RESEARCH PROTOCOLS AS A VEHICLE FOR THE (RE)PRODUCTION OF KNOWLEDGE

Bjørn Erik Mørk[a]
Margunn Aenestad[b]
Gunnar Ellingsen[c]

[a]Department of Telemedicine, Medical faculty,
University of Tromsoe, Norway
bjorn.erik.mork@rikshospitalet.no

[b]Department for Informatics,
University of Oslo, Norway
margunn@ifi.uio.no

[c]University Hospital of Northern Norway, Norway
gunnar.ellingsen@unn.no

Session C-2

Abstract

In this paper we focus on the role of research protocols in the production of knowledge. We have studied the creation and use of protocols within actual research projects in a medical R&D department. This department is cross-disciplinary organised and concerned with innovation of new technologies and procedures. The research protocols in use are modelled on the traditional protocols used in the medical academia, which is highly specialised along disciplinary borders. Our research questions focus on the implications of the research protocol for the novel cross-disciplinary and innovative approach at the department. We find that both the protocol and the practices around it, to some degree reproduce these divisions and limit innovation. Consequently, research protocols, along with any other element of the 'machineries for knowledge production', should be studied by researchers interested in gaining a better understanding of knowledge production.

Keywords: protocols, standards, cross-disciplinary work, epistemic cultures.

”Research protocols as a vehicle for the (re)production of knowledge”

Bjørn Erik Mørk a,
PhD Margunn Aanestad b,
PhD Gunnar Ellingsen c,

a. The Interventional Centre
Rikshospitalet
0027 Oslo, Norway
bjorn.erik.mork@rikshospitalet.no
b. Department for Informatics
University of Oslo
Postbox 1080 Blindern
0316 Oslo, Norway
margunn@ifi.uio.no
c. University Hospital of Northern Norway
9038 Tromsø
Norway
gunnar.ellingsen@unn.no

Abstract

In this paper we focus on the role of research protocols in the production of knowledge. We have studied the creation and use of protocols within actual research projects in a medical R&D department. This department is cross-disciplinary organised and concerned with innovation of new technologies and procedures. The research protocols in use are modelled on the traditional protocols used in the medical academia, which is highly specialised along disciplinary borders. Our research questions focus on the implications of the research protocol for the novel cross-disciplinary and innovative approach at the department. We find that both the protocol and the practices around it, to some degree reproduce these divisions and limit innovation. Consequently, research protocols, along with any other element of the ‘machineries for knowledge production’, should be studied by researchers interested in gaining a better understanding of knowledge production.

Keywords: protocols, standards, cross-disciplinary work, epistemic cultures

Suggested track: C Knowledge creation and innovation

5th European Conference on Organisational Knowledge, Learning and Capabilities,
University of Innsbruck, Innsbruck, Austria, 2.-3. April 2004

1. Introduction

Knowledge has many aspects, and since the literature on knowledge sharing and production[1] is wide and fragmented, it would go beyond the scope of this paper to deal extensively with it. We position ourselves in line with works that take a practice-based approach on knowledge and learning (Lave and Wenger, 1991; Brown and Duguid, 1991; Wenger, 2000), which emphasise how knowledge is local, social, situated and closely linked to practice. However, another central premise for our focus in this paper is that knowledge is cumulative and needs to be related and connected to previous and already established knowledge (Lazonick, 2001). In other words knowledge is not only local and situated but also linked to larger established 'systems of knowledge'. This may imply that knowledge generation does not happen freely, but is highly contingent on the environment of emergence. Our aim with this paper is to focus in particular on the role of established "mechanisms for knowledge production" (Knorr-Cetina, 1999) within a knowledge system, i.e. the methods, tools, practices, instruments and institutions that are being deployed. We present an empirical study of knowledge production where we have studied the production and use of research protocols within specific research projects. We see the research protocol as one example of a standard for knowledge production, and therefore as significant in shaping the knowledge that is being produced. As such we believe it deserves closer attention than it usually gets. Before we turn to establishing a theoretical foundation for this claim, we will briefly present our research aims.

2. Research aims

We have studied the practices related to production and use of research protocols in a medical R&D department. In this particular department work is organised differently from the highly specialised division of labour that is common elsewhere in hospitals. Cross-disciplinary teams collaborate in research projects with the aim of developing novel technologies and treatment methods. It is in particular the cross-disciplinary aspect together with the innovation focus that we find intriguing with this case.

We consider research protocols as devices for standardisation; they are intended to simplify the reality that is studied, to eliminate unwanted variation, and to generate knowledge that is

[1] Some prefer to speak about 'knowledge creation' (e.g. Nonaka and Takeuchi, 1995; OECD, 2000), but we use the term 'knowledge production' is in this paper.

robust, i.e. that can be transported out of the particular setting; be generalised and disseminated. The protocols are based on an understanding of the specific cause-and-effect relationships that are relevant, and what the actual relations between sets of phenomena are. In cross-disciplinary projects multiple actors will be involved in knowledge production. These actors may have different interests in research, but also different epistemic strategies for generating the knowledge they seek. How then, are such differences handled in a practical situation? How do these multiple epistemic strategies interact? Do they overlap and thus produce even 'stronger' knowledge claims? Do they easily connect and complement, or even reinforce each other? Are they mutually exclusive, so that the knowledge claims collide? Or will they be able to exist in parallel, without any need for interrelation?

Standards in knowledge production represent something solid and static that has been implemented in order to ensure 'valid' production of new knowledge. Hence we are interested in how the unexpected and unpredictable is handled, and how innovation processes can be influenced by this tension between established and new knowledge. Generally speaking 'innovation' refers to an invention, which can be either a new product or service. Zaltman's classical definition (1973:10) of innovation says that innovation is "any idea, practice or material artefact perceived to be new by the relevant unit of adoption." By definition innovation represents something new and adds up to old knowledge. This knowledge is in demand, and innovation can thus be defined as "a process wherein knowledge is acquired, absorbed, assimilated, shared and used with the aim to create new knowledge. This new or re-created knowledge becomes embodied in new products or services" (Harkema, 2003:13).) The innovation process in general, and in our case in particular can be described as non-linear and interactive (Freeman and Lundvall, 1988; Lundvall, 1992; Lundvall et. al, 2002), consisting of either *radical* or *incremental* innovations. Most innovations create small incremental improvements to existing products. Other innovations are radical in that they create entirely new product categories, require new competencies and can render existing ideas and techniques obsolete (Feldman, 2000:375). What we want to examine here is what role pre-defined standards for knowledge production ascribe to the unexpected and novel. Will it allow radical or just incremental learning?

Summing up our research questions concerning innovation in a cross-disciplinary setting:

1) How do the research protocols handle, and help to handle, multiplicity and heterogeneity in terms of epistemic strategies?
2) How do the research protocols influence how the novel and unexpected are allowed to emerge, accounted for and handled?

3. Theoretical background

Theories about knowledge production and learning can be regarded as 'focusing devices' (Lundvall, 1992) that bring forward and exposes certain aspects of learning processes, whereas others are left in obscurity. Hence the long lasting hegemonies of certain theoretical traditions can be damaging in terms of enhancing our understanding of learning processes and innovation. In this section we will present some approaches to this topic as they highlight different aspects. We do this in order to focus on our research questions which concerns the role of standards for knowledge production in general, and in a medical setting in particular.

3.1 Different approaches to the study of learning and knowledge production

In the 1970s and 1980s the discourse on knowledge in organisation studies arose as the concept of 'organisational learning' was widely discussed (for instance Argyris and Schön, 1978; Levitt and March, 1988). One figure in this discourse states that knowledge resides in the heads of individuals, and "is appropriated, transmitted and stored by means of mentalistic processes" (Gherardi, 2000:212). This perspective implies that knowledge exist prior to or independent of the subject. Another figure in this discourse regards knowledge as an asset distinct from the traditional tangible ones of capital, labour and land (ibid, Lundvall and Johnson, 1994), where knowledge is located in the organisation. We can also identify a third figure in this discourse, where the focus is on practice and how learning "takes place in the flow of experience, with or without our awareness of it" (Gherardi, 2000:214). The third approach to knowledge production and learning can be seen as a critique directed towards the traditional approaches to learning. According to this figure, we should look at the role of communities of practice for learning (Lave and Wenger, 1991) and innovation (Brown and Duguid, 1991) and on the role of culture for learning (Cook and Yanow, 1993; Weick and Westerley, 1996; Yanow, 2000). In the following three subchapters we will have a closer look at the cultural approach to learning, the role of communities of practice and boundary objects as well as some studies from the field of Science and Technology Studies.

3.1.1 A cultural approach

Organisational culture has been the topic of numerous studies (e.g. Schein, 1985; Martin, 2002; Parker, 2000; Alvesson, 2002). However, “to treat organizational learning culturally - interpretatively does not require an analysis of organizational cultures or the equation of organizations with cultures” (Yanow, 2000:258). The ‘cultural perspective’ embeds knowledge in culture and its artefacts (situated knowledge), while acknowledging the value of the cognitive perspective as complementary. Culture is defined as: “a set of values, beliefs, and feelings, together with the artefacts of their expression and transmission (such as myths, symbols, metaphors, rituals), that are created, inherited, shared, and transmitted within one group of people and that, in part, distinguish that group from others” (ibid:439-440). Hence, the focus is on collectives, their acts (including interactions), the objects and language used in these acts, and “the site-specific meanings of these artifacts to the actors in the situation as well as the site (or field-) based set of interpretative methods designed to access and analyze these data” (Yanow, 2000:251). Learning is a result of a multiple forms of knowledge that is reflected in practice and can be reproduced or transformed in these practices.

Weick and Westerley (1996:440) argue that the concept of ‘organisational learning’ qualifies as an oxymoron (self-contradictory concept), since “to learn is to disorganize and increase variety. To organize is to forget and reduce variety.” In order to get a better apprehension of learning one should look at how cultural systems such as language, material artefacts and action routines work (ibid:450). People learn intersubjective meanings that are embedded in culture, through a mix of order and disorder. Hence learning is to be pulled in multiple directions, without having any assurance of success (bid::456).

3.1.2 Boundary objects and Social Learning Systems

Star and Griesemer (1989) coined the concept “boundary objects” to account for how successful cooperation was achieved between multiple people and groups. Certain objects have different meanings in different worlds even though their structure is common enough to more than one world to make them recognisable.

Bowker and Star (1999) discuss the relationship between communities of practice and boundary objects. People learn through membership in communities of practice, and as they move from legitimate peripheral participation to full membership in the communities. In

scientific work members of different communities of practice with divergent viewpoints or perspectives meet (ibid: 296). Boundary objects "inhabit several communities of practice and satisfy the informational requirements of each of them. Boundary objects are thus both plastic enough to adapt to local needs and constraints of the several parties employing them, yet robust enough to maintain a common identity across sites" (ibid: 297).

Wenger (2000) explores three key elements of Social Learning Systems: communities of practice ("the basic building blocks"), boundary processes and identities. The existence of different communities creates boundaries, which are important since they connect communities and offer learning opportunities (ibid: 231-233). These boundaries can be bridged by people acting as 'brokers', by boundary objects (artifacts, discourses or processes) or through interactions. Wenger regards cross-disciplinary projects as good learning opportunities. In these projects knowledge of multiple practices are combined, and learning loops can be facilitated. Multiple disciplines can collaborate, and "people confront problems that are outside the realm of their competence but that force them to negotiate their own competence with the competence of others" (ibid: 238).

3.1.3 Science and Technology Studies (STS)

Studies within the field of STS of how scientists actually work have described the heterogeneous nature of work that goes into so-called scientific discoveries (Latour 1987; Knorr-Cetina 1992; Lynch 1985). A fundamental premise is that facts are not just discovered; their discovery is carefully set up and comes about through massive amounts of skilled work, involving many more actors than the scientist. Knowledge is a collective result, as e.g. Latour's famous study of Pasteur's work shows (Latour, 1988). Joan Fujimura introduces the term 'standardised package' to describe the strength of a novel scientific theory that comes associated with instruments (technologies) and established laboratory practices (methods). Such a standardised package was instrumental in the shift away from the predominant immunological understanding of cancer to a gene-based understanding during the 1980's (Fujimura, 1992). This concept has some similarities to Karin Knorr-Cetina's notion of the "machineries of knowledge production", from her studies of the epistemic cultures of scientific communities (Knorr-Cetina, 1999). Just as the concept of communities-of-practice, these concepts are based upon a contextual perspective on knowledge. Knorr-Cetina (ibid.: 1) defines epistemic culture as "those amalgams of arrangements and mechanisms – bonded

through affinity, necessity, and historical coincidence – which, in a given field, make up *how we know what we know*" (italics in original). Epistemic machineries define those more specific methodologies, techniques, and tools and instruments we use in our knowledge production and distribution. She claims that magnifying this aspect of science brings out the diversity of epistemic cultures, a diversity which creates what Knorr-Cetina calls epistemic monopolies within various fields and which are producing vastly different products, as a result of the differences in the objects of study in these fields and the historical evolution of the communities.

We think it is worthwhile to study not only how crucial these instruments are in actual scientific work, but also how these "machineries of knowledge production" are created, how these 'standardised packages' emerge. Several studies of various kinds of standards do present interesting insight relevant for this research aim.

3.2 Standards in knowledge production

Categories and classification schemes have been studied as an important form of standards highly relevant for the work of knowledge production. By allowing comparisons and connections such standards enable co-operation over spatial and temporal distance. However, several studies have emphasised that the categories we create, are shaped by, but will also shape the way we think and handle the phenomena they describe (Bowker and Star, 1999). The categories are not neutral representations, and we should recognise the political nature of any representation (Suchman, 1995). Another major emphasis in these studies is the insight that classification systems are never complete or universal. There is and will always remain an inevitable messiness in the real world which is not easily captured (Bowker and Star, 1999; Berg, 1997).

Apart from categories and classification schemes, also protocols, or standards for action, have been the topic of several studies. Timmermans and Berg (2003) have studied standardisation in medicine, among other aspect the increased emphasis on clinical guidelines for defining 'proper' or adequate care. They reiterate the point about how standards are thoroughly political, both in their generation (through negotiations between stakeholders), and in their effects of reshuffling responsibilities, risks, and relations. Protocols in the sense of clinical guidelines are a major object of study, but they have also studied

another kind of protocol, the research protocol, and its use within an oncology (i.e. cancer) research project. They describe how this very detailed protocol actually intermeshed with the work practice, and how it required negotiations and 'tinkering' to allow it to work. However, their focus is on the protocol-in-practice rather than on knowledge production as such.

At the same time as we are aware of the highly situated nature of protocols-in-use, we believe it makes sense to view these protocols within a broader context. The research protocols are not just given, they are objects that have come into being through a combination of traditions and normative contests between different disciplines about what science should look like. Standards such as these are part of the repertoire of epistemic cultures, and one practical example of such contests has been described by May and Ellis (2000). The study describes the conflicts about how to define and carry out a 'scientific' study within a telemedicine project. A major dichotomy here was the diverse interests, mainly between the practice- or patient-oriented participants and the documentation-oriented evaluators. There were diverging opinions on what relevant and useful knowledge was and how it should be produced.

Several, in fact most of the studies referred to in the previous section concerns medical work and health care organisations. One of the reasons for the abundance of studies in this field may be that medicine is highly knowledge-based and research-intensive. Medical knowledge production in general has been significantly influenced by the activity of producing knowledge about the effects of drugs and medications. An immensely powerful apparatus of methods has been developed for so-called controlled clinical trials, where central concepts are randomisation and double blinding of the trials (OECD, 2000). In order to eliminate the role of variations between the patients that receive a drug, the clinical trials are randomised, e.g. the patients are divided into one intervention group which will get the actual medication, and one control group in which the patient are given a placebo medicine. The studies are often also double blind, i.e. neither the patient nor the health care personnel knows which group any particular patient belongs to. This research approach is considered 'the gold standard' and has spread also into non-drug testing, e.g. into assessment of clinical interventions. An example could be the comparison of two different surgical techniques by creating two groups of patients, and blinding the patients to which variety of treatment they got (i.e. not inform them prior to the procedure). Operation time and complications would be two of the central

parameters to measure in that case in order to establish the result of the comparison. This approach measures effects rather than explains them and has been significantly boosted by the current emphasis on Evidence-Based Medicine (Timmermans and Berg, 2003).

The research protocol would thus ensure that these quality criteria were being met in the project, and as such the protocol is both material and symbolic. A research protocol might typically contain a section which motivated the research project, the research questions or hypothesis would be presented, along with the actual method for the practical execution of the project. The reason for describing the protocol as a standard is the fact that specific epistemological premises underlie its content and the protocol structures how and which activities shall be carried out. Yielding to this standard allows the knowledge that is being generated to be spread, communicated, and disseminated within the medical academic community. Adhering to the standard allows access, connectivity and interoperability (to use technically flavoured terms), but it also has some consequences, and we want to examine what these consequences are. We will discuss actual research protocols more in detail in the section which presents the empirical material, after our own research approach has been described.

4. Research methods

A cultural approach (e.g. Cook and Yanow, 1993; Yanow, 2000) to the site was selected, and qualitative methods were deemed the most suitable method of investigation. By using a case study the researcher is allowed to explore the phenomenon of interest in its natural setting and this is particularly appropriate when the boundaries between the phenomenon and its context are not clearly evident (Yin, 1989). Our case-study selection was based on the fact that the R&D department is unique in a Norwegian context, both as a result of the techniques and technologies developed there, and as a result of the cross-disciplinary organisation. We will describe the site further in the next chapter.

The data for this study has been collected in the period 2002-2004. The main method has been 16 semi-structured, in-depth interviews. We had a first round of ten interviews in 2002 focusing on cross-disciplinary work and organisation of research, and a second round of 6 interviews during January and February 2004. The latter interviews focused on the actual generation and usage of research protocols. In the semi-structured interview-guide we used

for the latter interview round the questions were organised into three different parts, relating to: 1) the process of writing and defining protocols for a research project, 2) the actual use of protocols during the project work and 3) the results of the projects where these protocols were used. The informants were selected on the basis of their role and their participation in different projects. The informants were the secretary, the director of the department (a surgeon), an anaesthesiologist, a surgeon, anaesthesia nurses, operation nurses, radiographers, a radiologist and engineers. The interviews lasted between 60 and 90 minutes, and all the interviews were fully transcribed to facilitate full and accurate content analysis of the verbatim transcripts. In addition we have performed document analysis of several research protocols in their different versions. These were discussed during the interviews as well.

We have also to a large extent based our analysis on extensive participant observation. Two of the authors (the first and the second author of this paper) have for several years been employed as PhD students, and have thus been involved in the general activities and in various research projects. The first author has also been the project co-ordinator in several research projects, including the projects related to beating heart surgery that will be further discussed later in the paper.

The approach to the data analysis was empirically based and theoretically driven. In other words we do not believe that the data speaks for itself as in the pure form of grounded theory. Both the interviews and the field notes have been transcribed, and put into matrixes in order to get a better overview of the material. Acknowledging that we may have misrepresented what the informants meant in our conversations with them, we have sent the drafts of the paper to the informants that we have quoted to control for misunderstandings and obvious mistakes. We also encouraged the informants to comment on the content of the paper.

5. Knowledge production at the Interventional Centre

Our aim with the study was to examine the role of research protocols as standards in knowledge production. In presenting our empirical material, we organise our findings into three sections. The first section provides a description of the setting, its organisation and routines around research projects and research protocols in particular. Next, we describe a technology development project, before we turn to describing three related clinical projects.

The reason for this distinction is that our study revealed differences in the character and the role of the research protocol between these two kinds of projects.

5.1 The Interventional Centre; organisation and use of protocols

The Interventional Centre is a Research and Development centre for image guided and minimally invasive therapies at Rikshospitalet University hospital in Oslo, Norway. The centre was established in 1996 to create a link between clinical practice, applied and basic research. The centre has the following tasks: 1. Develop new procedures, 2. Develop new treatment strategies, 3. Compare new and existing strategies and 4. Study the social, economic, and organisational consequences of these changes.

Currently the centre employs a cross-disciplinary staff of 25, and about 35 additional persons do parts of their work at the centre during one week. There are also 27 PhD projects currently linked to the Centre. Engineers, physicists, mathematicians or computer programmers constitute 30% of the staff. Both the specialised equipment and the staff at the Centre is supposed to constitute a common 'toolbox on neutral ground' to be used by other departments at the hospital as well as other research groups at other hospitals or institutions. Here time-consuming and risky procedures can be developed and tested outside the ordinary departments with their daily activities and the pressure toward achieving a high throughput of patients. At the same time the centre experiences an increasing demand for 'productivity'. In addition to providing actual patient treatment, the centre is expected and required to produce research results. However, 'research results' is not understood as any new knowledge in a broad sense, but is quantified in the format of *the three P's: publications, PhD degrees and patents.*

The centre has a matrix organisation in order to facilitate effective execution of projects. A leader group consisting of the five Line managers, the director, the secretary, the nurse manager, the business manager and a consultant decides on, among other issues, whether new projects should be accepted and started.

Projects at the centre are defined as: "a task that has been decided in a cross-disciplinary brainstorming that has a clearly defined goal, with a well-defined timeframe and economy, with an administration and a temporary organisation". Before a new project was accepted a

project proposal including a detailed research protocol should be presented to the leader group. Research protocols were thus required as a formalism, either from this internal leader group (which were concerned with resource allocation), but also as a prerequisite for applying for funding, for permission from the regional ethical committee (if patients were involved), for the allowance of research animals, or in processes of formalising cooperation project with academic or industry partners.

The template for the project description contains the following points:

1. Front page
Project title, project leader, participants, affiliations (Department/ Institute), contact addresses: URL, e-mail, keywords.

2. Introduction
Background/history, traditional methods, recent results/ development, main aim of the study/ hypothesis

3. Material and methods
3.1 Research design: Qualitative/quantitative study, prospective/retrospective study, descriptive study, interview/survey, RCT
3.2 Ethical aspects: Regional Ethical Committee approval, informed consent, written patient information
3.3 Methodological issues: Equipment, methodology, statistical approach, non-parametric statistical analysis, parametric statistical analysis.
3.4 Implementation: Clinical protocol, biomedical equipment needed, staff training/educational and preparatory issues, definition of resources from the participating departments, NCSP/ICD-10/RIS- codes
3.5 Timeframe and milestones : Planning, implementation, analysis, evaluation, publication.
3.6 Financial plan: Intramural financing, extramural financing

4. References

Figure 1: Project template for the Interventional Centre

As we can see in 3.4 the clinical protocol is mentioned, and elsewhere in the same document it is specified that the protocol must include the following elements: reasons, hypothesis, methodology, planned statistical analysis, expected results, literature list, name of all the participants in the project and collaborating institutions. As one of the informants said: “the protocol is […] the user’s guidance and the cookbook for how to do things. You should find all details there.”

For most projects, it seems to be the case that the protocol would be written mainly by one individual, most often a physician, although one of the engineers could be involved. A discussion round involving other personnel groups could also be undertaken, depending on the size of the project. Nurses, radiographers and the radiologist all mentioned that in some cases it was important that they were included early in the process of drafting a protocol, as they knew what would be practically feasible and could detect implications and consequences which went beyond the knowledge of the individual initiator. Usually, however, they were not

included in the writing of protocols, and were (at best) presented with it in a project meeting before the project started. One of the informants said: “One guy starts to write what *he* thinks is new, and then he cuts and pastes the rest, which he thinks is standard, from previous protocols.”

Nevertheless, the existence of written protocols facilitated information sharing within the team responsible for the actual execution of the work involved, at least at a general level. While the protocol contained detailed instructions for the actions of the researchers, it very rarely prescribed the action of the ‘support staff’ like operation nurses and radiographers. “It is not described at all, we are not included in the description” said one informant. Opinions varied between the informants whether it would be optimal to include all instructions in the protocol. On the one hand, being able to document the exact settings of the imaging equipment’s parameters and the positioning of the patient during imaging is of crucial importance for the repeatability and quality of the scientific work. On the other hand, this should be documented elsewhere, together with other work procedures. Thus some of the informants distinguished between the scientific research protocol and the routine work procedures. Nevertheless, the staff was more or less left to define themselves, on the basis of the information in the protocol, the other work procedures around the research project.

We might wonder whether there are any adverse effects of this narrow focus and individualized process of writing, and some of our informants provided evidence to support such a view. One effect is that consequences or pre-requisites for successful deployment might only be known after the project starts. For example an anaesthesia nurse reported the need to change the postoperative pain-killing medication regimes in an ad hoc manner, rather than being prepared to do a systematic assessment based on planned data collection. In addition to having providing better patient care, this would have enabled this part of the work as well to be published as a research contribution.

> *“When we induce massive ischemia like we did in that project, the pains will be immense and they will start very soon after the procedure is finished, sometimes before we wheel the patient out the doors. But in the start this was only visible to us nurses, since the anaesthesiologist is not always there at that point.“ (Anaesthesia nurse)*

In particular by the individuals active in research themselves, protocols were seen as devices for sharpening the research project's focus. The process of writing and discussing the protocols (with partners or supervisor) assisted the researcher in thinking through the problem, defining the research agenda, and creating a project with a reasonable likelihood of success. A major component of this 'sharpening' work is the activity of reduction and exclusion. In the world, there are too many problems to be solved and too much 'data' that can be gathered:

> *"If you do not properly define what you want and need, you end up with massive amounts of data, and like my colleagues X and Y these days, ending up with a great a problem of how to organise it and find something useful." (Surgeon)*

> *"If you cannot write anything before you start a project, you can certainly not write anything after you have finished it. … The protocol is in a way the first two-three chapters of an article…with background, material and research question. Later on you can therefore add the results and discussion, and the article is finished (…) It is a common mistake for beginners […] that they say 'since we do this, let's add a few questions on this and that' and then you end up with a lot of data, and you don't know what you're going to use it for […] I think it is better to make several small studies, which are focused and where the quality of your data will be excellent. We see that it is this kind of studies that get published in the large journals […] 90% of the research work is in defining a good protocol." (Surgeon)*

The quality assurance aspect (for research quality as well as for ethical reasons and patient safety) was mentioned by several of the informants in this respect.

> *"There are even some journals now that have started to demand, at least for large clinical studies it is a prerequisite that the protocol itself have been published in the journal before the actual study is started." (Engineer)*

5.2 An exploratory technology development project

The activities that led to this project were initially related to a very different project, where some engineers constructed a device that detected the surgeon's head movements in order

to control a surgical robotic assistant. The starting point was reported to be a rather incidental inquiry by a surgeon to an engineer whether this technology also could be used for measuring the movement of the heart muscle. An initial testing of this was being performed in the conjunction with a surgical operation within another research project. After 3 such initial tests a more focused approach for further work was adopted with an ultimate aim of commercialisation of a new product. A significant factor here was the interest from an anaesthesiologist who was taking part in these other procedures. His planned PhD work would concentrate on methods for detecting heart ischemia (death of the muscle's cells), and he could see the potential value of testing such an experimental device in addition to the planned testing of other methods. The engineer and the anaesthesiologist then wrote a research protocol, each doing the parts that they felt their competence allowed them, and submitted this protocol as part of an application for access to research animals. After being given ten pigs on which to test the device, the actual pilot study started. During the operations, the protocol in its paper version were physically brought into the operation room and consulted in order to do the steps in correct order, but after a couple of operations the initial protocol was being substantially revised. The reasons for this were based on some encountered problems in combinations with the anaesthesiologist's knowledge. "We know that ecco [i.e. ultrasound imaging] are very preload – and afterload dependent, and if this device is not, then it will be a major strength because then you can have continuous measurement which you can not with ecco" (Anaesthesiologist). The adjustments of the protocol consisted of changing the sequence of medication administration and other physical interventions during the procedure. The new information was added to the previous version in hand writing only. This protocol had a non-finished status, and the participants clearly saw this as an exploratory project, to be followed by more rigorous testing later. Pragmatic strategies were suggested towards the issue of how to handle the data collected before and after the change of research protocol. "I think we'll have to look at that afterwards, whether it seems to have influenced or not. If it influenced the data, we should make that a point, if not; there is no reason not to include the data." (Engineer)

In discussing this ad hoc approach in contrast to the rigidity required by the standard protocols, both our engineer informants emphasised the necessity for this way of working for technology development.

"You don't know where you are going, you don't know how you are going to do it, you develop things. […] Such a protocol is suited for clinical research where you have a hypothesis, the method is pre-defined, and you are just collecting the data in order to validate or falsify the hypothesis. While much of what I do, is actually to develop the method itself." (Engineer)

"One does one thing, but you don't know the implications of it or how large it is going to become. It is not planned at once, it's more that you do things and then 'wow, that was interesting', and then you might implement some changes. Clinical testing is more planned than technology development." (Engineer)

The non-planned character of much technology development could be handled by trying to define new activities and projects when new things emerged:

"What often happens is that is that one gets spin-off projects. That you during one project find that this was interesting, and that you need another solution in order to be able to do it. […] Protocols can be limiting […] If you have decided beforehand on what you shall find, then you don't find other things, unless you take care that it is being looked for […] I think we manage to capture parts of that here, since we are a cross-disciplinary and dynamic group […] even though it may not have been written and you don't have a strategy for it. We talk about things and start things." (Engineer)

5.3 Beating heart surgery: randomised clinical studies of novel surgical techniques

Several studies of beating heart surgery where a heart-lung machine is not used (also called off-pump surgery) have been a very central part of the activities at the centre. The first of these projects ('the off-pump project') started after a pilot study involving procedures on animals as well as around 60 human patients during the years 1996 through 1999. During this pilot phase the research protocol was refined and modified, and the next phase, a randomised clinical outcome study, was prepared. The clinical outcome study involved 120 patients and was a large and long-term project (1999-2002) that involved many actors from different departments at the hospital (radiology, thoracic surgery, physiotherapy, psycho-somatic, neurology). Defining the protocol involved numerous large meetings between researchers and other physicians from all of these departments through a lengthy time period

(around half a year). It resulted in a hierarchy of protocols; one main protocol was defined as well as a number of sub-protocols for the different individuals own projects. Put together the protocols documents filled a large ring binder and consisted of approximately 60 pages.

> *"Think about our beating heart projects, which involved many actors from several different departments at the hospital…they have been very successful and uncomplicated, as we could collect data from all the different levels…I have a whole ring binder with the main protocol and the sub protocols. There was an enormous logistic effort before this study started, but since we started the actual study it has been plain sailing …so I would definitely say that this was a good protocol." (*Surgeon*)*

However, the informants also pointed to other factors than the protocol that were crucial for the success of the off-pump project. First and foremost, the dedicated project leader, motivated project participants but also the fact that a project co-ordinator was linked to the project to deal with the more practical issues of patient logistics. The complexity and all the hidden work to make this project work should not be underestimated. In this project it was not obvious how topics that were not explicitly discussed in the protocol should be handled, and the 'abnormalities' in the normal situation had to be solved on an ongoing basis:

> *"A lot of information about more practical issues was not included in the protocol, and it was a lot of work to actually figure out how to handle these tasks. For instance how to order a hotel room (as they were not normal bed patients), where to order food, find out what food they could eat, where to order beds for the patients as well as assisting with the patients with finding the right location." (Project Co-ordinator)*

Several PhD students were using the data collected during this project, this included also a study that was not planned initially (i.e. a retrospective analysis with another research question). According to one of the informants the research outcome was to a large degree pre-planned. All modifications came in the pilot phase, and none during the randomised study phase.

> *"If we have patients where we can not carry through with the protocol, then we remove them from the study. […] When we operated on beating hearts, we predicted that if we could not do it with beating heart, we would have to go onto the heart-lung machine.*

So then the protocol said what to do with them and how to treat the data later. That is basic; what you are going to do with drop-outs, you have to have that defined in a randomised study. […] You should be able to predict […] The whole point of the pilot phase is that you change it […] And since we knew that we were going to move and get new equipment in the middle of the study, we […] randomised each patient group, before and after the move […] (Surgeon)

A follow-up project tested a device often used for beating heart procedure. However, it was stopped before a larger randomised study was initiated because unexpectedly bad results (for some of the patients) emerged, which was discovered on the three-month follow up control. The research protocol for this project was not comparable in size and stringency to the first project. This project (below called the symmetry project) was followed by a second follow-up project (the shunt project) starting in November 2003 and aiming at including 40 patients. The organisation of this project was very similar to the previous, but the actual research question was different and implied a more cross-disciplinary approach. Whereas the previous project had been more of a clearly surgical project, in this project the use and ownership of the data collected could potentially be interesting also for the other disciplines involved, cardiologists and anaesthesiologists:

Physician: "[…] and at least when it concerns the surgeons, it seems they don't know exactly what they want to do and to publish in relation to the cardiologists. Obviously NN thought he could write about this and that, but then the cardiologists said 'that's our material'. And I said that 'OK, if the hemodynamics are to be included, it will be natural that I am involved'. […] Such things should have been decided beforehand."
[in the symmetry study] Physician: "[…] there were no such crossing point between the surgeons and the cardiologists, it was more of a surgical study. […] The cardiologists are much more involved now […] it is very integrated in the shunt-study, while it was more separated in the other study. Here the main focal point is very cardiological, actually."

6. The role of protocols in knowledge production

At the centre knowledge production happens in close relation to actual, practical work. We see that collaboration between different personnel is facilitated by physical co-presence, as

the sharing of ideas and inputs are often incidental. The research is attempted standardised through the use of research protocols, but there is also a relatively high degree of freedom to adjust the protocols, at least when the study is a pilot study or a feasibility study.

The protocols at the centre express values, beliefs, and meanings are shared between or within groups or communities (Yanow, 2000). It may also be worth noting that we found that research protocols fulfil multiple roles. As we have seen, our informants were giving several reasons, both explicitly and implicitly, for the existence of and use of research protocols.

- The protocol as a device for sharpening the focus of the researcher: several informants mentioned the importance of the protocol writing process
- Protocols as boundary object (Star and Griesemer, 1989; Bowker and Star, 1999; Wenger, 2000) to facilitate the co-ordination of the research team
- Protocols as an aid to memory, securing comparative execution of single experiments in the practical situation
- Protocols as formalism, fulfilling somebody else's requirements. The basic motivation for the requirements is usually quality assurance in some sense.

So, turning to our research questions: How does the research protocol influence or interact with knowledge production in medical cross-disciplinary work? What effects does it have related to managing multiple knowledges and in allowing the novel to be discovered? Depending on the choice of theoretical approach different answers to these questions could be provided. We will briefly discuss some alternative interpretations in the following sections.

6.1 The meeting of multiple epistemic strategies

The general picture is that the different disciplinary parts of a research project seemed to exist harmoniously beside each other. These shared objects helped multiple communities to co-operate (Wenger, 2000). The surgeons carried out their part of the study, cardiologists registered the data they wanted, and the engineers did the studies they needed. The project was organised to include a collection of specialised competencies, usually with a hierarchy where the 'core' belongs to one discipline and the other participants are taking opportunity of the activities, e.g. off pump project was clearly seen as a surgery project. The observation of relatively unproblematic co-existence is also supported by the fact that in publishing research

papers it is common practice to include other project participants as co-authors, even if the field of research is a different one. However, not all problem issues are equally easy to divide according to medical specialty: In the third of the beating heart projects, where the research object was of a more cross-disciplinary kind, disputes emerged between different medical specialties. This was more discussed as an issue of ownership of data and publishing strategy, than an epistemological issue. In other words, the fundamental approach to knowledge production was shared between the participants.

In the technology project the research protocol was written jointly by one engineer and one physician, each doing 'their' part. There appeared to have been a quite clear and pre-defined separation between competence areas, so that this joint writing did not need to entail discussion or conflicts. In the same project we also saw how the anaesthesiologist's entrance into the project changed the previous setup of testing. From only testing the feasibility and usability of the device in itself, the project was brought into a setting where it became one of several studies of ischemia detection. Hence new aspects of the device had to be tested, which would allow it to be compared to other alternatives. This involved changes in the technical part of the research protocol. We see this is an example of mutual benefit of cross-disciplinary work. Rather than just performing work in parallel, not affecting each other's trajectories, these two knowledge disciplines fruitfully interacted to enhance the project design. This process can be interpreted as interaction between the user and the producer of a new product (Lundvall, 1992; OECD, 2000). At the centre the physical proximity between these groups and the way the department was organised facilitated learning by interacting.

A more serious problem seems to be indicated by the story of the anaesthesia nurse regarding the consequences of a narrow and individual-oriented approach to protocol definition. The overall efficiency and quality (e.g. from a patient's perspective, or from an overall process or resource-based consideration) of the procedures developed at the centre depended on how each of the diverse groups carried out their work, and accordingly, all of them needed to develop the required knowledge for how they should do their tasks. However, the tasks of the different groups were interdependent, so they would also need to learn cooperatively so that the tasks of each group fitted with the others' in order for the overall procedure to be defined in a best way. This may be made more problematic by the current practices around protocol definition, which belongs to the traditional specialisation approach

that is dominant within medical knowledge production. The reduction into clearly delineable problems, rather than a comprehensive approach, does not facilitate the creation of broad, process-oriented knowledge. A similar finding was reported by May and Ellis (2000).

6.2 Strategies for handling the unexpected

The engineers saw technology development as being fundamentally different from clinical studies. While the clinical studies were associated with large samples, performed in a repetitive way and employing statistical analysis of data, a crucial factor in technology development was seen to be open to exploit emerging opportunities as well as to solve emerging problems. Technology development was seen as a more long-term process and inherently less possible to pre-define or plan in detail than the clinical studies. In these kinds of projects the unexpected was seen as a potential resource for further development, and it was seen as important to be able to capture for example emerging new ideas. Making changes in the protocol was being done during a project, the potential compromise of 'scientificity' was not a major worry, and several pragmatic strategies were employed in that respect. To have practices and a form of knowledge production that is open and flexible enough for such changes (or so-called tinkering) (Berg, 1997; Berg and Mol, 1998) was important. It was not a failure to make changes, but rather a natural part of any explorative project. When something does not work in practice, tinkering is a kind of experiment to discover something that actually does work (OECD, 2000:27).

In the clinical outcome studies, however, the approach was the opposite. All potential variations, problems and occurrences should ideally have been predicted, and strategies should have been devised for handling (i.e. controlling) them. Unexpected variations or problems might threaten the scientific quality of the project. If we again take the un-researched pain-killing medication as an example, we see that the unexpected may still emerge 'outside of' the defined project, and chance decides whether it is discovered or ignored. It is not systematically sought after, but may remain 'invisible'.

6.3 Challenges for cross-disciplinary knowledge production

The framework of Wenger (2000) was an interesting approach for understanding how knowledge was produced in cross-disciplinary projects, and through boundary objects such as protocols. However, the lack of emphasis about the challenges and conflicts that can

emerge in these projects is problematic. In order to understand our case it is necessary to go beyond how events can be organised, learning projects facilitated and boundary objects developed. Depending on the aim of a project different strategies for developing new knowledge were chosen at the centre. Negotiations about these strategies were not always unproblematic, as different epistemic cultures met (Knorr-Cetina, 1999). Furthermore these challenges could not always be easily resolved "by interventions that are sensitive to the existence of boundaries" (Contu and Willmot, 2000:272). There are evidence that point to that some actors at the centre had model monopoly (Bråten, 1973), and were better able to express their ideas and form the research projects and protocol than others. Fortunately the different groups have been able to develop a protocol design that seem to work in most cases, instead of giving up the whole protocol, as the group that May and Ellis studied (2000).

New knowledge developed at the centre was both a result of research projects aimed at knowledge advancement, as well as a 'side-effect of production activities' (OECD, 2000). People learn intersubjective meanings embedded in the culture (Yanow, 2000) at the centre. Some of the differences we found between the projects we studied may also be interpreted along the lines of Weick and Westerley (1996). They argue that "to affirm the oxymoron of organisational learning is to keep organising and learning connected despite the fact that they pull in opposite directions" (ibid:456). By looking more closely at cultural systems such as language and material artefacts (such as the protocols), it was possible to apprehend how knowledge production was related to 'organising' elements at the centre.

7. Final remarks

The research protocol is a work tool; a memory aid, a cookbook, an artefact and a boundary object within the research team. Ultimately, however, its justification lies in that it ensures analysable data and publishable work. The value of publishable work is powerfully sustained by the external demand for 'productivity'; i.e. the expectations and requirements for the centre to produce research results. The template of the research protocol within the medical academia is imported into this setting, and yielding to this standard allows the knowledge that is being generated to be spread, communicated, and disseminated back to the academic community.

However, as with any standard that allows connections and access, there is a price. A standard will limit the range of choices, which is exactly how it helps achieve what it does.

Here our interest has not been to describe how this standard becomes meshed with local work practices, the 'tinkering' and work it takes to make a standard work (Berg, 1997). Rather we have examined 'the new order' that is being created (Berg and Mol, 1998).

We have seen that not all work and not all production of new knowledge falls within the domain of the standard, i.e. the research protocol. The protocol regulates the activities that are compatible with the knowledge tradition from where it emerged; i.e. the specialised, reductionist approach within medical academia. That part of knowledge production that does not fall under this category is performed outside of the protocol's domain, and thus somewhat marginalized. This may for example be the case for the knowledge generated in a pilot phase (temporally separate) for explorative technological development, or it is defined as 'non-scientific' work, e.g. the work of the 'support staff', nurses, radiographers etc. which aims at creating the necessary handling of other parts of the treatment process/trajectory.

Our task is neither to judge the practices and research directions at the centre nor to say that the protocols there are more problematic than protocols used anywhere else in the hospital or at other hospitals. However, our study may point to how practices and standards from a traditional context are partly reproduced within this centre. One implication of this is that there may be a danger of neglecting important aspects of the new knowledge needed around the innovations: namely process-level knowledge.

Accordingly our analysis point to that it is useful to have a cultural approach to knowledge production, as this is "as much about act and artifact and their meanings as it is about cognition" (Yanow, 2000:262). However, it is useful to combine this approach with other practice-based approaches and contributions from STS, as they shed light on different aspects. In order to understand how knowledge is produced and by whom, standards for knowledge production are important study objects. New practices and knowledge emerging from them may not spread as readily or widely as insights that are built on settled knowledge. Hence, scientific communities are not free to decide how to construct new knowledge at their own will, as they will be influenced by larger epistemic cultures also in any local context.

References

Alvesson, M. (2002): Understanding organizational culture, London: Sage Publications.

Argyris, C. and Schön, D.A. (1978): Organizational learning. Reading, MA: Addison-Wesley.

Berg, M. (1997): Rationalizing Medical Work. MIT Press.

Berg, M. and Mol, A.M. (1998): Differences in Medicine. Duke University Press, Durham and London.

Bowker, G.S. and Star, S.L. (1999): Sorting things out: classification and its consequences. MIT Press

Brown, J.S. and Duguid, P. (1991): Organisational Learning and Communities of Practice: Toward a Unified View of Working, Learning and Innovation. Organisation Science, Vol.2, No.1, 40-56.

Bråten, .S. (1973): Model Monopoly and Communication. Acta Sociologica, 16, 98-107.

Cook, S. and Yanow, D. (1993): Culture and Organizational Learning, Reprinted in M.D.Cohen and L.Sproull (eds) (1995) Organizational Learning. Newbury Park, CA: Sage.

Contu, A. and Willmott, H. (2000): Comment on Wenger and Yanow. Knowing in Practice: A 'Delicate Flower' in the Organizational Learning Field. Organization. Volume 7 (2) 269-276.Sage.

Feldman, M.P. (2000): Location and innovation: the new economic geography of innovation, spillovers and agglomeration, in G.L.Clark, M.P.Feldman and M.S. Gertler (eds.). The Oxford Handbook of Economic Geography. Oxford:Oxford University Press:373-394.

Freeman, C. and Lundvall. B.Å. (1988): Small Countries Facing the Technological Revolution. Pinter Publishers.

Fujimura, J.H. (1992): Crafting science: Standardized Packages, Boundary Objects, and "Translation". In A.Pickering (ed.): Science as Practice and Culture, University of Chicago Press, Chicago.

Gherardi.S (2000): Practice-based Theorizing on Learning and Knowing in Organizations. Organization, Volume 7 (2):211-223. SAGE.

Harkema, S. (2003).: Learning in innovation projects: an approach based on complexity theory, paper presented at OKLC 2003, Barcelona, Spain, 12.-13.April.

Knorr-Cetina, K. (1992): The Couch, the Cathedral and the Laboratory: On the Relationship between Experiment and Laboratory in Science. In A.Pickering (ed.): Science as Practice and Culture, University of Chicago Press, Chicago.

Knorr-Cetina, K. (1999): Epistemic cultures. How the Sciences Make Knowledge. Cambridge, Mass, Harvard University Press.

Latour, B. (1987): Science in Action. How to Follow Scientists and Engineers Through Society. Harvard University Press.

Latour, B. (1988): The Pasteurization of France. Harvard University Press.

Lave, J. and Wenger, E. (1991): Situated Learning. Legitimate Peripheral Participation. Cambridge University Press.

Lazonick, W. (2001): "The Theory of the Innovative Enterprise", in Malcolm Warner, ed., International Encyclopedia of Business and Management (IEBM), second edition, 2001:3055-3076.

Levitt,B.and March,J.G. (1988): Organizational learning. Annual Review of Sociology, 14,319-340.

Lundvall, B.Å. (1992): National Systems of Innovation. Towards a Theory of Innovation and Interactive Learning. Pinter Publishers, London.

Lundvall, B.Å., Johnson, B., Andersen, E.S. and Dalum, B. (2002): National systems of production, innovation and competence building. Research policy, volume 31, issue 2.

Lynch, M. (1985): Art and Artifact in laboratory Science. London.

Martin, J. (2002): Organizational Culture: Mapping the Terrain. Thousand Oaks, CA:Sage Publications.

May, C. and Ellis, N.T. (2000): "When protocols fail: technical evaluation, biomedical knowledge, and the social production of "facts" about a telemedicine clinic", in Social Science & Medicine 53 (2001) 989-1002.

Nonaka, I. and Takeuchi, H. (1995): The Knowledge-Creating Company, Oxford University Press.

OECD (2000): Knowledge Management in the Learning Society.

Parker, M. (2000): Organizational culture and identity. Sage Publications.

Schein, E. (1985): Organizational Culture and Leadership. San Fransisco, CA: Jossey-Bass

Star, S.L. and Griesemer, J. (1989): 'Institutional Ecology, "Translation," and Boundary Objects: Amateurs and Professionals in Bekeley's Musem of Vertebrate Zoology, 1907-1939, Social Studies of Science 19:387-420.

Suchman, L. (1995): Making Work Visible. Communications of the ACM,, vol. 38, no.9, pp. 56-64.

Timmermans, S. and Berg, M. (2003): The Gold Standard: The Challenge of Evidence-Based Medicine and Standardization in Health Care. Temple University Press.

Weick, K. and Westerley, F. (1996): Organizational Learning: Confirming an oxymoron, in Clegg, S. Hardy, C. and Nord, W.R (eds) Handbook of organization studies. London: Sage. (440-58)

Wenger, E. (2000): Communities of Practice and Social Learning Systems. Organization 7 (2) 225-246. Sage.

Yanow,.D. (2000) Seeing Organizational Learning: A cultural view. Organization 7 (2): 247-268). Sage.

Yin, R.K. (1989): Case study research. Design and methods. Sage Publications. Thousand Oaks. London.

Zaltman, G. and Duncan, R. (1973) Innovations and Organisations, New York: John Wiley & Sons