

Towards Understanding Requirements for eScience: the eDiaMoND Case Study

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Abstract

This paper presents findings from an investigation into requirements for eScience in the context eDiaMoND, a Grid-enabled prototype system intended to support breast cancer screening. Detailed studies based on ethnographic fieldwork reveal the importance of accountability and visibility of work for trust and for the various forms of ‘practical ethical action’ in which clinicians are seen to routinely engage in this setting. We discuss the implications of our findings for realising the Grid’s potential for sharing data within and across institutions and hence for the prospects of using distributed screening to make more effective use of scarce clinical skills. Understanding how to afford trust and to provide adequate support for ethical concerns is a particular challenge for eHealth systems and for eScience in general. Future eHealth and eScience systems will need to be compatible with the ways in which practical ethical actions are distinguished and embedded within work practices. We conclude that to ensure this and the achievement of the wider eScience vision, requirements investigations must focus on gaining a detailed understanding of work practices.

1. Introduction

eScience represents a potentially revolutionary shift in the way that science is undertaken. Many areas of science are becoming increasingly reliant on new forms of collaborative and multi-disciplinary working and the concept of eScience attempts to capture these new forms of working. John Taylor, Director General of Research Councils in the UK Office of Science and Technology, expresses the vision thus: “eScience is about global collaboration in key areas of science and the next generation of infrastructure that will enable it” (Taylor, 2001).

eScience presents novel and challenging issues for requirements gathering which must be understood and addressed if its vision is to be realised. Supporting large-scale collaboration requires detailed understanding of interdisciplinary work, an appreciation of the context in which scientific data is generated and used and how data may be presented and shared across scientific disciplines nationally and world-wide.

In this paper, we report on eDiaMoND, a major UK eScience project that aims to develop a prototype of a national Grid-based infrastructure to support digital mammography. We identify an area of critical importance to clinicians, that of ‘practical ethical action’ and

discuss its implications for eDiaMoND, for the requirements gathering process and for the success of Grid-based innovations in eHealth. The paper concludes by considering the implications of the study on the vision of eScience in general and on how requirements gathering processes may need to adapt in order to realise these new forms of scientific collaboration.

2. Background: The NHS Breast Screening Programme

Currently, one in nine women in Britain will develop breast cancer in their lifetime (Boseley, 2004). To provide early detection, the UK National Health Service (NHS) runs a Breast Screening Programme that involves inviting women between the ages of 50 to 64 to attend a screening session every three years, whereupon X-Rays of the breast (mammograms) are taken. Women attending for the first time have two views taken, but subsequently only one view is taken.

Once taken, the mammograms are then ‘read’ by radiologists, that is examined for evidence of asymmetries and potential lesions, and for any changes since the previous screening. Typically, the mammograms taken in a screening session are batched, that is put onto a viewer to be read together. Radiologists can reach a decision on each case (which may

involve reading 4 or more mammograms) in 15 seconds or less. Typically, in order to improve diagnosis, each case is 'double read', that is examined independently by two radiologists.

Around 1.5 million women are screened every year in the UK. The programme will shortly be extended to include women up to the age of 70, and the number of views taken per breast increased from one to two for every screening round. This will result in six million mammograms being taken every year.¹ This development is occurring precisely at a time where there is also a reported shortage of radiologists (Geldman, 2002).

3. The eDiaMoND Vision

At present, the NHS Breast Screening Programme relies almost entirely on the use of film (some private hospitals and symptomatic clinics are exploring full field digital systems). Using film presents problems for keeping the data secure and easily retrievable as well as more mundane problems of storage. The eDiaMoND project is building a Grid-enabled, federated database of annotated, digitised mammograms and patient information linking multiple clinical sites in the UK. A prototype is being developed with applications to support the work of screening, radiologist training (Soutter et al., 2003) and Epidemiology. The database will also be used for research purposes such as developing algorithms and search mechanisms for data mining, and developing and evaluating image standardisation techniques for computer-assisted image analysis and temporal comparison. The database thus represents a repository for data to be shared across disciplines and potentially becomes a new resource for scientific research.

Digital technologies in general are beginning to transform medical record keeping, diagnosis, access to healthcare and, indeed, the nature of the consultation itself (Heath et al., 2003). Progress has often been painfully slow, however, and the longstanding problems associated with capturing requirements for eHealth and for the digitisation of data have been compared to "building a bridge across the Atlantic." (Heath et al., *ibid*). The eDiaMoND project may be viewed as an exercise in understanding this process of transformation, by investigating how Grid technologies can assist in the delivery of healthcare.

¹ NHS Breast Screening Programme Website.
<http://www.cancerscreening.nhs.uk/breastscreen/index.html>

In order to develop this understanding, we have been conducting a comprehensive requirements gathering exercise. As part of this, we drew on detailed analysis of work practices in screening (Hartswood et al., 2000; 2002a; 2003a; 2003b) and conducted ethnographic studies (Anderson, 1994; Hughes et al., 1994) of work practices in a number of BSUs (Hinds and Coopmans, 2003). The aim of these studies was to observe in detail everyday working practices and to explicate the numerous, situated ways in which those practices are actually achieved. We also conducted quasi-naturalistic evaluations of prototype workstations with clinicians, *in situ* where possible. Clinicians also participated in design meetings and discussions, intended both to elicit their views on the vision of eDiaMoND, and also to aid our understanding of the current process of breast screening.

One focus for this requirements gathering exercise was to understand the potential implications of transforming a mammogram into a digital artifact and what benefits this might afford for the Breast Screening Programme through innovations in its work practices. One obvious consequence is that the digital artifact becomes accessible in different ways. Thus, eDiaMoND could potentially assist in handling the Breast Screening Programme's forecast increased workload by enabling cases to be sent to BSUs where the workload may be less heavy or where there are more experienced radiologists.

However, when considering these possibilities, the requirements gathering exercise identified various challenges to the seamless sharing of data as initially envisaged by the project. These concerns seemed inextricably tied to the high degree of sensitivity that clinicians have to observing ethical and trust concerns in the management and analysis of the patient data. Issues were raised as to who would have access to the data and for what purposes, both within the individual BSUs, across BSUs, and more generally across the different applications of the intended eDiaMoND system.

4. Sharing Data Within the BSU

The difference in mobility between digital and physical artifacts is of particular relevance to clinicians' practices in quite specific ways. For example, it is common for junior members of the BSU administrative team to carry out mundane tasks with patient records such as booking appointments. The data they handle is personal and sensitive and thus must be treated

in particular ways in order to conform to what is seen to be ethical. The work of manipulating physical artifacts, in this case patient records, provides a natural, locally visible account of itself; that is to say there is a visible pattern to the activity of booking appointments that can be overseen by others in the domain. The ability to arrange the visibility of these accounts provides for a great deal of flexibility in the management of ethical concerns, for example, to give someone an unfamiliar task, yet arrange the environment to afford a greater degree of scrutiny, enables trust to develop between individuals in a flexible way. The introduction of systems for working with digital artifacts raises significant issues for this type of conduct. The visibility and hence accountability of work is transformed also; interactions with the digital artifact on a computer system may be much harder to discriminate at the local level and a consequence may be that it becomes much harder to manage such activities.

Information systems have traditionally dealt with issues of this nature as problems of access control, denying and allowing people access to particular resources within the computer system. Databases are an archetypal example: users are identified and given roles that define their access rights. A database will typically hold its information in a series of related tables, each of which may then be declared as readable or writeable by a set of roles. In designing the structure of a set of database tables, one must account for a whole series of technical concerns, for example, to ensure that the integrity of the information is at all times assured, and that it may be accessed efficiently. Those data holding structures, designed to account for a series of technical concerns, also define the ways in which the data is accessible. For the BSUs, the difficulty lies in relating the two structures: our observations suggests that even if there is a free hand in designing the structure of an access control system, the rigid and inflexible nature of the structure does not reflect the flexible and seamless nature of the practical work of breast screening.

Practical ethical action may often be seen as mundane by those clinicians who work in such a way on a day-to-day basis. However, it is in fact quite detailed and implicitly accounts for a raft of concerns in a way that is hard for a static access control matrix to capture. For example, for a patient to be screened, their mammograms will be examined by a radiologist at the BSU where those mammograms were taken and, in general, it is not considered ethical for those images to be shown to anyone outside of that

environment. There are, however, exceptions: an unusual case may prompt a radiologist to show a mammogram to a visiting expert and this will be considered ethical so long as the act is in the patient's clinical interest. So, in deciding whether an action is ethical or not one must consider, not just what data is being accessed, or who is accessing it, but why it is being accessed. It is the semantics of the operation that are important, that an action is "in the patient's clinical interest".

Currently, various staff within the BSU play a role in ensuring the integrity of the clinical decision. Checks of names against files and records against decisions are made by clerical staff, dark room technicians, radiologists and radiographers. Various types of team work in BSUs depend on access to screening information. In a computer-based system handling digital artifacts, much of this would probably change. However, it is necessary to be sensitive to the dynamic nature of the BSU in respect of their 'safety culture' that is built around 'open access' to information. (Hartwood et al., 2000).

The eDiaMoND requirements exercise had to understand how and in what ways clinicians orient to ethical concerns in their daily activities. This necessitated locating the ways in which such open access to information enabled the work of screening to be achieved and stressing the importance of this aspect of the work. The ways in which these practices may evolve in the future influences our understanding of the requirements for supporting clinicians' work in the system. At present, guidelines suggest supporting a form of 'situated role based access' in which a team based skills approach can be developed allowing one or two persons within the BSU to delegate skills on a needs basis. How to support this approach is currently a focus for further research within the eDiaMoND project.

5. Sharing Data Across BSUs

The eDiaMoND screening application will enable the rapid movement of mammograms and patient related data between BSUs. This may be useful for transferring data from one BSU to another when a patient moves around the country. However, it also offers potential advantages to radiologists in their screening work. As stated previously, current practice is for each case to be read independently by two radiologists. During times of heavy workload, the eDiaMoND system could enable radiologists to send cases to radiologists in other

BSUs to perform second readings. Indeed, one of the more visionary possibilities would be remote, 'distributed reading', where the eDiaMoND system would manage the reading of batches of mammograms, allocating them to wherever there may be spare reading capacity. This would have the major benefit of maximising the use of scarce skills.

In relation to distributed reading, our detailed analysis of the work of radiologists and of BSUs indicates that this may not be so easily achieved. Our observations suggest that for double reading to work effectively, radiologists need to be able to trust the professional judgements of their colleagues. In current practice, the establishment and maintenance of this trust relies on the close sociality of the BSU through the ways in which it affords mutual awareness of reading decisions and the performance of colleagues (Hartswood et al., 2002a; 2003a). In summary, which colleague is performing the double reading is consequential for the professional reading of mammograms.

In the light of this, the prospect of distributed reading and the ability to work with globally mobile data raises important concerns. Surrendering the entire management of the reading workload to centralised control might have the effect of reducing the visibility of how the work is being accessed, managed and controlled. This is not to argue that the eDiaMoND vision of distributed reading is impossible to achieve, rather that its realisation must be sensitive to the requirements of collaborative screening work. It may be, for example, that rather than the eDiaMoND system automatically allocating cases to radiologists, individual radiologists should be able to select the colleagues with whom they would like to be paired for double reading.

In common with other technologically similar projects, when the facilities within individual components, such as the access control mechanisms of a database system, prove to be inadequate, it is left to the 'middleware' to capture the application level functionality. One possible solution to the issue of access control and ethical action would be a mix of the traditional rigid database permissions structure and more novel mechanisms that allow for flexibility and accountability. For example, one might delegate one's access control of an administrative task to a junior member of the team, but then digitally 'sign' that work afterwards to show that it has been done competently, ethically and under an appropriate degree of supervision. New ways to make digital work more visible and accountable might

also be considered. However, all of these layers of functionality not only make a system complex to develop, but also to reason about. Methods, techniques and toolkits for developing systems that allow for the type of practical ethical actions seen in this domain will be critical to the rapid and successful development of both research prototypes, like eDiaMoND, and the future deployment of usable systems.

6. Sharing Data Across Disciplines

The vision for eDiaMoND encompasses not only sharing data across BSUs, but also – and resonating with the eScience vision – sharing data across scientific disciplines. In the case of eDiaMoND, the availability of a national mammogram database would be of great value to epidemiologists investigating and identifying the contributing factors to breast cancer.

Medical or epidemiological studies rely on the collection of a large volume of sensitive data from real patients. Within their daily practices, epidemiologists orient strongly to ethical concerns in the collection and management of their data. In the UK, in order to conduct an epidemiological study, ethical approval must be secured from a research ethics committee to ensure that studies comply with relevant ethical and legal guidelines such as, the Human Rights and Data Protection Acts. These committees require that scientific investigators provide a specific research protocol for approval to be granted. Investigators must summarise in their case precisely how they will gather and analyse data and demonstrate a) how that information will be used and b) how it will benefit patient care. Researchers must also demonstrate that they have secured individual patient consent.

Once ethical approval has been secured and patient consent obtained, data can be collected and stored. However, this does not mean that data can be used for new purposes. Currently, there is great concern within the health service about safeguarding patient confidentiality in the use of patient data for research. Anonymising data is considered to provide a greater protection for the patient. Data held locally on a secure system and accessible by only one or two named people may not have to be anonymised. However, global availability of the data set would potentially allow researchers to perform studies some of which may be considered unethical, such as providing genetic information to insurance companies.

Sharing these data sets for use by a national or even global research community demands that the data be anonymised. Anonymisation

can happen in two possible directions: a) there should be no trace from the data to the patient's name and b) there should be no trace from the patient's name to the data. The nature of epidemiological research is such that each study has its own set of requirements and may collect different sets of data. Some core data does exist, but is not in itself an effective catalogue as typically other data is needed such as family history. If this is not available, then the core data may be rendered useless for epidemiological purposes. Over time, new factors may be explored as potentially contributing to breast cancer. Investigators may then apply for permission to have the anonymisation of their data broken and recover the link back to the NHS number of the patient.

Due to the evolving nature of their work, epidemiologists cannot specify a complete set of data requirements that hold from study to study. There may be a core of set of fixed data, but each study will also have individual data requirements. This set of data is a resource that individual researchers may spend many years constructing. That work in itself is increasingly recognised as part of the process by particular scientific journals that may require the publication of data sets in recognized databases (Dweck, 2003; Moreau et al., 2003). For epidemiologists, given the organisational context in which scientific publications and funding prevail, the amount of work put into generating the data means that they may wish to have complete their studies before sharing those data sets with other researchers through some global availability.

These issues of gaining patient consent, anonymisation of data and securing medical approval have proved very challenging for the eDiaMoND project. Fundamentally, there is little need for the eDiaMoND prototype to produce clinically valid results in the same way that an epidemiological study should. However, in order to be a useful system for the NHS Breast Screening Programme, the project needs to demonstrate awareness of these ethical issues and how they might be dealt with in future production systems. In order to demonstrate the use of 'real' data collected at the four hospitals involved in the collaboration, the project has had to secure approval not only from local research ethics committees for each hospital concerned, but also from the UK medical research ethics committee as data will be shared across different hospitals.

It has been important to understand how matters of patient consent may impact on the eDiaMoND system. In order for any data to be

processed (by which is meant manipulating the data in any way such as, anonymisation, digitisation, or entering into a database), patient consent must be obtained. In certain circumstances, implied consent is sufficient. This applies in cases where women have received leaflets or letters stating that their data will be used for training or research. By attending the screening session and having received the leaflet, it is taken that they are agreeing to their data being used for these purposes. However, as the nature of the information for mammograms is very sensitive, a implied consent may not sufficient and informed consent must be sought.

Informed consent attempts to identify what each patient allows clinicians, and consequently the eDiaMoND system, to do with their personal information. There are various ways personal information may be used in the context of eDiaMoND: it can be recorded on the database; it can be used only on the clinical site where the information was acquired; it can be transferred across sites if it can be seen to be of clinical benefit; finally, it may also be used for epidemiological or training purposes.

For these reasons, it has been important for us to study and understand in detail how clinicians utilise anonymisation procedures, and how this might impact on eDiaMoND system and the future use of the data. So, for example, clinicians will retain a record of the fake identity and the link to the raw data. In this way, it will be possible to satisfy possible scenarios where women have initially agreed to the use of their data for training, but subsequently wish to remove their consent. In addition, it has been necessary to determine what different types of data may be required by epidemiologists, radiologists, trainers and scientific investigators on the project with the aim of developing a format for the storage and presentation of the information in order to be useful for future studies (Power et al, 2004).

7. Discussion

In this study, we have had to engage in a very real way with issues of ethics and trust whilst determining requirements for the eDiaMoND system. Such concerns are thoroughly embedded within both eHealth and eScience. Dealing with ethical issues is not solely a matter of securing ethical approval for the collection and storage clinical data. How data is stored and represented, and how it is anonymised, has bearing on how it may be retrieved and used in clinical practice. Taking ethical concerns into

account demands a sensitivity on the part of system designers to the practical ethical activities in which clinicians are observed to routinely engage and which may have direct bearing on the eventual design of the system.

The issue of data sharing uncovered in eDiaMoND illustrates how, within eScience, there may be a difficult balance to strike between acquiring information regarding science and health that is in the public interest and may improve healthcare and scientific discoveries in general, and protecting ordinary citizens from unscrupulous use of their personal data. If systems are designed too tightly, they may become rigid, inflexible and difficult to use at the practical level. On the other hand, if they are too loose, they become vulnerable to abuse (Ashcroft, 2003).

The notion of informed consent is clearly an issue for the use of data throughout eDiaMoND. Levels of consent must be respected by all parts of the system, suggesting a need to have some semantic notion, or understanding of the reasons why a person may be accessing various elements of the information held in the database. We may need to flesh out these semantic categories further. It may also be the case that, for epidemiological studies, data access can always be treated in particular way. However, this is more technically problematic for practices of distributed reading where it may be more problematic to derive notions of clinical benefit.

The eDiaMoND study suggests that system designers need a way of approaching such issues at both the global and local level. With regard to the former, understanding how to approach the issues of accessing information and clinical benefit needs to be understood within the larger organisational context in which these systems will be deployed and used. However, in order to consider the global sharing of data, we need to identify through local working practices what the information is, what people do with the information and what working practices underpin the process. It is most certainly the case that the larger bureaucratic issues of gaining ethical approval are a major part of the exercise of building the eDiaMoND system. But through our fieldwork, a different conception of ethical concerns has been revealed that has a more subtle impact on the requirements for eHealth and eScience systems. From closer examination of anonymisation procedures and patient consent perhaps contradictory visions emerge that are driving practice: in this case good ethical practice versus the global sharing of data. How

this contradiction is resolved in the UK will be played out through larger organisational procedures and processes such as, government and NHS. We have yet to imagine how global considerations of policy and what constitutes good ethical practice will impact on the vision of global sharing of data.

At a local level, notions of ethics are embedded in working practices in multiple ways. Ethics and work practice are often tied together in various ways that may, for example, act as resource to allow certain work practices to occur or not. Or, indeed, to account for why people do the things they do. These activities are of immediate concern to requirements engineers. Future eHealth and eScience systems may need to understand in detail the ways in which these practical ethical actions are embedded and distinguished in scientific work. This is a different conception of ethics: not only a bureaucratic hurdle that must be jumped before development of a system can begin, nor one that can be dealt with in terms of policies or guidelines. Rather, it resides at the heart of the practical work that the clinicians do. These concerns inform the very actions clinicians have to take and are interweaved with work practices and technology. Thus, there are practical consequences for how eScience can be undertaken in the future.

Some aspects of the eScience vision, such as the notions of global collaboration and virtual organisations, have been researched in depth in fields such as Computer Supported Cooperative Work (CSCW) over the last twenty years and many important lessons have been learned regarding the issues involved in developing collaborative systems that fit with work practices (Rodden, 2004). In eScience, we are concerned with larger and possibly innovative practices of sharing data that are made technically possible by the Grid. The challenge for eScience in realising such innovations is to understand the nature of scientific work and collaborations, of scientific work practices, and to develop systems that correspond with existing and new scientific practices, whilst utilizing data that is fit for purpose.

To address these concerns within the eDiaMoND project, we have employed a variety of techniques. Concerted user involvement in software projects is now recognised as being critical to success. (Standish Group, 1995-1999). In both eDiaMoND requirements investigation and in subsequent prototype development we have sought to involve users from the outset in a range of ways: encouraging radiologists to

participate in iterative design meetings; and in early quasi-naturalistic evaluations of various prototypes in order to gain essential feedback from radiologists into the requirements process.

We have complemented these familiar and widely used techniques of user involvement with ethnographic studies of work practices in BSUs. In recent years, requirements engineering has seen a turn to ethnography as part of a more systematic attempt to understand the social context of system use. The objective is simply to gain first-hand experience of the work that is being designed for in all its routine detail. The value for designers of having this understanding has been confirmed in numerous project settings (Heath et al., 2000; Hughes et al., 1994; Jirotko and Goguen, 1994; Jirotko and Wallen, 2000). What is clear from such studies – and confirmed once more in the case of eDiaMoND – is that conventional requirements elicitation techniques – even those which prioritise user involvement – generally are unable to systematically reveal the organisation of complex work practices and how they are achieved collaboratively, in context. In the case of eDiaMoND, our ethnographic studies played a vital role in understanding issues of practical ethical action and the ethical concerns that arose from these which were not clear at the outset and may have severely impacted on the successful completion of the project if they had passed unnoticed.

Ethnographic studies of the workplace have proved themselves as a powerful technique in CSCW for revealing tacit practices and understandings, but such findings are not necessarily easily related to design questions. Questions remain about the precise role of workplace studies, nor is there a single recipe for how to conduct them within the context of a given project. Techniques for making ethnographic findings more easily usable for system designers and developers are the focus of continuing research (Hughes et al., 1997; Viller and Sommerville, 1999; Jirotko and Luff, 2000; 2004). This research acknowledges that approaches to requirements investigation must necessarily be chosen in the light of wider project issues of time, resources, work domain, etc. Accordingly, the options being explored for using ethnographic approaches range from the re-use of ethnographic studies as ‘design patterns’ (Martin et al., 2002) to *in-situ* design and development (Hartwood et al., 2002b).

Finally, a prerequisite for adopting such techniques in requirements gathering processes involves securing commitment from project members, particularly developers and project managers who may not be accustomed to them.

8. Conclusions

The eDiaMoND project has raised many fundamental questions about the relationship between the work of breast screening and the technological capabilities that Grid computing might provide. For example, in distributed, collaborative working, the Grid can facilitate a sharing of expertise that is currently impossible. Creating this flow of knowledge and information could have a significant effect on the practices through which the skills of reading mammograms and understanding causes of breast cancer are developed and maintained.

The grand vision of the eScience Programme is to change the way in which Science is conducted. From this perspective, the Grid is not about trying to sustain an ever upward trend in the power of scientific computing, but rather trying to enhance the very practices through which science is achieved. Given the complexity of the domains, the huge quantity of scientific information and necessary visualization processes, and the need for tools and processes to support global collaboration, this most certainly is a new and challenging area for requirements engineering.

eHealth, as a part of eScience, has correspondingly strong technological visions of what Grid computing can make possible. In eDiaMoND, such visions have not always been found to be entirely consistent with understandings of existing practices. However, the collaboration of our clinical partners and the detailed understanding of work practice we have gained has provided a firm foundation for addressing technological visions and re-specifying them in ways that may make their accomplishment more achievable in the long-term. In our experience, ethnographic methods are an essential tool for understanding eScience requirements and we would argue strongly for their wider take-up within eScience projects.

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