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The Electronic Patient Record – sufficient quality for clinical research?

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Abstract
Electronic Patient Records have many purposes in hospitals. They are expected to be a foundation for clinical treatment and care processes, reimbursement issues, and research purposes. Accordingly, there is a gap between the information found in the EPR and the information required for clinical research. We explore what this gap consists of, how it is managed, and who is responsible for closing it. We wish to highlight the work that goes into this process, conducted by both the research staff as well as the ordinary health workers. In doing this we seek to move away from the perception that research data is automatically given as long as a hospital-wide EPR is in use. What is the nature of integrated systems in clinical research based on the notion of quality, as well as secondary use of documentation?
1. Introduction

Electronic Patient Records (EPRs) have several purposes in hospitals. They are expected to be a foundation for both clinical treatment and care processes (Ellingsen 2004), reimbursement procedures through the diagnosis-related group (DRG) coding systems, and clinical research purposes. Clinical research or clinical trials are studies that test how new medical procedures may improve the treatment of patients. Each study answers specific scientific questions and tries to find better ways to prevent, screen for, diagnose, or treat a disease. Clinical trials may also compare a new treatment to a treatment that is already available. The trials are often global, spanning institutions worldwide, and with the pharmaceutical industry serving as coordinator on a local and global level. The general idea is, by using a large-scale EPR, it is possible to extract whatever information is needed for research purposes, especially if the EPR consists of a large amount of structured data elements that can be extracted, compared, accumulated, and summarized (Berg and Goorman 1999). In this way, an EPR is expected to respond to the recent call for large-scale information infrastructures such as Cyberinfrastructure (CI) (Ixchel et al. 2010; Ure et al. 2009; Edvards et al. 2009; Ribes and Finholt 2009) or eScience (Ixchel et al. 2010; Ribes and Lee 2010), which may support scientific research activities.

However, this view is problematic in research studies spanning several countries, where the data is supposed to be used independent of a given context. Such studies require more granulated, slightly different data, as well as data that have a higher quality than what is needed in daily clinical work. This basically leaves us with a gap between the information found in the EPR, and the information required for clinical research. In this paper, we explore what this gap consists of, how it is managed, and who is responsible for closing it in order to make the information in the EPR usable for research purposes. Our contribution is to draw attention to the work that goes into this process as it is conducted by the research staff, as well as nurses and physicians. In this way we want to move away from the perception that research data is automatically given as long as a hospital-wide EPR is in use.

Empirically, we have studied a collection of data for clinical research in the oncology department at the University Hospital of Northern Norway (UNN HF), which has a long tradition of participating in clinical trials. Theoretically, we draw on the information infrastructure literature (Ellingsen and Munkvold 2009) and supplement it with Orlikowski’s notion of collective capability (Orlikowski 2002), in order to pinpoint the effort that goes into generating research data.

The remainder of this paper is organized in the following way. First, we elaborate on the theoretical foundation of the paper. Then we describe the method used, followed by a case analysis. Finally, we offer a conclusion and the implications that were found, where we reflect on how the case fits with the notion of information infrastructure and a secondary use of information.

2. Theory

The discourse about information infrastructures as a foundation for scientific research is omnipresent. Notions such as Cyberinfrastructure (CI), eScience and eInfrastructure in different ways emphasize commitments to the establishment, and that may largely support collaborative scientific research, data sharing, and dissemination of findings (Ribes and Lee 2010). Similarly in healthcare, Electronic Patient Records (EPRs) are expected to be an infrastructure for clinical research, where different stakeholders may use the data for various research purposes. For instance, in the U.S., pay-for-performance models have emerged, enabling commercial enterprises paying for healthcare data to derive products and services to sell (Safran et al. 2007). As a consequence, the American medical informatics association (AMIA) has recently initiated a national discourse on the secondary use of data for research. Points to mark are benefits and risk, particularly concerning patient rights, anonymity, auditing the use of the data, and how to give feedback on results from the research (Safran et al. 2007). Although patient rights are not the main concern of this paper, they emphasize that the discourse on research data for clinical research is high on the international agenda.
Still, it is not entirely clear what an EPR designed for research purposes should look like, what the content should be, and how it can simultaneously support daily practice and clinical research. What immediately comes to mind with regard to the content of the EPR is the presence of many health-related terminologies and classification systems, which ensure consistency and comparability across institutional and national borders. Some examples include the global World Health Organization (WHO)-based ICD (International Classification of Diseases), which is a medical diagnoses system. There are also terminological standards for more specific domains and classes, such as the ICF (International Classification of Functioning, Disability and Health). In nursing, international nursing-specific diagnoses such as NANDA (the North American Nursing Diagnosis Association) and associated interventions NIC (Nursing Interventions Classifications) are considered to be a foundation for research in the care practices. Further, there are international coding schemes for procedures in surgery and treatment from ICD -10, Codes for procedures in pathology from SNOMED RT, and NORACO codes for radiology. Further, the laboratories are accredited with ISO – 17025 which internationalized both in method and validation. Moreover, sufficient quality of the practical coding activities in clinical research is ensured through the guidelines of Good Clinical Practice, which is an international ethical and scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected in accordance with principles derived from the Declaration of Helsinki, and that the clinical trial data are credible (Ash et al. 2004).

As a consequence, it might seem that much of the codified data that is collected as part of ordinary clinical practice maybe easily fed into research activities. This may largely lead to the view that data bound for research merely depends on the existence of a working EPR, where the key concerns basically come down to selecting, extracting and combining the data that is of current interest (Bowker and Star 1999). In reality, however, the process is more complex than this. Ure et al. (2009) found recurring socio-technical problems in the development of infrastructure for sharing and re-using data across sites for e-Health research. The problems are linked to the contradictions between underlying assumptions about data as a commodity whose reuse is not compromised when it is extracted from the context from which it has been captured, and the reality of data as being entangled with, and constituted through, local practice. For instance, Ixchel et al. (2010) described how new technologies supporting increasingly data-intensive and collaborative science raised significant challenges when increasing the supply and accessibility of scientific data is no guarantee that data will be utilized by scientists. Overall, a key problem in using infrastructures (i.e. EPRs) for research purposes is that the data was initially collected with another purpose in mind (Karasti and Baker 2008; Zimmermann 2008). This echoes Berg and Goorman’s (1999) point, when they argued that the further information needs to be able to circulate (i.e. the more diverse contexts it needs to be usable in), the more work it takes to disentangle the information from the context of its production.

However; different types of heterogeneous work practices participating in trials worldwide need to adapt to standards in clinical research, and to be sure, many studies have pointed out how standardisation is translated and intertwined with local practices (Timmermans and Berg 1997). Based on a case study on two standardised medical protocols, Timmermanns and Berg (1997) introduce the notion of ‘local universality’ to pinpoint how a protocol (i.e. a standard) always has local variants and both shapes and is being shaped by local practice. They argue that universality is always local universality, and that local universality depends on how standards manage the tension involved in transforming work practices, while simultaneously being grounded in those practices. We sympathize with this perspective, but indicate that the standards in the case referred are basically about providing operational instructions for dealing with specific life-threatening situations, which, as Timmermans and Berg (1997) correctly show, may have local operational variants in practice.

In comparison, however, much of the data included in clinical studies requires a certain level of standardisation and quality that goes beyond a single research site where there are strict guidelines about how to collect and process the research data. Wang and Strong (1996) have investigated what data quality
means to data consumers and outlined a conceptual framework for data quality that includes several aspects. From the concepts listed, we find two especially interesting to our case considering the discrepancy of quality between two sources of documentation, accessibility and relevance to the consumer. For instance, given the different coding schemes for laboratories, it is easy to believe that these standards apply to the guidelines for clinical research as well, and that they are easily comparable and extractable. However, the reality is slightly different, as each trial has one or several procedures that diverge from local standards, and become global standards for those participating in the particular trial. These guidelines typically go beyond what is required in daily clinical practice (the local variants), thus enforcing a strict level of standardisation that cuts across many research sites. Consequently, many clinical studies may instead be described as ‘universal locality,’ in order to emphasize how local heterogeneous practices, including the largely hidden work performed by nurses (Timmermans and Berg (1997) are a part of generating research data that is standardised and comparable across different local sites.

Given the necessary awareness towards clinical research in daily work, we draw on Orlikowski’s notion of ‘collective capability’ (Orlikowski 2002). She describes a case in which a highly successful organization named Kappa achieves its global success due to a collective competency among the members of the organization in how to deliver innovative yet complex products in a timely fashion. She develops a perspective on practice, which highlights the essential role of human action to get things done in complex organizational work as an active and recurrent accomplishment (Orlikowski 2002). In this regard, the notion of ‘collective capability’ may be useful for emphasising the established local practices around the creation of high quality research data. Similarly, Kogut and Zander (1992) argues that organisations provide a sense of community where discourse, coordination, and learning are structured by identity. Organizations also develop people’s capacity act out “useful” practices rather than “best” practices. This is based on both common goals, and the fact that the way the work is accomplished is similar across locations. Hence there are differences within the organization depending on country and culture. In relation to our case, this reflects how different clinical departments have local variations in how work is accomplished in fixed daily routines, though standardized research procedures still force each department to report in accordance with some shared standards. Through enacting a common orientation to their work, all employees constitute an ongoing and collective knowing of how to do what Orlikowski call “global product development.” In our case, that is the production of data for clinical research among (potentially) globally distributed participants (Orlikowski 2002).

3. Method

The research was conducted at the University Hospital of North Norway (UNN HF), which has about 5,000 employees, including 450 physicians and 1,000 nurses. The data collection took place at the Oncology Department which is a Regional Centre for Medical Oncology and Radiation Therapy in Northern Norway. The department was established in 1985, with 120 employees in four units, the Ward, the Radiation department, the Outpatient clinic, and a Clinical research unit (EKF). The department has an extended activity and treats patients from the Northern health region, which includes 462,000 inhabitants distributed over the span of 112,950 square kilometres. The ward has 30 beds distributed around singular, double and four-bed rooms. The approximated “bed time” is 6.2 days. The ward has 43 nurses, all personnel included, and 3 assistant nurses. Patients often receive their first treatment at the ward, and are later transferred to the outpatient clinic or their local hospital for further treatment. This constitutes one of the major challenges, namely collecting data from different sources at different hospitals. Collecting data from small local hospitals is challenging due to the absence of a research culture and clearly defined procedures.

The importance of social issues related to computer-based information systems has been increasingly recognized increasingly over the last decade, and this has led IS researchers to adopt empirical approaches which focus particularly on human interpretation and meanings (Walsham 1995). Interpretive research
can help the IS researcher understand human thought and action in social and organizational context (Klein and Myers. 1999). Consequently, our study adheres to an interpretive research tradition. In general, qualitative research methods like interviews and observations are optimally suited to understand a phenomenon from the point of view of the participants, and in its particular social and institutional context. Such a research approach can provide deep insight by answering “why”, and “how” things are they way they are (Ash et al. 2004). Ethnography produces in-depth understandings of real-world social processes. If properly done, it can provide detailed insight into the concepts and premises that underlie what people do, but are often unaware of (Forsythe 1999).

Further, the first author has nine years of experience as a study nurse at the oncology department that empirically is included in the fieldwork. During the observation period, in January to March 2008, handwritten field notes were transcribed shortly after gathering information. Five interviews were conducted. The interviews lasted an average half an hour to an hour. All of the semi-structured interviews were transcribed shortly after the interview. The questions were similar, few in number, and open-ended. All of the transcription has been done by the first author according to Malterud (2003) this is crucial in order to clarify uncertainties and the meaning of unclear sentences.

Our findings have been debated between fellow students and the second author, who has a thorough understanding and experience in working with Information system (IS) studies in healthcare.

4.0 Case

4.1. Implementing the EPR at the University hospital of Northern Norway

In January 2004, the University hospital of North Norway implemented a new large-scale EPR named DIPS EPR delivered by the vendor DIPS ASA. DIPS ASA was the dominant player in the Norwegian healthcare sector, with the largest customer base in the EPR field. The so-called DIPS paperless EPR concept has been implemented in more than 30 hospital sites in Norway and has increasingly reached more than 50,000 users. Similar market penetration by paperless EPR has not been seen anywhere else in the world. Compared to the former paper journals, it supported a holistic approach to the patient where it was easy to obtain and retrieve relevant information. Currently, DIPS ASA is on the threshold of redesigning its EPR, where a major goal is to budge the DIPS portfolio to a more modern architecture, which is expected to serve as a stepping-stone for DIPS ASA’s effort to internationalise its portfolio of clinical information systems. Therefore, it is important for the vendor to improve its understanding of how the EPR can serve as an infrastructure for research purposes.

The DIPS EPR is categorized and standardised to a certain degree, and is thus considered to be a good starting point for extracting information for research purposes, as one of the researchers at the university hospital puts it. “Data could easily be stored within the EPR or easily extracted from the EPR, in such a way that allows for the analysis and development of reports within EPR or potentially outside EPR system for more complex data analysis” (Physician). In practice this applies for more structured data elements and archetypes.

Accordingly, the expectation during the time DIPS EPR was initially implemented was high. For instance, researchers saw the possibility of extracting categorized information e.g., about blood pressure, medication, development in disease, or other clinical variables of interest directly from the EPR to research databases.

However, over four years, the physicians’ opinion was that the EPR was still based upon the same system as the old-fashioned "paper-journals". The only difference was that information had become electronic. The potential benefit of storing data electronically was thus far from being fully exploited. Researchers at the Clinical Documentation and Evaluation Centre at UNN HF were quote saying that the categorization of clinical data should be implemented according to well-known and internationally established standards that conform to the requirements of clinical research.
“Registration rates increase and the data quality is improved by categorization. Today, clinical departments do registration as a separate activity, which is time consuming and demands extra resources (Physician)”.

Being a University hospital requires focus on clinical research, and the Oncology Department had a long tradition of participating in such clinical trials. Personnel working at the department knew that the patients often got their treatment through clinical trials, and that a special effort had to be made to get the patient through the treatment trajectory. The environment was always ready for research patients, but the challenges could be difficult to handle in a heterogeneous environment.

4.2. Initializing a research project at the Oncology Department

Getting the wheels running at the department prior to each new clinical trial depends on all professions taking an active role in daily work and routines.

Preparation for clinical trials at the Oncology Department was channelled through national groups that typically consisted of physicians with high levels of competence in the relevant area of disease, and represented each of the five regional university hospitals in Norway. In addition, each hospital often participated in trials initiated by the medical industry on an individual basis. Each trial, regardless of initialization had a primary investigator on the national level, and one at each research centre. The appointed physician was ethically, practically and legally responsible. Before entering a new trial, the head physician and the study nurse were informed about the specific procedures claimed in the protocol, and on how to operate the Case Report Form. A Case Report Form is a paper or electronic questionnaire specifically used in clinical trials. The Case Report Form is the standardized source for documentation in clinical trials for collecting data from each participating site. The CRF is standardized with the same guidelines, values, and specifications for each participation country. In addition, the content is put out in English, and the respondents have to write their answers in English as well. All data was documented in the CRF, including adverse events. The formula for success is a strict coordination of every part involved, including oncologists, radiologists, nurses, and technologists from the Medical Biochemistry laboratory, and especially the study of specific documentation sources.

The case report form has historically been handwritten, but electronic record systems have been more common during recent years. In cases where an electronic record system is in use, the sponsor or research group behind the protocol provides the research site with a computer containing the appropriate software. Hence, the CRF is unique, and it is secured through “the law of patient treatment” and ethical guidelines through Good Clinical Practice (GCP) 1

The sponsor of the clinical trial developed the CRF to collect the specific data they need in order to test their hypotheses or answer their research questions. The size of a CRF could range from a handwritten one-time 'snapshot' of a patient's physical condition to hundreds of pages of electronically captured data obtained over a period of weeks, months, and years. It can also include required check-up visits months after the patient's treatment has stopped. Case report forms contained data obtained before and during the patient's participation in the clinical trial. When the study administrators or automated mechanisms process the CRF’s that were sent to the sponsor by local researchers, they made a note of queries. Queries are questionable data that must be explained, like for instance “what the physician see as the main reason for any adverse event reaction”. Further, there are often separate forms for filling in such information. To

1 Good Clinical Practice is an international ethical and scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected in accordance with the principles that have their origin/that originate in the Declaration of Helsinki, that the clinical trial data are credible to use/for using/for the use of patient data in research, and that there are guidelines both to protect the patient’s anonymity and security through the protocol treatment. All patients participating in the protocol treatment have to sign a consent allowing the physician to use information from the patient trajectory throughout the study. (http://www.emea.europa.eu/Inspections/GCPgeneral.html_d.31.02.08)
ensure quality control, these queries were usually addressed and resolved before the CRF data was included by the sponsor in the final clinical study report.
Most studies were quality assured through sequent monitoring from the responsible group or medical company. Monitoring happens when the Clinical Research Associate (CRA) typically working for the medical industry gathers information due to the collection and registration of patient documentation from the patient journal to the Case Report Form.

4.3. Including patients
Screening for eligible patients to be included in clinical research is a cumbersome process. Hence, after patients are selected for inclusion, the trajectories are also different when it comes to the number of hospitalizations, and the frequency of tests and evaluations. The patients are thrilled to receive such close attention and follow-up. The patients were informed about the possibility of enrolling in a study in advance, more specifically, before entering the department or right after their arrival. Patients normally took blood samples and a CT-scan before hospitalization, and in the case of their inclusion, samples had to be taken after this was determined. This is because of the possibility that the local procedures diverged from the standard procedures, and according to the guidelines, all study-specific information, or information that deviated from normal procedures had to be performed after the informed consent was provided. However, the informed consent allowed personnel to transfer information from the EPR to the clinical research form. Thus, the physician’s signature also testified to the fact that the responsibility was legally and ethically handled correctly, and that the patient’s security was ensured. The responsible parties for coordinating clinical trials focused on the patient trajectories, from finding eligible patients throughout treatment and the follow-up. The strategic planning of the trajectories was partly about using all available personnel in clinical practice, including the nurse, the clerks, and physicians in general, to contribute towards the process of supplying the investigator and collaborating departments with the study specific information. There were several work tasks, from finding suitable patients, coordinating the information flow by making flow-charts, filling in information on the case report form, and conducting consultations with the patients and the physicians for pre-trial coordination. The coordinator was also responsible for preparing “short versions” of each protocol, which were published on the internal web pages and on paper for the physicians to carry around.

The trajectory consisted of, e.g., weekly treatment visits, demanding laboratory tests, taking blood pressure, and conducting an evaluation every second or third week based on radiology, chemistry, or clinical signs. The physician (investigator) was responsible but the study nurse collected information, contributed in providing treatment, and a collaboration with other hospitals and healthcare institutions that were included in the treatment and follow-up of the patients.

4.4. Collecting data
The collection of data for clinical research purposes depended on accurate pre-study preparations from the physician and study nurse responsible. Each research trajectory was further dependent on collaboration with radiologists, laboratory technicians from Medical biochemistry as well as nurses, physicians and clerks in the department. Blood specimens had for instance often other labels or designations in comparison with national or local requirement specifications. There were standard tests, like for adjuvant treated breast cancer outside clinical research. For instance, all methods are internationally the same and validated strictly according to the standard, also because the laboratory is accredited with ISO-17025. Clinical trials are handled separately by designated personnel at the laboratory, and they have developed their own electronic system to keep track of the different procedures attached to each clinical trial and a labelling system coordinated with each department. All clinical trials were registered in the database with a unique code, hence some specimens were handled in accordance with the ISO, and others required divergent action both due to the preparation method, but also for long-term storage conditions.
In practice, this denoted a significant change in routines. Every specimen collected had to be labelled with a study specific code, which was further relayed onto the laboratory technicians to execute the specific
manoeuvre. When the requisition was attached with the right code, the laboratory personnel knew which tests to take and how to store or prepare them.

There were similar challenges in ordering an x-ray or CT-scan from the radiology department. Measuring a disease using, for example, a CT-scan has to be done via standardized procedures. In addition, there are several other requirements, and deviation from the standard procedures. Typically, these deviations determine the number of measurements and how they are performed. Standard procedures normally required a general decision about whether there was regression or progression of disease. Clinical research normally requires that all cancer lesions are measured and compared to the previous taken CT-scan. Hence, it became inherently important to give study specific information to the radiologist as a part of the radiology requisition. In addition, the clerks helped with distributing the right flow-charts, and were often responsible for filling in the right codes on the blood sample charts, or the radiology requisition. In general, the clerks functioned as quality indicators in making research procedures visible.

The study nurse used great effort in coordinating and collecting all of the information applicable to each study; thus, personnel were not the only ones who were used for securing high quality information. The “Yellow note” was a possibility in the DIPS system to admonish the physicians to take specific laboratory tests or other study specific procedures. What items were important to document in this particular protocol, and how should they be documented? It was also used to obtain answers to questions about the study or the patient during the trajectory. After filling out the suitable information or questions, the note was sent to the physician. The study nurse would receive information on whether the note had been received, or a message in return answering the questions added. The yellow note appeared when the physician opened the particular patient EPR. It appeared in an automatic list of work tasks together with other tasks concerning this particular patient. The same yellow notes were used on the outpatient clinic; the nurse used it to give messages to the physicians before the patient visits. This could be adverse reactions due to treatment, patient requirements like suspension of treatment, or the need of a medical certificate due to treatment. “We use the yellow notes in the communication with the physicians, sometimes this is the only way we communicate (Nurse 3)”.

However, when it comes to strict documentation, additional information was only required in the CRF, like paper forms from local hospitals, general practitioners where the patients often took laboratory tests or CT-scans during the study trajectory. This is handwritten information attached to the CRF in a ring binder, and stored with it for as long as the guidelines for clinical research demands, normally 15 years. This information is a source- data document, thus the CRF needed a document source, which in this case was a paper form from the local hospital.

4.5. Deviations from the normal procedures

Collecting data for clinical research was a cumbersome process. Specified information easily disappeared when the outpatient clinic nurses failed to fill out the applicable forms, or in the transition of patient between different institutions, e.g. information as the start and stop time for chemotherapy administration was only collected and stored for clinical research. Each type of chemotherapy regimen had two work charts, one for regular treatment, and one for similar treatment in clinical trials. The study nurse commented “After gathering experience, I have seen that the work-charts for chemotherapy are essential for documentation related to patients in clinical research. I don’t have the time to monitor every patient visit personally. The routines at the Outpatient Clinique have to be changed so that we don’t lose more information (nurse 1)”. The work chart and the work chart description were partially constituted by a type of quality assurance for ensuring that the procedures were performed in the right order, depending on time limits for infusion of treatment etc. It also contained crucial information concerning adverse events, which ensured that the coordinators inform the patient during the treatment. In addition, they had the opportunity to adjust the work chart individually for each clinical study. If the study required a start and stop date for chemotherapy treatment, it could be added to the chart for this particular study. All information concerning treatment was potentially added to this form.
The coordinators would typically and retrospectively screen the nursing reports for valuable information that could clarify occurring situations caused by lapse of routines. Some information was often documented in the EPR, as one nurse said “We are a bit sloppy about where we put information like blood pressure and temperature, it is supposed to be written in the patient chart system but sometimes it is impossible to find. Instead of attaching the information during the day we put it in the nursing report, and as you understand this don’t satisfy the study nurse (Nurse 3)”.

Hence, in another example, the physicians usually found the results for blood pressure in the clinical curve papers. The lack of this specific information resulted in documentation failure, but extended time was always used to find potential “misplaced” information, and make sure that the information was placed in the EPR.

Further, and equally important, data for giving ECOG status was often found in the nursing reports and the nursing plan. If this concrete information was lacking from the physician incoming journal or discharge note the most reasonable place to look for this type of “soft” data was in the nursing plan. Soft data typically describes the patients physically, social, and psychological condition.

4.6. Transferring data from the information source to the CRF

We have seen how the data is gathered, and how the transportation and production of clinical and study specific information depends on a strictly enforced management accomplished by the coordinators in charge. Following, if the quality of what is produced is equivalent to the requirements listed in the case report form, the documentation would be easily extractable. The study nurse was responsible for “transferring” data from the EPR and the different paper forms to the case report form. The process was conducted manually, and consists of a reproduction of information, a duplication of data like blood pressure, weight, and temperature. The standardization of adverse events demands other transferring procedures where several inputs of information answer to the adverse event standard. The document trajectory implicates the use of different standards, which are common for clinical research through guidelines. These standards are not commonly used outside of the protocol treatment, but adverse events like nausea are diagnostically connected to this standard. In order to find the right degree of for example, nausea, the CRF guidelines determine its level of toxicity. Common Terminology Criteria for Adverse Events v3.0 (CTCAE) includes Adverse Events applicable to all clinical trials regardless of chronicity or modality. How often during 24 hours, does the nausea require use of medication, what dose and type of medication, and whether there is weight loss due to reduced food ingestion, etc. The questions result in characterizing nausea as an adverse event due to treatment, and, if properly listed, possible to find in the daily reports of nurses and physicians. In order to scale the degree of severity of adverse events retrospectively, it becomes equally important that the information is suitable to solve the process. However, because of the gap between information needed for day-to-day clinical work and the severity ranking of the same reaction in clinical research, the production of data is cumbersome.

There were two ways of transferring data. The most commonly used method was to screen the EPR and other information sources with the case report form open, filling in the requested information by hand retrospectively. The other method required the nurse to use an extensive amount of time, and constituted a scenario where the study nurse and the physician were present, carrying out the treatment and securing the documentation by filling in the forms during the patient stay. This was a backwards procedure requiring an extensive use of time. It was also only possible for treatment given locally, thus for patients given treatment at local hospitals, there were other challenges and requirements concerning the quality of documentation. First, it was always difficult to coordinate study specific procedures between two hospitals that were not interconnected with EPR systems. Hence, communication took place using the worksheets which were downloaded from the University hospital internet pages. However, there was a great deal of insecurity surrounding collaboration between institutions, the departments at the local hospitals lacked the “research culture” as mentioned, and if the “contact” failed to appear the information could easily not be collected as planned.
Further, specific content varied from protocol to protocol, between cancer diagnoses, and whether the intention of treatment was curative or palliative. Most treatments were evaluated with CT-scan, others with disease specific markers (tumour-markers) like pain or ECOG-status. These scales and criteria are used by doctors and researchers to assess both how a patient's disease is progressing and how the disease affects the daily living abilities of the patient, as well as determine appropriate treatment and prognosis or Prostate-specific antigen (PSA).

Other important variables are equipment like scanners and fax machines for transferring data, the source-data itself, applications like the case report form used to organize the information, the use of standards that facilitates interconnection and interoperability between networks and the people, nurses, clerks, patients and physicians that produce the information.

5. Discussion

We have structured our discussion as follows: first, we discuss the quality of information which is not given but dependent on work practice, work practice coordination, and interest. Secondly we discuss “universal locality” based on the strictly enforced standardization of research information; and third, we focus on a “collective capability” based on knowing in practice, or the essential role of human action in knowing how to get things done in complex organizational organisations.

5.1. Quality for daily practice and quality for clinical research

Wang and Strong (1996) investigation on what data quality means to data consumers pinpoint concepts with great importance towards obtaining further knowledge about the processes that we have studied. From the concepts listed, we find two especially interesting to our case considering the discrepancy of quality between two sources of documentation these are accessibility and relevance to the consumer. Research data is certainly more relevant to some than others, some gain profit by attending clinical trials and others don’t, but there is still “openness” towards research in the department. Further, the access to relevant information is discussed throughout our case as a cumbersome process with deviating results, built on different documentation sources and research sites, and partly solved by using a study nurse as local coordinator. Further, it is obvious that the quality, because of the different tools for standardization, and discrepancy in the significance of quality also has different meaning in different contexts. Adverse events are for instance regulated by strictly arranged standards through Common Terminology Criteria for Adverse Events v3.0 (CTCAE), which is applicable to all clinical trials regardless of chronicity or modality.

In clinical practice, this is transparent; physicians at the radiology department have certain criteria for describing CT and MRI scans in their daily practice and quite different criteria for patients attending clinical trials. This contrast becomes even bigger if the local hospitals are dragged into the evaluation of research patients, since physicians “habitually” follow local procedures, and it is difficult to influence their evaluation method. Another example mentioned is the blood specimen collection. The logistics are arranged between the study nurse and the laboratory technicians, but the procedures are handled in the laboratory, and coordinated by the clerks.

Further, and more general, in practice, there is a need for extended information defined by the protocols. The work-sheets, use of yellow notes, and ECOG status documentation are integrated tools that ensure the gathering of information. The use of such standardized devices seems crucial. Improvisation is only necessary if the system has failed, and repair work needs to be done, for example, by collecting new data to fill in holes in the CRF.

5.2. “Universal locality”

Based on a case study of two standardised medical protocols, Timmermanns and Berg (1997) introduce the notion of ‘local universality’ to pinpoint how a protocol (i.e. a standard) always has local variants and both shapes and is shaped by the local practice. Their case is basically is about providing operational
instructions for dealing with specific life-threatening situations, which as Timmermans and Berg (1997) correctly point out, may have local operational variants in practice. In comparison, however, much of the data included in clinical studies requires a certain level of standardisation and quality that goes beyond a single research site where there are strict guidelines on how to collect and process the research data. These guidelines also go beyond what is required in daily clinical practice (the local variants), thus enforcing a strict level of standardisation that cuts across many research sites, countries, and continents. Consequently, many clinical studies may rather be described “as a universal locality” to emphasize how local heterogeneous practices, including the largely hidden work performed by nurses, physicians, and clerks participate in (the effort of) generating research data that is standardised and comparable across different international research sites.

According to Leidner (1993), information should be conceptualized as always being entangled with the context of its production. Disentangling information from the context in which it is produced is possible, but that entails work (Leidner 1993 p.51)”. This work is accomplished differently on a local level, but each work practice strives to abide by the strict universal guidelines that follow each protocol. Berg and Gorman (1999) propose a “law of medical information”. The further information needs to be able to circulate (i.e. the more diverse contexts it has to be usable in), the more work it takes to disentangle the information from the context of its production. In our case, and because of the specificity of research information, this socio-technical approach needs to be expanded in order to cover research as a part of the context as well. When a patient is a part of a clinical trial, the context is the procedures that vary among trials, and the sums of local adjustments that cope with the requirements of the universal standard are multiple. Hence, the different local adjustments performed separately in each institution will not affect other local practices.

5.3. A collective capability

By using Orlikowski’s notion of “collective capability” we will point to the essential role of human action in how to get things done in complex organizational work (Orlikowski. 2002). The work done by the personnel, clerks, nurses and physicians in the department are all geared towards the research activities in daily work. The clinical personnel are constantly aware of, and prepared to handle, clinical research procedures when needed. This implies that the different professions (in a positive sense) actually monitor each other’s work, which again contributes to robustness in clinical research activity. The inclusion of a patient in a clinical trial is accordingly followed by an interdisciplinary modus operandi.

Currently, the flow of information between patient documentation and the case report form in clinical research is fragmented. The information that is shared through the EPR does not cover all needs for information in research, and someone has to ensure that “open spaces” do not occur. In our case, a coordinator is hired to maintain these actions, and thereby make sure that the procedures are remembered by all clinical personnel. The quality of patient documentation needs to be of a certain standard to fit the demands and standardizations of the clinical research protocol. This means that the process of transferring data is more than merely copying directly from the EPR to the CRF. The quality of documentation is ensured by having employees be responsible for this process, like the research nurse.

6. Conclusion

We have seen that the transmission of information toward clinical research is fragmented, that more standardized information is incorporated and that a collective capability is created to remind users to gather this extended information, which pinpoint the importance of knowing in practice. There is a gap between the information found in the EPR and the information required for clinical research. We have explored what this gap consists of, how it is managed and, who is responsible for closing it in order to make the information in the EPR usable for research purposes. We have linked this to the concept of a “universal locality” inspired by the work of Timmermanns and Berg (1997), which on the contrary to their work makes the opposite claim in clinical processes. We have highlighted the work that goes into
this process, which has been conducted by both the research staff as well as ordinary health workers. With this we want to move away from the perception that research data is given as long as a hospital-wide EPR is in use.

7. References

Safran, C. et.al. (2007); Towards a national framework for the secondary use of health data: An American medical informatics association white paper. Journal of the American Medical Informatics Association, Volume 14 number 1 jan/feb.