Emerging Standardization

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Abstract

This paper discusses the dynamics associated with the implementation and deployment of an information infrastructure designed to standardize work practices. The analysis is based on a case study conducted in a pharmaceutical R&D organization. The infrastructure in use, comprising a computerized system and surrounding organizational procedures, seems to support work practices not always as originally planned. The paper discusses the role played by local characteristics, contingencies, and practices in shaping a standardization protocol implemented to standardize work practices. Building on actor-network theory, the paper concludes that the standardization of work practices is the result of the dynamic interplay between technology and its users rather than the consequence of a planned and well-defined design project.

Keywords: Standardization, implementation, actor-network theory, infrastructure in use

1. Introduction

Information and communication technologies (ICTs) have become one of the most common solutions implemented to standardize work procedures and information flows in private and public organizations. Many authors have discussed how to develop, choose, and implement these technologies in the most effective way. In this context, research on information system development methodologies have proposed and discussed procedures for making the process of developing information systems more efficient and effective. Similarly, managerial studies have focused on researching optimal solutions for analyzing and choosing ICTs to leverage organizations’ performances. However, less attention has been given historically to the study of how ICTs enforce and shape work practice standardization. Nevertheless, scholars have recently shown increasing interest in the study of the definition, development and evolution of technological standards and in the role standards play in the deployment of ICTs, designed to define, support and improve organizational practices. Building on actor-network theory, we intend to better explain the complexity of the process which shapes the intertwined effects ICT has on work practice standardization.

This paper discusses how an information technology, designed to standardize the process and quality of data collection and analysis in a pharmaceutical company, evolves, changes, and is shaped within the practices of the organization using it so that, rather than standardizing these practices, it changes with them. The paper initially summarizes the debate on the nature and evolution of standards and standardizing technologies and their effects on work flow standardization. It follows a case study conducted at a pharmaceutical company, here referred to as Alpha Company1, where

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1 The names of the organization, its departments, products and applications have all been changed.
an ICT system has been implemented to standardize the work practices involved in collecting data during the drug registration process.

2. Theoretical Background

The study of work practice standardization and other means of homogenizing the variety of work behaviours lies at the centre of a vast and multidisciplinary literature. Historically, the importance of standards and classification protocols as ways of making work procedures and practices uniform has been discussed from different perspectives. Bureaucracies have been described as organizations which rely on rules, norms and routines to reiterate behaviours when similar circumstances occur. Bureaucracies rely on standardized answers, classified and ordered to provide homogeneous paths of responses to similar events whenever they occur (Mintzberg, 1983), to reduce transaction costs and the complexity of an organization’s tasks (C.U Ciborra, 1993; Moe, 1984).

The role of norms, rules and resources in a social setting, meanwhile, can be thought of as the set of standards (structure) that affects the process that shapes social order, and therefore organizational practices. Giddens (1984), for example, identifies social structures as being composed of rules and resources that facilitate and/or constrain interaction in social settings. Rules and resources provide the contextual constraints individuals draw upon when acting and interacting. These rules and resources are the categories through which social orders are constructed and reconstructed recursively. An organization’s action is therefore the result of structurational processes that are deeply affected by the norms and rules that constrain the organization’s action. Similarly, Aviron (2000) discusses institutional theory, identifying the nature of institutions as taken-for-granted standardized sequences of activities, which establish and maintain the modus operandi of the organization. This path of action can create powerful myths (Aviron, 2002), which act as the background upon which changes in organizational activities are constrained but also enabled.

These different perspectives show that, at a macro level, the key characteristics of standards and norms are their being the product of social institutions which produce but also reinforce them over time (Douglas, 1986).

Moreover, norms, rules and standards permeate our daily lives as citizens, workers and members of social systems. Our way of coordinating activities, finding places we are looking for, understanding context and other tasks, are mediated by systems of classification which are built on specific norms, rules and standards. These systems of classification are often considered to be in the background of our action, as if they were invisible (Bowker & Star, 1999). However, they are not in the background of the occurring event. They often define the event itself. Think, for example, of the system of classification that defines the admission requirements to a university college. In this case, the system of classification is an important factor in selecting the students who will be accepted to the college and those who will not. The population of the college is hence also defined by the specific system of classification used to filter and rank the submitted applications.

Building on the idea that standards and classification protocols are not neutral in the shaping of organizational practices and actions, we discuss here the role of information systems in standardizing work practices. Within this aim, the paper seeks to provide a better understanding of the micro aspects that define the standardization of work practices that are enforced via the adoption of information systems. The study assesses the effects of technology in the context of its use and then looks at the dynamic that emerges.

A large body of literature has studied both the processes that produce standards and the effects of their adoption on the socioeconomic context in which they are deployed.

These studies can be classified between the extremes of technologically-deterministic and constructivist ontological stances. At one end, technological determinism assumes that technology and its impacts are given and defined; at the other,
constructivism tends to assume that technology does not matter because it is always, and inescapably, socially constructed (Lundberg, 2000).

The juxtaposition of these two stances on the relationship between technology and people is the basis for debate on the role of standards and their users in stabilizing and diffusing standards in socioeconomic contexts. Standards can, in fact, be conceived as the result of the process of socio-political negotiation and construction, which is stabilized in technological artefacts (O. Hanseth & Monteiro, 1996). This view is argued by studies on the social shaping of technology (Bijker, Hughes, & Pinch, 1987; Bijker & Law, 1992; MacKenzie & Wajcman, 1985). On the opposite side, technologically-deterministic stances argue that technology is what fosters organizational change. Here, standards define the nature of technological us use and the direction of the process of change associated with technological implementation (Williams & Edge, 1996). Between these two extremes, a multitude of alternative explanations can be provided. In this paper we choose to take an intermediate position, led by the ontological stances of actor-network theory (ANT). ANT argues that it is the relational process of socio-technical actors that defines the trajectory of their relationships. It is neither technology nor its users in command of this trajectory but the relationship itself; both technology and users are shaped through their relationship (Cordella, 2010).

This choice is justified by the increasing interest that ANT has received in studies on technology and its use (Information technology and People, Special issue: Actor-network theory and information systems, 2004, the establishment of JANTTI) and by the specific focus of the research presented here. We want, in fact, to disentangle the process that defines the relationship between ICT and standardized work practices. We want to shift attention from the actors that define the process, as discussed in socio-constructivist and techno-deterministic studies, to the process that defines their relationships, as suggested by the theoretical formulation of ANT (Cordella, 2010).

### 3. Standardization in Context

Studies of standards and classification protocols have traditionally analyzed either the process that underpins their development or which leads to their stabilization.

Bowker and Star (1999) largely discuss the contextual nature of the process of classifying and hence the socio-technical nature of standards and classification protocols. Their studies specifically emphasize the technical, cultural, social and political elements involved in these processes and their intertwining nature, which they stress is crucial to understanding the nature of a classification protocol. Given this focus, they describe and discuss how standards and classification protocols develop and evolve, and their characteristics in specific contexts. Their studies are based on a detailed analysis of systems set up to categorize diseases, work, races, and other elements and they discuss not only the role of these classification protocols as tools that create groups of homogeneous data, but also the socio-political dimension they play, which provokes advantages or suffering for specific groups, individuals or situations.

The work of Bowker and Star (1999) provides a good example of how classification protocols, standards, and the associated technological systems can be studied as socio-technical networks where physical artefacts and social systems construct and shape the nature of the standard itself (Hughes, 1997).

The complex nature of this socio-technical interplay, however, allows for the use of many different angles, as does the large number of actors that shape the socio-technical network. Hanseth (1996), for example, takes a different analytical approach to that of Bowker and Star (1999), highlighting the role of “the irreversibility of the installed base” as the self-reinforcing mechanism produced by the growth of the technical system. In this case, the focus of the research is on the
processes that reinforce the technical characteristics as a consequence of the layering of technical choices over time and of the alignment of technical, institutional and users’ choices. This research highlights, once again, the joining of technical and user-related path dependencies as the main factors that shape the socio-technical network. Similarly, Hanseth and Monteiro (1996) discuss the nature of technical standards, looking at how “any given element of an information infrastructure constrains others, that is, how it ‘inscribes’ a certain pattern of use”. Accordingly, standards can be “classified” by the level of their “power of inscription”. The stronger the inscription, the more aligned is the socio-technical network and the more effective is the inscribed programme of action. Standards can then be discussed and analyzed by looking at the embodiment of inscription they are made of. Once again, it is the technical actor that is here considered the most appropriate object of study for understanding the evolutionary path taken by the socio-technical network.

A further insight into the study of the socio-technical nature of classification protocols and standards comes from Timmermans and Berg (1997) that, in studying their nature and configuration, shed light on the diverse nature of standardization outcomes emerging from the interplay in these relational networks. Standardization efforts do not necessarily require a central actor. Looking at the evolution of medical protocols, they find that standards procedures emerge as the outcome of the real-time work that occurs in localized processes of negotiation within pre-existing institutional, infrastructural, and material relations. Once again, standards are discussed as the outcome of relational networks defined within time and space contextual variables. Technology can inscribe a path of uses but is de-scribed by the users in the act of using it (Akrich & Latour, 1992; Timmermans & Berg, 1997). The local context and the situatedness of the action that embeds the use of classification protocols and standardization technologies is thus the right place to look, if the aim is to understand the processes that outline the nature of these technologies after considering their socio-technical dimension. Following this idea, Timmermans and Berg (1997) argue that a typical characteristic of classification protocols is their openness because they are “the result of work widely and loosely dispersed through space and time. Neither (their) origin nor (their) development can (thus) be traced back to singularities”. According to these authors, a standard and the associated classification protocols are open-ended and closure is never really achieved. The context of the use of a specific protocol of standardization defines, over time and through space, the continuous evolution of the protocol itself.

Using a different focus in the analysis, but reaching similar conclusions, Bowker (2002) highlights the interconnectedness of classification protocols with the legacy of data systems and the technical, cultural, historical, and political reasons underpinning the process that leads to the design of a data collection system. The proposed understanding of the nature of the problem stands on the argument that data collection systems, and hence standards, are the outcome of layering of legacy systems:

“What we need to know about data in a database is far more than the measurement standards that were used, and on the other hand, I have argued that atomic elements of a database such as measurement standards, contain complex histories folded (Deleuze, 1996) into them, histories which must be understood if the data is to persist. To summarize, each particular discipline associated with biodiversity has its own incompletely articulated series of objects. These objects each enfold an organisational history and subtend a particular temporality or spatiality. They frequently are incompletely articulated with other objects, temporalities and spatialities – often legacy versions when drawing on non-proximate disciplines.”(Bowker, 2002)

All these contributions lead to the view that classification protocols, and in general technologies, are co-defined and emerge through the situatedness of the actions of users, who improvize and invent new programmes of action once the technology is situated and contextualized within routines (Suchman, 1987).
Building on these findings, we argue that the use of a classification protocol as standard to define organizational procedure has to be considered in the specific context and time of action. These are, in fact, the most determinant elements of the nature of the impact of standards on an organization’s routines. This conclusion is based on the empirical evidence that emerged from studying the practices and constraints that surrounds the deployment of a classification protocol, implemented to globally standardize data collection and analysis procedures during drug testing at the multinational pharmaceutical company, Alpha.

4. Research methodology

In this section, we discuss our research design, data collection, and analysis methods. This study employs a case study method. The case study method was chosen because it is well situated to examine the interaction among different contextual variables that define a specific situation, and through it the researcher may use thick description to try to understand the complexity of the phenomenon.

The case study research method uses an empirical investigation to gain detailed knowledge of a contemporary phenomenon within its real-life context, when the borders between phenomenon and context are not clearly evident, and when multiple sources of evidence are used (Yin, 2003). We entered the field with a broad area of study in mind, mainly related to the exploration of how information infrastructures are deployed in large multinational organizations, but with no specific research question. Thus, we hoped to narrow the focus after conducting the initial interviews and observations. Such uncertainty is common before data collection has commenced and case analysis is a useful approach for developing and refining concepts for further study (Benbasat, Goldstein, & Mead, 1987).

Qualitative data collection mechanisms, including in-depth interviews and an analysis of existing documentation, were used to gather evidence about the processes of data standardization. Observations and documentation were used only to confirm the findings of the interviews, which were the main source of data. The case study on which this paper is based was conducted over a period of eight months, during 1999. Interviews were held with study monitors and doctors in Sweden, Germany, Hungary, Spain and Poland. In addition, other personnel involved in the project at the Alpha Corporation were asked questions, and multiple discussions took place with managers at various levels. The interviews were semi-structured, each completed within one to two hours. When allowed, interviews were tape recorded; when this was not possible, detailed notes were taken by the interviewer. Construct validity was strengthened within the study through the use of multiple sources of evidence, and by having key informants discuss and review the draft case study reports.

5. The case study: Background

In late 1997, Alpha Corporation started a project to make data collection uniform in its clinical trials and homogenize the work procedures used to collect data. To achieve this goal, its Clinical R&D department led the implementation of an Internet application named “ODC” and developed new work processes aimed at standardizing the data capture system and process used in the clinical trials. The application was designed to manage and support the remote data capture process used in clinical testing of patients. The aim of the application was to move responsibility for data entry, (i.e. the transcription into specific files of the data collected during the drug testing), from the study managers (the so-called monitors) to the doctors in charge of the study. The purpose of the new system was to improve the homogeneity and quality of the entered data, with the aim of shortening the time needed to correct them and put them in the necessary format (cleaned
as per the industry) for the submission of certified documentation to the Food and Drugs Administration (FDA). The quality and homogeneity of the collected data is in fact an important factor in successfully registering a compound with the authorities. If the data are correctly entered and there is no need for extra work and verification before their analysis, the overall registration process is faster and the commercialization phase longer, with obvious benefits for company revenues. Accordingly, the data entry process is a very important aspect of R&D and commercialization activity in the pharmaceutical industry.

6. The ODC application: History, characteristics, and aims

ODC was first developed by Alpha as an administrative application to support the management of clinical studies at the corporate level. It was used in the company’s headquarters as an Internet Study Administration tool (ISA). During this phase, the application was only accessible to the Clinical Department, where it was used to monitor the various phases of drugs testing and closure. It was not yet developed to homogenize the process of data entry and collection and the associated work practices.

Due to the success of the tool in supporting the Clinical Department, and as a result of the wave of radical change that permeated some of the largest corporations in the industry (Cordella & Simon, 2000), the tool was re-evaluated and subsequently adapted to support the functions needed for the management and standardization of ongoing studies. The application was transformed to satisfy these new requirements and the needs of the new users, the so-called study monitors and the physicians in charge of the drug testing process.

In the new version, the application was developed into two different versions to match the new requirements: one designed to be used by the physicians and the other by the study monitors.

The physicians were to use the application to directly update the corporate central database with the latest data collected from their patients. Their version of the application was a web-based interface, accessed via an internet browser. After a security check, the application led them through the process of entering into the database the data they had collected from the patients. They had only to connect to a specific website, located on the Alpha central server, in order to enter and transfer the locally-collected data to the headquarters. A computer, a modem, and an Internet connection with a provider was given to each physician involved in the project.

Before the introduction of the ODC system, physicians transcribed the patients’ data into a paper folder, the Case Report Form (CRF), provided by the Alpha Corporation. When this paper-based system was in place, data registered in the CRF were cross-checked by the study monitors during their periodic visits to the physician’s surgeries, which occurred every one or two months. The data checked during the visits were only entered in the central database once the study was finally finished, at which point the paper CRFs were completed and collected from the physicians’ offices. All of the data were entered into the database at the company headquarters by data entry specialists. Only once all these procedures were completed did the data become available for analysis. The overall process was long and time consuming.

With the ODC-based system, the data were inserted directly into the digital CRF, and thus to the central database, by the physicians themselves. The application was designed as an interface to the pre-existing central database of the company, which contained the information collected during the testing phases of all the company’s drugs. The aim of the ODC platform was to provide the support needed to properly store the data in the database at the precise moment they were collected. The goal was to have all of the data from the drug testing phase cleaned almost on the same day the testing ended. The centrally-stored data could then be used and analyzed to support the preparation of the documentation required by the registration authorities for the commercialization licenses.
The monitors, equipped with a laptop, a modem, and an Internet connection, used different software and different functionalities of the ODC application to those used by the physicians.

The monitors’ application was designed to manage the various studies run in the different locations (physicians’ centres). Using their ODC application, the monitors could check the data entered by each physician, the number of enrolled patients and the progress of the study, for each patient and each trial site they had to supervise. However, these functionalities did not permit them to verify the consistency between the entered data and the original source. They still had to visit the centres approximately every two weeks to check that the physicians had entered the right data in the system. The monitors had an ad hoc utility in their version of the application that allowed them to remotely control the entered data. However, this function did not prevent physicians from making errors when copying the original medical records into the digital CRF. The correspondence between the collected and entered data could only be guaranteed by matching the original source to the entered records.

The online system and the subsequent methods of data collection and control were conceived as a strategic solution to the data collection process. The development of the application and the maintenance of the ODC system were only considered as technical support and not as being strategically important to the success of the application. Thus, from the outset, the development was outsourced to external consultants.

ODC was in fact implemented to meet the need for standardization and quality across Alpha’s global data collection system. The pre-existing IT infrastructure, mainly represented by the central database, was used as the platform for the development of the new system. The central database, once only used at the headquarters to analyze the already collected and cleaned data, was customized to support direct data entry through a web-based interface. These changes in the process required a redefinition of the procedures used to maintain quality control in the data collection process.

In the paper-based data collection methodology, the records were entered into the database once they had already passed the standardization process that ensured a match between the data, the database, and the quality requirements. This standardization process was the result of the interconnected work of physicians, monitors, and corporate data managers. The new methodology, based on the ODC system, changed the standardization process and the role of the agents involved in it. The aim of the project was to ensure the data and data collection process complied with the database structure. The users were strictly guided in the data collection and entering process by the characteristics and structure of the digital CRF. They could not make any ad hoc changes, because the digital interface did not permit local customizations. The requirements of the predefined data collection process were inscribed in the ODC system, as a standard to be followed across multinational environments.

7. Case analysis

The ODC functionality developed to enable the physicians to directly enter data into the database was an HTML interface that “opened” the central database to local data entry by external users. It could be considered as a gateway to the central database. This gateway opened the core corporate database to external users, but also imposed on the users certain rules, characteristics, and structures of data, which they had to follow when they interacted with it. It was not neutral to the definition of the final functionalities of the data collection process.

The web-based interface was customized for the database, which is based on the English language and tailored to recognize only data entered via the English QWERTY-based keyboard. This created problems and errors when users entered data via keyboards based on different standards and/or languages. Local differences were no longer filtered and cleaned as they had previous been by the monitors through ad hoc supervision or by the specialized data entry team when transcribing
the data from the paper folders into the database. The process of collecting and entering data, before the ODC system deployment, was divided into steps. Each step represented an opportunity for monitors and physicians to clean and standardize the data. The data were made to fit the requirements of the database during the process of collecting, cleaning and entering the data. In the new system, it was the web-based interface, customized to accept only data that fit the technological requirements of the central database, that filtered and homogenized the entered data.

With the adoption of the ODC system, the role of the monitors in the cleaning process changed. Although the monitor still intermediated in the data entry process to ensure it complied with the ODC system, the main check for errors, mistakes or unusual records, was done on the basis of the information they received from the central system. Once the physician had entered the data into the system, the data were recorded in a temporary folder. When incorrectly-entered data were detected by the system (e.g. out-of-scale measurements), the monitor was informed via a specific functionality in their version of the system. These errors usually referred to predictable data, such as heart rate or blood pressure. If a meaningless unit was entered, the system signalled it. When the physician was informed of the error, by the monitor, he/she was supposed to correct it. This process was supported by a specific function embedded in the software, which allowed the monitor to directly communicate with the physicians using a digital notification tool. However, the monitors usually notified physicians of errors during their regular visits to their surgeries. In order to meet the aim of having final, cleaned data, collected and homogenized at most a few days after the last patient’s trial ended, monitors were supposed to re-check the entered data for minor remaining errors.

The ODC system was designed to make the process and procedure of data collection in all locations smoother and homogeneous. Unfortunately, local characteristics, unique to their specific context, were not included or standardized by the ODC system. These specific characteristics, combined with uncontrollable tinkering by the users, affected and made partially vulnerable the attempted standardization by ODC.

In many countries, for specific local, legal or organizational reasons, in combination with the digital CRF of the ODC system, physicians also had to complete a paper CRF during the drug experimentation process. These local requirements had an impact on the output of the overall process of data collection based on the ODC applications. To enter the data into the digital platform could take up to an hour. Due to the important security procedures that had to be followed by the company, the data entry process could not be suspended; each session had to be completed during a single connection. The system automatically interrupted the connection and the data already entered was lost if two minutes of inactivity were detected. These security requirements often did not match the needs of the final users, the physicians. They experienced difficulties finding an appropriate period of time during their often busy days to complete the data entry in one go. In contrast, the paper folder was always available and could be filled in partially during occasional breaks. The physicians involved in the ODC project who operated in countries or institutions that still required the completion of a paper CRF folder, very often completed the paper option before the digital one. Once they had time, such as in the evening, at weekends, or other non-working times, they transcribed the data registered in the paper folder onto the digital platform. This task was also on occasion delegated to nurses. This un-prescribed behaviour often resulted in a delay between data collection and data availability on the system.

Moreover, the Internet connection was not always and everywhere reliable. When the Internet was not fast enough or where broadband was not yet available, such as in countries with an inefficient IT infrastructure, the paper CRF was still used as a substitute for the digital ODC platform. In these contexts, physician were formally allowed to fill in the paper folder first and complete the digital version later, when the connection was working, or when they had enough time to use
the slow web-based application. The overall procedure was thus renegotiated to match the local characteristics and needs. This obviously impacted the overall management of the study and the definition of the monitors’ work.

Frequently, for a variety of reasons, including those discussed above, monitors went to trial centres, having checked the digitally-stored data and made related comments and annotations (the so-called proof reading list), only to find that new data and/or patients had been entered. Therefore, the proof reading list, considered the final stage of the data check, did not reflect the real status of the data collected at the study site. This mismatch resulted in a less productive session than hoped for between the monitor and the physician. The monitor had not checked the new data, which was not yet registered in the system, so they could not be reviewed during the meeting with the doctor. This resulted in delays of up to a month in the data registration and cleaning process.

As previously described, to support the data entry and fix the most obvious errors, the system provided an automatic checking procedure. This function worked offline, at night on the central database. The list of errors was then sent to the monitors. Once they received the list, they had to notify the relevant doctors, who then had to correct them. Doctors did not receive any automatic notification by the system if they made errors in data entry. The monitor had two ways of notifying the doctors. One was provided by the system and the other was to use the telephone or inform them in person. The former option consisted of a digital query system, where monitors posed questions to physicians using an ad hoc tool in the system. The latter option was more frequently used and functioned better because the doctors seldom read or answered online queries from the monitors. When the doctor was notified of errors via the online system, they were required to write a report but if the monitor notified them by other means they were relieved of this requirement.

The improvised solutions using direct personal communication rather than the support provided by the electronic platform completely altered the overall effectiveness of the system. The documentation produced during the electronic correction procedure was used to evaluate the efficacy and efficiency of the new, Internet-based system. None of the corrections undertaken via other means was documented, however, and thus the conclusions regarding the success of the system were altered.

8. Lesson learned: Contextual, technological, and user constraints

The case provides an interesting insight into the effective role played by information technology in enforcing control and homogenization over organizational activities and work procedures. In this case, information technology is implemented to make the data collection process uniform in different study centres. The technological design and deployment of the system consider the process of data collection as given, and only problematic due to the lack of a standardized procedure across the organization. In the design and deployment of the information system, the users are mainly considered not to affect the output of the new, IT-mediated process. The classic assumption of a dichotomy between technology and people, stemming from the industrial age, still seems to dominate our understanding of the relational interplay between the two. The nature of technology, envisioned as a tool that can process and transform raw material better than humans can, justifies and drives the design and implementation of the ODC application in this organizational context.

In the following, we question this dichotomic assumption, discussing the roles of both technology and people in defining the standardization process enacted through the ODC system at the Alpha Corporation. As already discussed, the ODC system appears to constrain and at the same time to be constrained by technological and human features (Orlikowski, 1992; Suchman, 1987). Accordingly, the implications of the system for the data collection process must be re-analyzed in the light of the dynamic interaction that took place between technology and people during the system’s implementation and use.
The ODC application was designed and implemented following the perspective that IT is a fundamental tool for enhancing control and co-ordination of organizational activities (C.U Ciborra, 2000). The complex findings that emerge from the analysis of the system implementation show that this vision was too simple to capture the real consequences of the adoption of a new IT system in this organization’s multi-layered environment. The new IT-based system and the procedural changes needed to use it, were managed and understood using mental frameworks and “approaches that were effective for the mechanical organization, and assembly-line type of technologies and processes” but that are no longer valid for the adoption of complex IT systems in knowledge-based organizations (C.U Ciborra & Hanseth, 2000). These IT systems are in fact embedded in ramified webs of technologies and social context. They can only be understood if considered in their broad socio-technical context. Only by considering the associated complexity is it possible to understand the technological system, its effects on the organization, and the combined effects of the organization and the system. In a nutshell, the aim of this discussion is to understand the dynamics, drift, domestication, hostility and rejections (C.U Ciborra, 1994, 1999; Dahlbom & Janlert, 1996) that characterize the complexity of the adoption of an IT-based classification protocol and the use of this protocol. In the following, all these unpredictable dynamics are analyzed and considered normal ingredients of the implementation process, rather than pathologies in the deployment of IT systems in organizations.

The complexity of the interplay between the classification protocol and its users is here re-analyzed considering the abovementioned dynamics as lively components that shape and reshape the interplay between technological artefacts and people (Cordella, 2010). Technology and people are here not considered static and stable concepts but are defined and redefined through the interplay that generates dynamic relationships between the two (Callon, 1987; J Law, 1992). In the case of the ODC system, all of these dimensions affect the planned, centralized control and coordination strategy. These effects bring about “unplanned constraints” that jeopardize the successful implementation of the new technology. In the design and implementation plan, these events were in fact not even considered possibilities.

One of these constraints is the language used in the data collection system. The American market for pharmaceutical products is very large and has very strict regulations regarding drug registration. Once a drug is registered in the United States, it is very easy to rewrite the application to fulfil the requirements of other countries’ drug registration authorities. This is the first reason for customizing the system to the English language. The second is that English is the international language and so it is clearly appropriate that the general process should be standardized based on this language to reduce the costs of data collection and management. The system did not include an English spelling checking function which would have supported users in the data entry process to some extent. However, even if it had been included, such a facility could only correct misspelling errors and not those of translation from the medical folder in the local language to the digital CRF in English. This implies that someone has to check the language and fix the errors. However, the problem of translation requires specialist knowledge, given that it is necessary to translate the anamnesis and illness description. Thus the data have to be carefully cross-checked by the monitors. They have the final responsibility: they amend the language and all others aspects, ranging from doctors’ translation errors to unclear data.

The system was changed to satisfy requirements that emerged during its use. Some new problems arose with the greater understanding of the system’s requirements. The awareness of customization needs became evident in the implementation phase and more so when the system began to be widely used. Changes introduced when the system was already in use, especially those relating to data checking procedures—new parameters were introduced with the aim of improving the quality of data collection—generated a lot of new problems. Data which complied with the initial protocols failed to comply with the revised one. Corrections had to be made to data that had already been entered and files that had been closed. During the first phase of implementation, the data checking system was based on a pre-defined set of rules and
standards. Any errors found were fixed according to these rules. As the system was used, new needs emerged in response to the drug experimentation process and some of the fixed rules had to be changed accordingly. These changes modified the reference set of the system. As a consequence, new errors were found, while others were no longer recognized as errors. Doctors and monitors then had to adapt to the new changes to satisfy the requirements of the newly implemented standards. At the same time, part of the already-collected data had to be re-scanned to guarantee conformity with the newly introduced range of variables. Obviously, this change slowed down the whole procedure and created new and unexpected problems.

To deal with previously entered data, changes were needed in modules of the digital CRF that doctors and monitors had already double-checked and closed. Re-opening and changing these modules required a complex procedure that involved monitors, doctors and the company headquarters. The redefinition of the standards resulted in extra work and complexity for the persons involved in the process, often leading to a longer and more demanding procedure than under the previous paper-based system.

Other emerging problems were related to the use and implementation of the system. To gain access to the system, monitors and doctors had to use an Internet browser. The monitors used the IT-supported systems provided by the local Alpha offices, while the technology for the doctors was provided by the monitor, on the basis of the technological specification provided to them by the Alpha. However, the specifications received by the monitors only covered the necessary hardware configurations. No specific information was given in terms of the software that had to be used. The ODC system was initially based on a specific HTML version that was only fully compliant with specific versions of browsers, such as Internet Explorer 4 and Netscape 4.5 or higher.

Doctors with older versions of the browsers (which was quite common at the time of the study) encountered serious problems in using the system and thus recording and transmitting the collected data. Solving this problem was not as easy as it might seem since the monitors in charge of providing the technology to the doctors were not aware of the problems caused by incorrect versions of browsers. This often resulted in malfunctioning of the system for a long period and, consequently, delays in the registration of the data. The type of browser installed locally also caused problems to the proper functioning of the standardization system. The interface and some simple operations were different when the task was processed via Internet Explorer rather than Netscape. For example, with Internet Explorer, the layout of the page was different and thus the training provided by the monitors had to take these differences into consideration. Moreover, minor “operative” problems were linked with simple differences between the browsers. For example, in Internet Explorer, the tab key could be used to move the cursor from one entry form to the other, while Netscape did not support this shortcut. The monitors were unaware of these differences, the reasons for them and their implications. The help provided to doctors sometimes resulted in disorienting suggestions. During the implementation and use of the system the monitors had to answer questions related to technical and operative problems, though they were not competent to do so. They had to understand the problem, and find a solution and/or a competent person able to fix it but they did not have sufficient technological knowledge or skill to fulfil this role and thus such problems occupied a large part of their time, leaving less available for their main activity: managing and improving the quality of the data collection process.

A further and unexpected problem emerged when an English version of Internet Explorer was installed on computers running an operating system based on a different language. For example, in Hungary, the installation of the English-based browser was necessary because the required Hungarian version of the browser (see above) was not available. This installation resulted in continuous system crashes because of the conflict between the Hungarian version of the operating system and the English version of the browser. To fix the problem, an English version of the system had to be
bought and installed. The solution to the problem seems quite simple, in the end, but the identification and implementation of this solution (the reinstallation of the operating system) was delegated to the monitors.

This incomplete list of effects, problems and “errors” that emerged during implementation could easily be used to blame someone in the organization as incompetent in managing the process. It is obvious that it should have been possible to predict or avoid some of the aforementioned “problems” but it is also true that these problems emerged during and as a consequence of the implementation of the ODC system in the organization. They are easily recognizable ex-post, as consequences of the endogenous changes brought in by the IT-based classification protocol, but some of them were unpredictable ex-ante. IT system development and the following implementation process cannot be considered a straightforward procedure of technology adoption. It requires a broader consideration of the socio-institutional network in which it is embedded (Lanzara, 2009).

The ODC system was designed and implemented by Alpha to standardize and hence increase the central control over its data collection. The aim of the project was to make uniform not only the process of collecting data but also the final, collected data. The system was seen as a machine that would transform the patients’ data into homogeneous numbers, comparable regardless of the country, language, or other diverse contexts from which they were gathered, without having any other effect on the organization. No other potential effects were taken into consideration. The IT system was seen as a mechanical system which would help fulfill a specific need in the organization. On the contrary, adopting a new system means re-conceptualizing the nature of the work, the process, and its outcomes (Bloomfield, Coombs, Owen, & Taylor, 1987; Lanzara, 2009). The ODC system was designed to increase the uniformity of the process of data collection, using the standard laid down as a tool to translate local differences into a codified, uniform output. The tool was designed to make compatible the differences at the local level. As emerges from the analysis of the case, the effect of the standard on the data collection process was more complex: the ODC system, as with all IT-based systems, cannot simply be considered as a tool for the improvement of organizational performance (C.U. Ciborra & Hanseth, 1998), but must be considered in the broad, dynamic context in which it is deployed (Orlikowski, 2000; Star, 1999; Suchman, 1987) and the associated relational dimensions have to be considered, analyzed and discussed (C.U Ciborra, 2000; Cordella & Simon, 2000).

9. An ANT perspective: Emerging standardization

The standardization brought about by the ODC system, which was designed to achieve univocal work practices in the process of data collection, was highly affected by the local dynamics that emerged in, and shaped the use of, the system. To consider these dynamics, we need to look at the standardization process through the relationships involved since it is these relationships that continually shape and reshape the process (Brown & Duguit, 2000; Timmermans & Berg, 1997). As a consequence, the analysis of the standardization protocol (the ODC system) cannot exclude the socio-technical context within which it is deployed. This means considering in more detail the reciprocal interaction between technology and people in the specific context that influences and is influenced by both of them (J Law, 1992; John Law, 1999). The use of a protocol not only crystallizes and thus shapes the local data into a common framework which makes them manageable at a global level; it also affects and reshapes the associated work practices through the outcome of the process of standardization. Accordingly, the ODC system and work practices of the doctors, monitors and others involved are defined by the struggles faced on many different fronts, at different times, by many different network builders. A process of standardization based on structured work practices and technological standardization means an open-ended network where closure is never really achieved (Timmermans & Berg, 1997). The standardization process has to be considered the dynamic result of continuous interaction between work practices and technical artefacts. It does not have a completely predictable trajectory. It cannot be
crystallized except in contingent and specific spatial and temporal references. The standardization process emerges from these complex dynamics (Monteiro & Hanseth, 1995) and is co-constructed within its relational context (Monteiro, Ellingsen, & Munkvold, 2007).

Moreover, the standardization that takes place at the local level is not necessarily uniform as emerges in the case study. Local characteristics, contingencies and practices craft the use of the protocol (Bowker, 2002) so that it is impossible to conceive the overall output as the homogeneous sum of the local activities. The classification protocol produces effects on the local context of data collection but the local data collection process defines how the classification protocol is used and thus, eventually, the associated output. This means that the protocol of standardization, like other global IT systems, is obviously framing part of the process, but is also continually redefined through its implementation and use at the local level (Cordella & Simon, 2000; Ole Hanseth & Braa, 1998).

As already discussed in the literature, IT artefacts are not simple tools that are defined per se, but are defined by and define complex networks of relationships (Akrich & Latour, 1992; Callon, 1991; John Law, 1999; Suchman, 1987). Only through considering the dynamics of these relational networks is it possible to understand the dynamics associated with the adoption and use of a standardization process. In this case, the consideration of the relational status of the standardization process gives a different understanding of the overall process of standardization and its output.

In the case of the ODC system, the output of the process of standardization and thus the resulting control over it, is in this paper discussed as the result of a dynamic interplay determined by the interaction between technology and its users.

The standardization process, and in this case the aimed-for centralized control, is discussed as an emerging process, based on adaptation and continuous change, rather than a static monolith reflecting a predefined design. It also changes as a consequence of the output produced by the same process of standardization. Moreover, it is affected by local contingencies where the technology is tinkered with, to satisfy the specific needs of the local context. It is impossible to reconstruct the original data from the standardized data. The standardization process is tinkered with locally, but is translating the local into an artificial global framework of reference. The consequence is that the expected global uniformity is affected by the contingent and local practices in using the protocol of standardization. This has to be taken into consideration when implementing standardization processes so as to achieve control and uniformity of data collection. The aimed-for uniformity is the output of a dynamic process, so it cannot be considered as the mere result of the implementation of a technological process; standardization occurs as an emerging interaction. Standardization emerges from the context.

10. Conclusions

This article discusses the process through which a standardization process homogenizes data. Based on a case study, the article discusses the process that transforms data collected in different contexts into uniform data that represents a phenomenon that can be defined globally. The means of standardization is an information technology-based protocol that aims to transform the data collection procedure into a homogeneous process. This process is expected to make the quality and characteristics of the collected data homogeneous in turn. The technology used for this standardization is not uniquely analyzed on the basis of the produced output, but within its organizational context. The output of the process of standardization, and thus the ensuing control over it, is considered to be the result of a dynamic interplay between technology and its users.

The standardization process is thus here conceived as a changing process, based on adaptation and continuous changes, rather than a static monolith that reflects the ex-ante design. It also changes as a consequence of the output
produced by the process of standardization. Moreover, it is affected by local contingencies, as a result of which the technology is tinkered with, to satisfy specific local needs.

The output of this process of standardization strongly reflects the adaptation and interplay that takes place between the technology and the needs of its users. The consequence is that the expected global uniformity in the data and the collection process is affected by the local use of the protocol of standardization. This has to be taken into consideration when implementing standardization processes to achieve global uniformity. The aimed-for uniformity is the output of a dynamic process and thus cannot be considered merely the result of the implementation of a predesigned and fixed set of rules and standards. Standardization processes emerge from the context, rather than shaping the context according to predefined categories.

11. References


