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Standardization in Action

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Abstract

This paper discusses the dynamics of implementing and deploying a standardization process based on an IT infrastructure. The analysis is based on a case study conducted in a pharmaceutical R&D organisation. The standardization infrastructure in use, constituted by a computerized system and the surrounding organisational procedures, seems to be different from the one expected as a result of the ex-ante design of the infrastructure. The paper discusses the role played by local characteristics, contingences, and practices in the definition of the nature and effects of the standardisation protocol implemented to improve the control over data collection and analysis. The paper concludes that the output of the process of standardisation and thus the following control over it should be discussed as the result of a dynamic interplay determined by the interaction between technology and its users rather than the consequence of a planned an well defined design project.

Keywords: Standardisation, implementation, actor network theory, infrastructure in use

1 INTRODUCTION

Information and communication technologies have become the most common standard to support information flows in private and public organisations. Many authors have discussed how to develop, chose, and implement in the most effective way these technologies. In this context, research in information system development methodologies have proposed and discussed procedures to make more efficient and effective the process of developing information systems. Similarly managerial studies have focused on the research of optimal solutions to analyse and choose information and communication technologies to leverage organisations' performances. However, less attention has been historical given to the study of the effect of ICTs as tools to enforce classification procedures and the role they play in the development, diffusion and evolution of organisational practices. Only recently scholars have shown increasing interest in the study of the definition, development and evolution of technological standards and classification protocols and the role they play in ICTs deployment aiming at defining, supporting and improving organisational practices.

This paper discusses how a standardised technology, designed to uniform data collection and analysis, evolves, changes, and get shaped within the practices of the organisation using it. The paper first overviews the debate about the nature and evolution of standards and standardising technologies and hence presents in details the finding of a case study conduced at AstraZeneca. Analysing the case study in the light of the leading literature the paper contributes providing a further insight on the evolutionary nature of standardising technologies highlighting the role played by local constrains and practices on these dynamics.

1.1 Theoretical Background

The attention to the role played by standards and classification protocols in ordinary, organisational and social life is not new and provides an interesting background for the study of classification protocols based on ICTs systems.

Historically, the importance of standards and classification protocols has been discussed from different perspective. Bureaucratic systems have been described as organisation that use rules, norms, and routines to reiterate behaviours when similar circumstances occur. Standardised answers are classified and ordered to provide homogeneous paths of responses to similar events faced by partners' organisations located in different places, reducing in this way transaction costs and the complexity of the tasks of the employees.

The role of norms, rules and resources in social setting can also be seen and discussed as the structure, conceivable as set of standards, that affects the process that shapes social order. Giddens (1984) for example discussing the interdependency of human action and social structure identifies social structures as composed of rules and resources that facilitate and/or constrain the interaction in social settings. Rules and resources are providing the contextual constraints that individual draw upon when acting and interacting. These rules and resources are the given categories upon which social orders get constructed and reconstructed in recursive way. Quite similarly, Avgerou (Avgerou, 2000) discusses institutional theory identifying the nature of institutions as taken for granted standardised sequences of activities which establish and maintain the *modus operandi* of the organisation that can create powerful myths (Avgerou, 2002) which can constrain but also enable change within the organisation.

At macro level the key characteristics of standards and the associated systems of classification can than be identified with their being the product of and maintained by social institutions (Douglas, 1986)

Moreover, classification and standards are permeating our daily life as citizen, workers and member of social systems. Our way of co-ordinating activities, finding places we are looking for, understanding context etc., are mediated by system of classification that are often considered in the background of our action as if they were invisible(Bowker and Star). However, these systems of classification are not

in the background of the occurring event. They often define the event itself. Think for example at the system of classification that defines the admission requirements to a university college. In this case the system of classification is an important factor for the definition of the students that will be accepted in the college and those who will not. The population of the college is then also defined by the specific system of classification that is used to filter and rank the submitted applications. In this case, the system of classification is an important factor that influences the decision about the students that fulfil the needed criteria to be accepted in the specific institution.

This broad overview of the nature of standards and classification protocols, is here used as a background for the research of this paper that is aiming at providing a better understanding of the micro aspects that define and redefine ICT base classification system when they are studied in the context of their use.

1.2 Standardization

The study of classification protocols and technological standards in organisation settings is not new. However, the last decade as presented an increasing interest in the study of the socio-technical dimension of classification protocols and standards, to highlight the importance of the interplay of the protocols and standardisation technologies within the social context using them.

Following this stream of thought, Bowker and Star (1999) largely discuss the contextual nature of the process of classifying and hence the socio-technical nature of classification protocols giving specific emphasis to the technical, cultural, social and political elements. Given their perspective the focus of the analysis is on the understanding of how standards and classification protocols develop and evolve, and what are their characteristics once studied in a specific context. The intertwining nature of classification protocols and hence standards is discussed in the light of their political, cultural and social dimensions. The authors clearly stress that the understanding of the nature of a classification protocol require the study of the intertwined nature of the socio-technical dimension of classification protocols. They ground their studies on detailed analysis of systems that have been set up to categorize diseases, work, races, etc., discussing the role of these classification protocols not only as tools that create groups of homogeneous data, but rather looking at the socio-political dimension played by these protocols that in the context of their use provoke advantages or suffering to specific groups, individual or situations.

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

The complex natures of this socio-technical interplay can however allow the use of many different angles as is the large number of actors that can be identified as elements that shape the socio-technical network. Hanseth (1996) for example, takes a different analytical angle compared to Bowker and Star (1999), highlighting the role of “the irreversibility of the installed base” as the self reinforcing mechanism produced by the growth of technical system. In this case the focus of the research is on the processes that reinforce the technical characteristics as consequence of the layering of technical choices over time, which gain momentum as reiterated effect of the alignment of technical, institutional and users’ choices. This research however highlights once again the concatenation of this 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” looking at the level of their “power of inscription”. The strength the inscriptions, the more the socio-technical network is aligned and more effective the inscribed program of action is. Standards can than be discussed and analyzed looking at the embodiment of inscription they are made of. Once again is the technical actor that is here

considered as the most appropriate object of study for the understanding of the evolutionary path taken by the socio-technical network.

A further insight in the study of the socio-technical nature of classification protocols and standards comes from Timmermans and Berg (1997) that wile studying the nature and configuration of these socio-technical systems shed light on the disperse nature of standardization outcome of the interplay in these relational networks. Standardization efforts do not necessary require a central actors. Looking at the evolution of medical protocols, they find that standards procedures emerge as the outcome of real time work that take place within localised processes of negotiation within pre-existing institutional, infrastructural, and material relations. Once more, standards are to outcome of relational networks defined within time and space contextual variables. Technology can inscribe path of uses but is de-scribe[1] by users in the act of using it (Timmermans and Berg, 1997; Alkrick and Latour, 1992). The study of local context and the situadeness of the action that embeds the use of classification protocols and standardization technologies is thus the right place to look at if the interest of the research is to understand the processes that outline the nature of these technologies once considered in their socio-technical dimension. Following this understanding Timmermans and Berg (1997) argue that 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" Accordingly to these authors a standard is open ended and closure is never really achieved. The context of the use of s specific protocol of standardization is defining over time and space the continuous evolution of the protocol itself.

Using a different focus in the analysis, but getting to 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."

All these contributions address elements that lead to the consideration that classification protocols, and in general technologies are co-defined and emerging by the situatedness of the action of users that improvise and invent new programs of action once the technology is situated and contextualised within routines (Suchman 1987)

Following this understanding here we argue that the use of a classification protocol as standard to define organisational procedure has to be considered in the specific context and time of action. These are In fact the most influential elements for the definition and understanding of the nature of the impact of the standards on the organisation procedures. This conclusion is grounded on the empirical evidence that emerged from tha study of the practices and constrains that surrounds the deployment of a classification protocol implemented to standardize globally data collection and analysis procedures during drug testing at the pharmaceutical multination company AstraZeneca.

[1]Definitio of de-scription

2 THE CASE STUDY

2.1 Background

In late 1997 AstraZeneca implemented an Internet application named “COOL” and the related work processes to standardise the data capture system and process in clinical trials. The application was designed to manage and support the remote data capture process during clinical testing on patients. The aim of the application was to move the data entry, (i.e. the transcription in specific files of the data collected during the drug’s testing on the patient), from the study managers, the so called monitors, to the doctors in charge of the study thank to a digitally standardise protocol. The purpose of the new system was to improve the homogeneity and quality of the entered data, shortening the time necessary to have them completely corrected and in proper format (in the industry jargon, cleaned) for the preparation of the documentation for the submission to the FDAs. The quality and homogeneity of the collected data is in fact an important factor for the successful registration of 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 commercialisation phase longer with the obvious benefit for the company revenues. Accordingly, the entry data process is a very important aspect of the R&D and commercialisation activity in the pharmaceutical industry.

2.2 The COOL application: history, characteristics, and aims

The first version of COOL was developed as an administrative application to support the management of the various clinical studies undertaken by the corporate. It was used at the headquarter level as an Internet Study Administration tool (ISA). During this phase the application was only accessible by people working at the Clinical department to supervise the state of the various phases of the drugs testing. It was a study administration tool without any practical utility developed to homogenise the process of data entry and collection support the actual management of the study.

Considering the success of the tool to support the Clinical department, and in conjunction with the wave of radical change that was permeating the company in relation to a large reengineering process (Cordella and Simon, 2000), this administrative tool was re-evaluated and subsequently adapted to support the functions needed for the management and standardisation of the 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 testing phase.

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

The physicians are supposed to use the application to directly update the corporate central database (AMOS) with the latest collected data from their patients. The application designed to support physicians in the data registration process is an interfaced that is accessed via an internet browser. The physicians access the AMOS central database through a web-based page and simple internet connections. After a security check, they are guided by the application for entering the data collected from the patients into the database. They have only to connect to a specific website located on the AstraZeneca server to enable the previously described procedure and thus transfer the locally collected data to the headquarter.

A computer, a modem, and an Internet connection with a provider was given to each physician involved in the study.

Before the introduction of the COOL system, the physicians transcribed the patient’s data into a paper folder, the Case Report Form (CRF) that was provided by AstraZeneca. When this paper based system was in place data registered in the CRF were crossed checked by the study monitors during their periodic visits (one every month or two) at the physician surgeries. The data checked during the study

progress were only entered in the central data called AMOS when the study was finally finished, the paper CRF completed, and finally collected from the physicians offices. The registration of data in the database was done at the company headquarter where data entry specialist entered the data in the AMOS database. Only when all these procedures were terminated the data became available for analysis. The overall process was long and time consuming. With the COOL based system, the physicians are supposed to insert the data collected from patient directly into the digital CRF, which is now directly located into the AMOS database. The application was designed as an interface to a pre-existing company central database which contains all the information collected during the testing phases of the company's drugs. The html-based platform is the framework designed to supports and enables the direct registration of data in the database. The aim of the application is to provide the support to correctly store the data in the database at the precise moment they are collected. The proposed goal is to have the all data of the drug testing phase cleaned almost the same day the testing ends. The data stored in the AMOS are then used and analysed to support the preparation of the documentation required by the registration authorities for the commercialisation licenses.

The monitors, equipped with a laptop, a modem, and Internet connection, use different software and functionalities of the COOL application compared with physicians.

The monitors' application is designed to support monitors in the management of the study that runs in the different location (physicians' centres) in the geographic area they have responsibility for. Using their COOL application they can check the data entered by each physician, the number of enrolled patients and the study progress for each patient in every trial site they have to supervise. However, these functionalities do not permit to check the correspondences between the entered data and the original source. The monitors, every second week or so, have to visit the centres to check if the physicians have entered the proper data in the system. The monitors have an ad hoc utility in their version of the COOL application that allowed them to remotely control the entered data. However, this function does not prevent physicians from making possible errors when the original medical records are copied in the digital CRF. The correspondence between the collected and the entered data can only be guaranteed when the original source is confronted with the entered records.

The on line system and the subsequent method of data collection and control were seen as the strategic solution to the data collection process. The development of the application and the maintenance of the COOL system were only considered as technical support and not a key issue for the success of the application. From the outset the development of the application was outsourced to external consultants. This decision was taken because the development and maintenance of the application were not considered strategically important.

COOL was in fact implemented to match the need for standardisation required by a global data collection system. The aim of the project, as already described, was to ensure uniformity and quality for the data collection around the world. The pre-existing IT infrastructure, mainly represented by the AMOS database, was used as the platform for the development of the new system. The AMOS database, once only used at headquarters level for the analysis of the already collected and cleaned data, was customised to support the direct data entry through a web-based interface. These changes in the process required a redefinition of the procedures developed to maintain quality control in the data collection process.

In the paper based data collection methodology the records were entered in the database when they had already passed the standardisation process that ensured the correspondences between the data, the database, and the quality requirements. This standardisation process was the result of the interconnected work of physician, monitors, and the corporate data managers. The new methodology, based on the COOL system, changes the standardisation process and role of the agents involved in it. Aim of the project is to make the data and the data collection process compliant with the database structure. The users are strictly guided in the data collection and entering process by the characteristics and structure of the digital CRF. They cannot make any ad hoc change because the digital interface does not aloud local customisations. The system is tailored to match the requirements of the

predefined data collection process inscribe in the COOL system, as standard for the data collection procedures that take place in multinational environments.

2.3 Case analysis

The COOL functionality developed to enable physician to direct enter data in the database is an HTML interface that “opens” the central database to local data entry. It is the interface to the AMOS database for external users. It can be considered as a gate to AMOS.

This gate opens the core corporate database to external users, but also imposes the users to follow the rules, characteristics, and structure of the database when they interact with it. It is not neutral to the definition of the final functionalities of the data collections process.

The web based interface is customised onto the database that is structure on the English language and it is tailored to recognise data only entered via the English QWERTY based keyboard. This creates problems and errors when users are entering data via keyboards based on different standards and/or languages. Local differences are no longer filtered and cleaned by the monitor through ad hoc supervision and\or by the specialised data entry people during the transcription of the papers folder into the database. The process of collecting and entering data, before the COOL system deployment, was divided into steps. Each step represented an opportunity to clean and standardise the data. The data were uniformed according to the requirement of the data base standard during the process of collecting, cleaning and entering data. Now is the web-based interface, customised on the technological requirement of the database that filters and homogenises the entered data.

With the adoption of the COOL system, the task of the monitors in the cleaning process is changed. Although the monitor still intermediates the data entry process to ensure its correctness with the COOL system, the main check for errors, mistakes or unusual records, is done on the basis of the information they receive from the central system. Once the physician has entered the data into the system, the data are recorded in a temporary folder. When incorrectly entered data are detected by the system, the monitor is informed via a specific functionality in their version of the system. When the physician gets informed by the monitor about the found error, he/she is supposed to correct the identified errors. This process is supported by a specific function embedded in the software that allowed monitors to directly communicate with physicians using a digital notification tool. However, more commonly the monitor notifies the founded errors to the physicians during the regular visits at the doctor’s surgery.

As already discussed, the aim underpinning the redesign of the overall data collection process is to have the final, cleaned data, collected and homogenised at the latest in few days after the last patient’s trial is finished. Monitors are supposed to intermediate the data collection process to ensure the correctness of data entered during the patients’ trials. Once the trial has been concluded, the entered data have to be re-checked for minor remaining errors so that within few days they are completely cleaned and ready to be used for the writing of the application to the FDAs.

The COOL system is designed to make the process and procedure of data collection in all locations smoother. Unfortunately, local characteristics, unique for the specific location or context, are not affected and thus homogenised by the standardisation process implemented via the COOL system. However, these specific characteristics combined with uncontrollable users tinkering, affect and partially make vulnerable the attempt to standardisation managed via the COOL applications. In many countries, for specific local, legal or organisational reasons, in combination with the digital CRF of the COOL system physicians have to complete a paper CRF during the drug experimentation process. These local requirements have an impact on the output of the overall process of data collection based on the COOL applications. To enter the data into the digital platform can take up to an hour. Considering the important security problems that must be guaranteed by the company, the data entry process cannot be interrupted and each session has to be completed during a single connection. If two minutes of “non operation” occur the system automatically interrupts the connection and the data

already entered gets lost. These security requirements often do not match the needs of the final users, the physicians. Doctors, in fact, often experience difficulties in finding an appropriate time during their busy day to complete the digital folder without interruptions. On the contrary, the paper folder is always available and can be filled in partially during the occasional breaks of the doctors' working days. The physicians involved in the COOL project that operate in countries or institutions that still require the registration of data in the paper CRF folder, very often first complete the paper option instead of the digital on. Once they have time, such as in the evening when their duties are finished, during the weekends or in other special moments, they transcribe the data registered in the paper folder onto the digital platform. This task it is also on occasion delegated to nurses. This un-prescribed behaviour often results in a delay between data collection and data availability on the system.

Moreover, the internet connection is not always and everywhere reliable. When the Internet is not fast enough or where broadband in not common yet, as in countries with an inefficient IT infrastructure, the paper support is still used as a substitute for the digital COOL platform. In these contexts, physician are formally aloud to fill in first the paper folder and only afterwards, when the connection works, or when the doctors have enough time to use the slow web base application, to fill in the digital version of the CRF in the COOL system. The overall procedure is thus renegotiated to match the local characteristics and needs. This obviously impacts the overall output of the study management and the definition of monitors work.

Frequently, because of different reason, such as the previously discussed, monitors go to the trial centre having checked the digitally stored data with the related comments and annotations (the so called proof reading list) only to find that new data and/or patients have been entered. Therefore, the proof reading list, considered the final passage of the data check, does not reflect the real status of the data collected in the specific study site. This mismatch results in a less productive session between the monitor and the physician. The monitor has not checked the new data, which is not yet registered in the system, so that they cannot be reviewed during the meeting with the doctor. This can result in a delay of up to a month in the data registration and cleaning process.

As previously described, to support the data entry and to fix the most banal errors, an automatic check on the entered data is implemented in the COOL system. This function works off line and runs during the night on the AMOS database. The list of errors is sent only to the monitors. Their task is thus to inform the doctors and have them to fix the found errors. This functionality is thus supporting the errors check function of the monitors, but does not help the doctors supporting their data entry process. Doctors do not receive any automatic notification by the system if they make errors in the data entry.

Once the monitors have received the error list, they have to contact the doctors to fix the errors discovered. The monitor has two different options to get the errors corrected. One is provided by the system and the other is based on telephone or personal communication between monitors and physicians. The former consists of a digital query system, where monitors pose questions to physicians using an ad hoc tool in the COOL system. The latter, which is also the most frequently used, consists in the monitor making a phone call to the doctor explaining him/her the error with the relative request for correction, or to discuss the corrections during the visit at the doctors' surgery. The second approach to error debugging is the most functional because doctors use the system only as a data entry tool rather than a communication tool with the monitor. Problems with connection speed also complicate this on-line communication system. Consequently physicians do not read the on-line queries and do not answer them. As a consequence monitors enacted different procedure to notify found errors and get them corrected. When a doctor is contacted in alternative ways than the one prescribed by the COOL system to solve errors, they are obviously exonerated by the writing of the report that is normally required if the notification and request is sent via the digital query system of the COOL system.

These improvised solutions based on the use of direct personal communication rather than via the support provided by the electronic platform are also altering the results of the overall effectiveness of the system. The documentation that is produced during the electronic correction procedure is used for

the evaluation of the efficacy and efficiency of the new, internet based system. Consequently, none of the correction undertaken via the non-electronic platform is documented and thus the conclusions regarding the successfulness of the system are altered.

2.4 Lesson learned: contextual, technological, and users constrains

The case here presented provides an interesting insight to discuss the effective role played by classification protocols and information technology in enforcing control and homogenisation over organisation activities. In the case here discussed information technology is implemented to make homogeneous the data collection process in the different study centres. In the design and deployment of the classification protocol the users are mainly considered neutral to the output of the semi-mechanised process of data collection. The dichotic assumptions between technology and people, classic of the industrial ages, seems to dominate the understanding of the relational interplay between technology and people. The nature of technology, envisioned as a tool that better process and transforms raw materials rather then humans is justifying and underpinning the understanding, design and implementation of the COOL application in the organisational contexts. In the following we question this dichotic assumption about technology and people discussing the role of both technology and people in the standardisation process enacted via the COOL classification mechanism at AstraZeneca. As already discussed, the COOL system appears to constrain and at the same time to be constrained by technological and human features (Suchman, 1987, Orlikowski, 1992). Some of these constrains are the consequence of technologic characteristics of the system, others of its use. Accordingly, the implication of the system on the data collection process must be re-analysed shedding light on the dynamic interaction that takes place between technology and people during the system implementation and use.

The COOL application was designed and implemented following the rational that sees IT as a fundamental tool to enhance control and co-ordination over organisational activities (Ciborra, 2000). The complexity that emerges from the analysis of the system implementation shows that this vision was too simple to capture the real consequences of the adoption of a new IT system in this complex organisation's environment. The new IT-based system and the following changes were managed and understood using mental frameworks and "approaches that were effective for the mechanical organisation, and assembly-line type of technologies and processes" but that are not any more valid for the adoption of complex IT systems in knowledge based organisations (Ciborra and Hanseth (2000). The former are in fact embedded into complex and ramified webs of technologies and social context. They can only be understood if considered in their broad socio-technical context. Only considering the associated complexity it is possible to understand the technological system, its effects on the organisation, and the combined effects of the organisation and the system. In a nutshell, the aim of this discussion is to understand the dynamic, drift, domestication, hostility and rejections (Ciborra, 1994, Ciborra, 1999, Dahlbom and Janlert, 1996) that characterise the complexity of the adoption of a IT base classification protocol and the use of this protocol. In the following, all these unpredictable dynamics are analysed and considered normal ingredients of the implementation processes rather than pathologies in the deployment of IT systems in organisations.

The analysis of the complexity of the interplay of the classification protocol and its users is here re-analysed considering these dynamics as lively concepts that dynamically shaped and reshaped the interplay that takes place between technological artefacts and people. Both technology and people are here not considered static and stable concepts but considered defined and redefined in the interplay that generate the dynamic relationships among the two (Callon, 1987, Law, 1992). In the case of the COOL system all of these dimensions affect the planned centralised control and co-ordination strategy. These effects are discussed as emerging "unplanned constrains" to the intended effects of the implementation of the new technology. Following the design and implementation plan, these unexpected events where in fact not considered possible.

One of these constraints is the language used in the data collection system. The American market is very big and with very strict regulation as to drug registration. Once the drug is registered in the United States it is very easy to re-write the application to fulfil the requirement for the registration with other countries registration authorities. This is then the first reason to customise the system on the English language. The second is that English is the international language and so it is obvious that the wide process should be standardised on this language to reduce the costs of data collection and management. Even if English is the standard language for all the process, the system does not embed an English spell check to support users in the data entry process. Obviously, a spell check could only correct errors, which are a consequence of misspelling, not of translation from the medical folder in local language to the English. This implies that someone has to check the language and fix the errors. However, the second problem -that one of translation- is not easy to solve as it requires the translation of the anamnesis and the illness description and has to be carefully cross checked by monitors. An automatic agent could easily solve the first problem once the data are entered, but cannot perform the second, most important function, the translation check. The monitors are thus charged with this responsibility: they amend the language and all others aspects that range from doctors' translation errors to unclear entered data.

The system was changed to satisfy requirements that emerged during its use. Some new problems arose in accordance with greater understanding of the system's requirements. The awareness of customisation needs became evident not only during the implementation phase but also when the system became widely used. Changes introduced while the system was already in use, especially the one in the data check procedure, have generated a lot of new problems. During the first phase of the implementation the data check system was based on a pre-defined set of rules and standards. The errors found were then fixed according to these rules. As the system was being used, new needs emerged, as existing requirements were changed. These new specifications were a consequence of the new requirements, necessity and specification, which also emerged during the drug experimentation process. In consequence, some of the fixed rules had to be changed to mach the new requirements. The introduced changes modified the reference set of the system. As a consequence, new errors were found while others were no longer recognised as errors. Doctors and monitors had then 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 the conformity with the newly introduced range of variable. Obviously, this change slowed down the whole procedure and created new and unexpected problems.

The consequences of these changes not only affected the contingent data entry process, but also the previously entered data. Furthermore, changes are now needed in modules of the digital CRF that doctors and monitors had already been double checked and closed. To re-open and change the already closed modules requires a complex procedure that involves monitors, doctors and the company headquarter. The obvious outcome of this redefinition of the standards of compliance is a request of extra work and complexity for the persons involved in the data collection process, often resulting in a longer and more demanding procedure compared with the pre-existing requiring paper based system.

Other emerging problems are related to the use and implementation of the system. To gain access to the system, the monitors and the doctors have to use an Internet browser. The monitors use the IT supported systems provided by the local AstraZeneca offices, while the technology for doctors is provided by the monitor on the bases of the technological specification that AstraZeneca gave them. However, the specifications received by the monitors only concerned the necessary hardware compliances. No specific information was given in regards to the software that had to be used. The COOL system is based on a specific HTML version that is fully compliant with only specific versions of browsers, such as: Internet Explorer 4 and Netscape 4.5 or higher.

Doctors with older versions of the browsers encountered serious problems in using the system and thus recording and transmitting the collected data. To solve these problems was not easy as it seemed at a first glance. The monitor in charge of the "implementation" of the local data entry machines did not know that there were potential problems related to the browser's versions. The slow and

approximate decryption of problems performed by insufficiently IT qualified personnel, the monitors, often resulted in long malfunctioning of the system and in consequent retards in the registration of the data. Not only the version of the browser, but also the type of browser locally chosen, has been causing problems to the proper functioning of the standardisation system. Both the interface and some simple operations are different if the task is processed via Internet Explorer rather than Netscape. For example, if Internet Explorer is the chosen browser the layout of the page is different and thus the training and the suggestion to the users, provided by the monitors, had to take into consideration these differences. Moreover, minor "operative" problems are linked with simple differences between the browsers. In Internet explorer, for example the tab key can be used to move the cursor from one entry form to the other, with Netscape this does not work and so forth. The monitors were unaware of these differences, the reasons for them and their implications. Therefore, 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 were not competent to do so. When this circumstance happened, they had in the first place to understand the problem and hence to find a solution or/and a competent person able to fix it. They do not have sufficient competence to fulfil this task and to find out adequate solutions to technological related problem. The research for these solutions occupies large part of their time so that less is available to 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 version of the browser (see above) was not available in the Hungarian version while the registered version of the operating system running on the computers was the Hungarian. Installing the English version of the browser on a computer running the Hungarian operating system resulted in continuous system crashes because of the conflict between the version of the system and the 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, but the identification, and the implementation of the solution, the reinstallation of the operating system, was delegated to monitors.

This incomplete list of effects, problems, and "errors" that emerged during the implementation can be easily used to blame someone in the organisation as incompetent and unable of managing the implementation of the IT systems. It is obvious that it was possible to predict or avoid some of the aforementioned "problems" but it is also true that these problems emerged during and as consequence of the implementation of the COOL system in the organisation. They are easily recognisable ex-post, as consequence of the endogenous changes brought in by the IT-based classification protocol but some of them ere 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-technical network it is embedded in.

The COOL system was designed and implemented to standardise and hence increase the central control over the data collection. The aim of the project was to uniform not only the process of collecting data, but also the final collected data. The system was seen as the machine that without any other effects would have transformed the patients' data in homogeneous numbers so that they are comparable independently by the country, language etc, they come from. None of the other potential effects of the system are taken into consideration. The IT system is seen as a mechanical system that helps to fulfil a specific need of the organisation: nothing more!

On the contrary, to adopt a new system means to re-conceptualise the nature of the work, the process, and its outcomes (Bloomfield et al., 1987). The COOL system was design to increase the uniformity of the process of data collection using the standard as a tool that translates the local differences into a codified, uniform output. The tool is designed to make compatible the differences at local level. As it emerges from the analysis of the case, the effect of the standard on the data collection process is more complex: the COOL system, as all IT based systems, cannot be simply considered as a tool for the improvement of the organisational performances (Ciborra and Hanseth, 1998), but must be considered

in the broad, dynamic context in which is deployed (Orlikowski, 2000, Star, 1999, Suchman, 1987) and the following relational dimensions have to be considered, analysed and discussed.

3 CONCLUSIONS

The standardisation brought about by the COOL system, which is designed to achieve a univocal process of data collection, is highly affected by the local dynamics in the use of the system. To consider these dynamics also require the analysis of the standardisation process from a perspective that enlighten the relational dimension that result in a dynamic process that shapes and is reshaped in the relationship (Brown and Duguit, 2000, Timmermans and Berg, 1997). As a consequence the analysis of the standardisation protocol (the COOL system) cannot exclude considerations about the socio-technical context where it is deployed. This involves the need for more considerations about the reciprocal interaction among technology and people in the specific context that influences and is influenced by both of them (Law, 1992, Law, 1999). The use of a protocol not only crystallises and thus shapes the local data into a common framework to make them manageable at global level, it is also reshaped by the results of the process of standardisation. Accordingly, the protocol is defined by the struggles faced on many different fronts, in different times, by many different network builders. A protocol is open-ended and closure is never really achieved (Timmermans and Berg, 1997). It is the dynamic result of this continuous interaction. It does not have a completely predictable trajectory itself. It cannot be crystallised unless it is contingent on specific space and time references. The standardisation process emerges from this complex dynamic (Monteiro and Hanseth, 1995).

Moreover the standardisation that takes place at local level is not necessarily uniform as it emerges in the case study. Local characteristics, contingesis and practices craft the use of the protocol (Bowker, 2002) so that is impossible to conceive the overall output as the 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 eventually the associated output. It means that the protocol of standardisation, as other global IT systems, is obviously framing part of the process, but it is also continually redefined by its implementation and use at local level (Cordella and Simon, 2000, Hanseth and Braa, 1998).

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

In the case of the COOL system, the output of the process of standardisation and thus the following control over it is here discussed as the result of a dynamic interplay determined by the interaction between technology and its users.

The standardisation, and in this case the aimed centralised control, is discussed as a changing process based on adaptation and continuous changes rather than a static monolith that reflects a preddifned design. It also changes as a consequence of the output produced by the process of standardisation. Moreover it is affected by local contingences where the technology is tinkered to satisfy specific needs of the local context. It is impossible to reconstruct the original data back from the standardised data. The standardisation process is tinkered locally, but is translating the local into and artificial global framework. The consequence is that the expected global uniformity is affected by the contingent and local practices in the use of the protocol of standardisation. This has to be taken into consideration when standardisation processes are implemented to achieve control and uniformity in data collection. The aimed uniformity is the output of a dynamic process so that it cannot be considered as the mere result of the implementation of technological process.

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