failure of this transition, however, would not only negatively affect the company, but also the two MEG laboratories. Who would support and maintain the MEG systems if the company did not?

7 Conclusions

The case shows how the transformation of MEG from an instrument of brain research into a means of making clinical decisions requires change both in the structure of the network and in the forms of interaction between its actors. We proposed that the concept of a local activity system is fruitful in studying the dynamics of this type. An innovation network can be analyzed as a network of developing activity systems, each having its historically formed object, know-how and resources. The interests and points of view of the participants become understandable on the basis of the history and current problems of their activities.

The case showed that a transition in the innovation network does not take place without problems. The actors and networks tend to work according to the motives, premises and rules of the previous phases of development, which may contradict an attempt to create a new market and corresponding network collaboration. We suggest that the trap found in our case might be typical of the science-based innovations emerging from the basic research contexts. The motives and expertise of producers and developers are connected to the scientific and technical content of the innovation. Neither the orientation to the user activities nor the expertise related to product design and marketing are very strong. The development of the product is funded because of the novelty of technology and the reputation and quality of the research related to it. As a consequence, the properties of the product emerge more from the motives of scientific activity than from the user needs. Therefore, the development of user collaboration in the early stages of the innovation process is particularly important in these types of innovations.

This case suggests that the analysis of the tensions of the innovation network has an obvious merit if compared with the mere description of controversies or divergent viewpoints of the actors. The analysis raises problems that are directly relevant both to the producers, developers and the users. The problems and contradictions call for solutions and learning.

This recognition can stimulate the participants of the network to reconsider their conceptions of the common object and the mutual forms of collaboration.

This case also suggests that the concept of activity can be fruitfully used in the articulation of the potential needs, that are not yet ready there to take. They are something that evolves in time and are constructed together with the producers and users. We presupposed that a two-level analysis is needed to chart the evolving user needs. First, it was suggested that an analysis of use value is needed in terms of history and the critical problems of the user activities. Second, the analysis of the situated use of the product was suggested. However, the data showed that an additional level is required, the level of the construction of the collective, global tools needed in the use of the product. On this level, the necessity for collaboration between several communities is obvious.

The user activity covers a chain, or a network, of actors within the hospital environment: the measuring laboratory, units specialized to diagnostic imaging, and surgeon groups. Therefore, the collaboration between various clinics is indispensable for the establishment of the measurements service. Both the production of tools for clinical decision-making (such as reference data) and the organization of the use of MEG within the hospital organization require analysis on the level of network relationships and collaboration between the actors in the network.

The construction of these networks can be characterized in terms of business activity and in terms of the development of user activities. In business economics, the creation of a network is characterized as "a reconfiguration of roles and relationships of actors in order to mobilize the creation of value in a new form and by new players" (Norman & Ramirez, 1993), or as the creation of institutional conditions for market transactions (Green, 1993). From the perspective of use value, these networks are the means of transformation of medical practices and collaboration (Blume, 1992), in order to create new knowledge and tools for advanced forms of medical work. Both aspects should be included in the analysis.

Because the data of this paper consists mainly of the discourse in the user seminar, issues related to the situated use of the device and the disturbances of measurements have been analyzed in another paper (Hasu & Engeström, 2000). Also the organization of the measurement services in an American hospital (Veteran's Hospital in Albuquerque) has been studied (Hasu, 2000). These studies have shown convincingly the significance of the division of labor and organizational issues for the implementation of the device. They also uncovered the difficulty experienced by the producers and users in forming a shared perspective on the causes of the disturbances in measurements.

The dialogic and interventionist approach of our study differs both from the mainstream sociological and economic studies of innovations and from the tradition of design studies. In the studies focusing on the dynamics of innovation networks, the researcher collects data but does not actively intervene in the innovation process. In the participatory design studies, in most cases, the researchers are simultaneously developers of the product. In our study, the dialogue with the participants of the innovation process emerged in a natural way out of the research process. Having interviewed the key actors, we had a fairly good overall conception of the motives of the participants. We also had observations of the quality of collaboration between them. On the basis of this knowledge, we had an opportunity to participate constructively in the dialogue between the producers and users. The user seminar produced

valuable data for the researchers and, at the same time, offered an opportunity for an actor dialogue about their mutual relationships and the product itself.

The analysis presented in this paper was given to the practitioners in the form of a conference paper two months after the seminar. The key practitioners commented on the paper before the conference. These discussions served three complementary functions. First, they were a means of validation of the researchers' conclusions. Second, they helped maintaining and constructing trust between the researchers and practitioners. Third, they were used by the practitioners as a means of reflecting on their own activity. The user seminar and the conclusions of this paper, as mentioned before, led to practical measures on the part of the producers. The research, therefore, confirms the possibility of a dialogical and interventionist approach in innovation studies.

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