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Ownership of Intellectual Property Rights in Medical Data in Collaborative Computing Environments

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Abstract. e-Science is concerned with enabling global collaboration between scientists, and in the case of e-Health, with facilitating both medical research and diagnosis. This potentially revolutionary shift, from local to global, presents the possibility that patient data, previously trapped inside the hospital at which it was physically acquired, could be mobilized in new kinds of scientific research and computational analysis in collaborative activities at physically distributed institutions. Opportunities for broad collaboration and sharing of data also present significant legal and ethical concerns. Laws relating to the intellectual property rights ("IPRs") in individual patient records, databases that aggregate medical data, are complex, and the results of their application can be unclear. Developing a clear legal framework that fairly accounts for the needs of patients, clinicians, researchers and those in commerce will be essential to the successful development and deployment of such innovative infrastructures that permit broad collaboration. The IMaGE project is a one year collaboration between lawyers, social scientists and computer scientists. Our key goal is to develop a UK-based intellectual property ownership model for the sharing of digitised medical data in a collaborative computing context. This paper outlines some of the challenges we have encountered and our preliminary analysis of them.

Introduction

The IMaGE project was established to study the **i**ntellectual property rights of **m**edical data in **g**rid **e**nvironments. It seeks to address some of the legal and ethical challenges that have been raised in response to technologies being developed within the UK e-Science programme. In order to consider these concerns more tangibly, the project will focus on a retrospective study of one particular recent e-Health initiative.

eDiaMoND (www.ediamond.ox.ac.uk) was a flagship UK e-Science project that sought to develop a collaborative platform for sharing medical mammography data. Central to this project was the acquisition, from a series of collaborating hospitals, of large volumes of anonymised patient information and image data. Although now in its final stages, the project nevertheless raised pressing issues worthy of consideration. In particular, it was often unclear precisely who owned the intellectual property ("IP") in the data on which the project depended. This uncertainty became a major concern for the project and continues to represent a significant barrier for the future development and deployment of e-Health

technologies.

By combining legal research and analysis, interviews with the key eDiaMoND team members, and consultation with other significant stakeholders, the IMaGE project will investigate the implications of this technological shift from local to global collaboration (Taylor, 2001) toward what Foster and Kesselman describe as “virtual organisations” (1998). The project will address, not just who currently owns the IP in such digital resources, but also who *should* own the IP in the data and databases used for medical diagnosis and collaboration. For example, the ownership of the IP associated with the medical data could be placed in the hands of the UK government, patients, hospitals, medical professionals, or even some other independent entity. By unpacking these types of issues and systematically reviewing the data flow through a collaborative system, from the development of a standardized mammogram format through initial patient intake and data acquisition to implementation and deployment of a distributed system for collaboration and diagnosis, the project will analyse the effort expended to add value to these data at each point in the system and to determine whether minimum standards of originality are met for the recognition of IP in the value added to these data. This process will then attempt to resolve potential IP ownership conflicts by balancing the data needs of medical practice, scientific research, and industrial innovations. Still in its early stages, this project is challenging and interdisciplinary. As of April 2005, initial interviews with key members of the eDiaMoND project have been conducted and much of the preliminary legal research is under way.

eDiaMoND: a Distributed Collaborative Platform for Health Care and Research

eDiaMoND aimed to develop a next generation Grid enabled prototype to demonstrate the potential benefits of a national infrastructure to support digital mammography. It was a large interdisciplinary e-Science project, jointly funded to approximately £4.25m, involving multiple academic and commercial partners[1]. The project received extensive public interest, including articles published by Wired (eDiaMoND), the BBC (BBC, 2002), and even a press statement by Prime Minister Tony Blair (eDiaMoND).

The context for this project was the UK National Breast Screening Programme, which currently examines women from the ages of 50 to 64 every three years. Mammograms are X-rays of the breast and are currently based on film technology. Under the programme, at a screening clinic, a woman will have a series of these mammograms taken by a radiographer. After the films have been developed, they are displayed onto a light-box so that they can be examined for potential signs of cancer by two radiologists (a specialized kind of medical doctor). In the vast majority of cases the image will indicate a clear diagnosis and the woman will be asked to return at her next regular appointment. However, if an image is seen to contain a warning sign, the woman will be asked to return to the clinic for a full assessment. This may involve conducting a biopsy, or the taking of further images, perhaps using other modalities. Breast screening therefore shares many common features with other scientific tasks; it is by nature detailed methodical work that is concerned with using complex equipment to take specific measurements of scientific phenomena.

The radiologists' abilities to identify potential cancers in these mammograms are central to the process. To the untrained eye, a mammogram is a spidery blur, but to the radiologist it

[1] The project involved a core of 30-35 staff spread over 12 locations, including: 5 Universities, 4 NHS Trusts, a multi-national company, and a rapidly expanding university spin-out enterprise.

is something that can be normal, unusual, or even amazing. Radiologists have a specialized language for talking about different regions of the breast, and a vocabulary for describing features within it (micro-calcifications, spiculative masses, etc). This is a complex skill that is taught through a mix of scientific theory and apprenticeship (Hartswood, 2002, 2003).

The Digital Mammography National Database (eDiaMoND) focused on the application of Grid technologies within the UK National Health Service Breast Screening Programme. Central to this vision was an expected shift from film-based to digital mammography technologies. Once mammograms were in digital form, it was anticipated that a database would be required to store and manage them. eDiaMoND sought to develop such a database on a national level, and then apply Grid technology to manage a series of services to utilize those data. The Grid presents a series of potential benefits for digital mammography: radiologists will be able to share images and expertise in new ways; new Grid enabled Computer Aided Decision algorithms will be developed and used to assist in the reading process; and epidemiologists will be able to use vast stores of accumulated image data to research cancer in new ways.

Currently, one in nine women in Britain develops breast cancer in her lifetime (Boseley 2004) and the screening programme is a critical part of the NHS's cancer prevention strategy. It is, however, a massive undertaking: some 1.5 million women are screened each year and work is being done to extend the programme to screen women up to and including the age of 70 (a 50% increase in workload). All of this comes within a context of a national shortage of radiologists (Geldman 2002). The system proposed by eDiaMoND would allow radiologists to share expertise and reading work between clinics, irrespective of the geographical location of the radiologists involved. In this regard the technology was intended to benefit not just the process of scientific discovery or the training of radiologists, but also directly to improve the care of patients.

Approach

The interdisciplinary nature of IMaGE will mean combining a thorough understanding of relevant laws, a detailed view of the opportunities afforded by eDiaMoND's Grid technology, and a comprehensive sense of the clinical and ethical consequences of any proposed changes. Although our focus is on investigating IP issues for collaborative Grid environments, the project necessarily began with a review of publications, cases and statutes relating to relevant forms of ownership in non-electronic, non-medical, and non-Grid contexts. In parallel with this legal research, a retrospective analysis of the eDiaMoND project was initiated. This was done through unstructured interviews with key members of the eDiaMoND team and other stakeholders in the project, and by reviewing documents that were produced. The analysis provides: first, a background on eDiaMoND and the technology it sought to develop; second, a sense of the challenges and problems; and third, a catalogue of the agreements created to enable the project and the ways these agreements were understood by key members of the team.

Informed by this empirical material, policy analysis and jurisprudential research, the second phase of the project will focus on the development and evaluation of various models of IP ownership for mammograms and their associated medical data. These may include: patient ownership, governmental ownership, hospital ownership, industry/researcher ownership and joint ownership by a non-profit body (which may include stakeholder representatives such as patients, researchers, government, treating physicians and medical technicians). The models will be evaluated through a series of focus groups, both with members of the eDiaMoND project and other significant stakeholders, such as patient groups and clinical staff. These exercises will investigate the extent to which any model meets both the

challenges presented by technical innovation and the ethical and clinical needs of individuals.

The final phase of the project will focus on dissemination. Recommendations will be suggested indicating whether, and if so, how the law might be changed to account for the preferred model of ownership and these findings will be disseminated through appropriate channels.

Medical Research Databases and Intellectual Property

At the heart of the eDiaMoND project was a substantial archive of patient information, but the legal status of this information became an issue. For example, by building a massive collection of mammograms it was possible to develop and then 'train' new kinds of computational algorithms by using those data. As a result, such algorithms may become commercially valuable. The scientific, commercial, and medical value of these data heightens the need to clarify the law governing the rights and duties of the various parties involved (hospitals, patients, researchers, government officials, universities and others).

The project's data were acquired by a team of four universities, each working with a breast screening clinic that could examine patients from one or more legally independent NHS trusts, and independent agreements with each had to be struck before data would be released. At each clinic, technicians were employed to convert film-based mammograms into digital images, and enter and anonymise patient information. Radiologists at the clinic were also employed to add professional annotations, so that some of these cases might have been used for training and other research applications. Many of the patients in the database had to provide explicit written consent for the project to use their information; however, some of the data used by the project were acquired before this step had been deemed necessary. Once data had been acquired and anonymised, they were encrypted, and transferred out of the clinic and to a university, where they could be uploaded onto the Grid.

The *ad hoc* nature of the agreements between clinics and universities, the details of the employment of technicians and radiologists, the varied nature of the consent that was granted by patients, and the relationship between NHS trusts and screening clinics, made the legal ownership rights difficult to establish. As one member of the eDiaMoND project remarked: “We initially said to [our] lawyers, 'who owns the data?', and they never came back with an answer!” [050317:1400-292]

From a legal perspective, three legal regimes may govern the ownership and control of eDiaMoND data. First, there is the formal IPRs regime: medical images are protected under copyright; database rights may govern aggregated sources of medical information; and patent law may protect derivative technologies. The law of contract, which may regulate particular IP rights through individual licences and/or assignments, may then affect the formal IP legislation. Similarly, there may be applicable codes of conduct, tort liability, or ownership rights implied from employment contracts. Finally there are personal and human rights protections which may affect consent and privacy issues.

Once the applicable IPRs are discerned, and once the legal status of each is resolved under current law, custom and practice, a model of ownership can be developed to answer the question: who should own and control the IPRs in an optimal fashion that balances the needs of all the participants in this collaborative system? Reference to human and personal rights and, specifically, general issues of consent and privacy is important as these may

suggest an instructive model for a system of IPR ownership and control. Additionally, the ideal model of ownership must comport with these considerations, and must be complementary to the existing institutional control of medical data and database by the pertinent ethics board. Furthermore, as there is potential to permit researchers outside the UK to access the database, it will be necessary to examine, at least minimally, the treatment of such IPRs under the laws of those countries with whom the data are likely to be shared within the next five years, such as other EU countries, Commonwealth countries such as Canada, Australia and New Zealand, and the United States.

Under existing laws, it is assumed that generally, the individual hospitals own the IPRs in the mammogram images and associated data, subject to the privacy rights of the patients involved. However, this state of affairs is largely ad hoc and case-by-case, and the standard notions of contract and copyright involved have only been developed in the circumstances of a physical, non-collaborative, non-Grid environment (e.g. R v Department of Health, ex parte Source Informatics Ltd [2000] 1 All ER 786). Moreover, because the vision of Grid technology includes the possibility of sharing resources and data at an international level, different ownership regimes between countries may also have to be accounted for (e.g. The Mammography Quality Standards Act 1992 (42 U.S.C. § 263b)).

Establishing a clear and definitive legal position in relation to the ownership of medical data will be important in a number of regards. First, it will be critical in preventing expensive litigation. Second, for projects like eDiaMoND, and its successors, a clear legal position will greatly enhance the opportunity for academic research and industrial innovations. Third, such a clarification will be necessary for the successful integration of networked technologies into medical practice.

> "If the NHS want to adopt PACS [Picture Archive and Communication Systems] and all digital systems, and the concept of joined up health care, then they haven't addressed some of the fundamental issues, which is, who actually owns the medical record?"
>
> [050317:1400-6]

The ambiguity of ownership is evident here and elsewhere: a distinction may exist between who owns and can license use of the *physical* record, and who owns and can license use of the *copyright or database right* in the expression or information contained in that record. Without a clear vision of the IPRs at stake and a determinative resolution of the ownership of those rights, commercial investment in new technologies and systems for the control and distribution of such data will lag, as potential investors may seek out other opportunities that do not bear the burden and cost of potentially expensive litigation. Ultimately, it is our aim that legislation will be adopted to resolve the issue of IPR ownership of medical data in the UK for as many possible factual scenarios involving medical data as possible. It is our goal to develop draft legislation as one of the outputs of this project.

Notions of Ownership in the eDiaMoND Project

Though the legal situation is complex, the eDiaMoND project was nevertheless able to acquire medical data and develop sophisticated systems to demonstrate the power of Grid computing for digital mammography. The ways in which the project achieved this, the agreements that were made, the way these agreements were understood, and the opinions that were formed by its stakeholders are consequently a key component in the IMaGE project. Such perspectives, particularly those relating to the control, responsibility or benefits connected with medical data, will be critical in informing our thinking on future arrangements for ownership.

Initial interviews, conducted predominantly with members of the eDiaMoND project,

presented viewpoints highlighting four significant stakeholders in the data gathered by the project: patients may provide data, but must consent for the use of such data in research; ethics committees have a great deal of power in deciding what may, or may not, be done with those data; clinicians, as the primary point of acquisition are currently the physical custodians of those medical data; and researchers, who must negotiate ethical, legal, and other concerns, in order to benefit the state of medical knowledge. Each of these groups have concerns that in some way have an impact on the practical activities engaged in by eDiaMoND.

1. Patients

Although a patient may not be the legal copyright holder of any medical data acquired during screening, they may nevertheless be entitled to grant or withhold consent for any use of those data. Their consent for use of their data in their direct treatment may be inferred implicitly; however, to use such information for research or even training requires further explicit consent.

Until recently some thought that this consent for research or training purposes could also be granted implicitly; for example, posters displayed in a clinic might have been considered sufficient to inform patients of the ways in which their data might have been used, and provide them with an opportunity to opt out. In the last couple of years, ethics committees have taken an increasingly firm stance. In particular, explicit, rather than implicit, consent is now mandatory. Patients must provide explicit written consent, and must verify that they have been fully informed about the nature of the research, how they will be involved, and what will happen to their data. [050317:1400-45]

This type of consent may be hard to obtain, since patients may have to be written to, or approached individually as they await treatment. Some researchers see this as a barrier to scientific progress and favour broad categories of patients' consent allowing a wider range of research to take place using their data.

> "What we've been fighting for is a form where I can say: I'm happy for my data to be used, any research project, in the world, any pharmaceutical company, I don't care if they make money out of it, so long as they benefit science, I don't care. But I don't want you to take my DNA, I don't want you to have certain aspects of my record, you should be able to choose... I think [current arrangements are] damaging research." [050317:1400-80]

Other researchers would go further and suggest that once patient data have been properly anonymised, the data should be openly available, giving the patient no control at all.

> **Interviewee**: Yeh, you ultimately have a responsibility to the patient, but it certainly seems to me that the whole [issue of consent] has gone a bit over the top recently.
> **Interviewer**: So how would you map out a sensible future for this situation?
> **Interviewee**: I think, insisting all data is anonymised, and once that's the case then effectively there is no patient who owns it, so you can do what you like with it.
> **Interviewer**: It becomes public domain?
> **Interviewee**: Yeh. [050401:1400-274]

The recent requirement for explicit consent has made new archives of medical data harder to obtain, and thus increased the value of data collected before the change. This was of

particular relevance to the eDiaMoND project as their database of mammograms was gathered from both old and new sources. So, although each image was to be stored in the same way, the nature of the consent that had been granted for the use of that image may have been different from case-to-case.

These concerns, connected with the gathering of large datasets from different sources, may in fact end up being addressed by the technology itself. Future networked systems with digital rights management functionality could readily provide new solutions to the issues of consent. Data held using Grid technologies may allow a patient even more control over the use of their information. For example, perhaps patients might be remotely informed of a research proposal and then remotely consent to their involvement, or conversely, electronically withdraw their data from a study. However, while technology may alleviate the problem by providing an easy mechanism for acquiring fine-grained consent, there still exists a fundamental tension between scientific freedom and patient rights, which any future framework must take into account.

2. Ethics Committees

One of the other major forms of control on the use of medical data is the process of ethical approval. While patients may be given the power to decide whether or not to allow their data to be used for a particular project, the ethics committees have the power to shape and control the nature of those projects. It is their role to ensure that researchers observe the rights of patients. Ethics committees have the power to decide whether a research project is allowed to proceed, or alternatively may demand that existing plans are modified to account for their concerns. “Actually [the ethics committees] had a huge amount of power, a frightening amount of power, and still do, and the reason why they're there is to protect the patients, and that's their job.” [050317:1400-315]

Researchers portray the process of ethical approval as a stringent one, where every detail is examined, down to the actual consent forms that patients may sign. Moreover, even if approval is granted, it will be on very limited terms, to use data for a very specific purpose and for a limited period of time. In the case of the eDiaMoND project, although acquiring data was expected to be a time consuming activity which could have resulted in an archive of lasting value, it was initially expected that these data would have to have been destroyed once the project's two years of funding had expired. As one researcher put it: “it's almost like we're looking after [the data] on behalf of the ethics committee.” [050317:1400-393]

Many patients may welcome stringent ethical scrutiny. However, it seems uncertain whether innovative projects such as eDiaMoND fit adequately within the existing structures for approval. Ethical committees are more commonly a mechanism for controlling the conduct of medical research such as drug trials, where patients may be physically involved in the research itself, for example by involving them in data collection activities which would not necessarily be a part of their regular medical treatment. By contrast, eDiaMoND sought only to use anonymised patient data that already existed within the clinics.

The nature of the technology itself presented further issues. The concept of Grid is of seamless distributed collaboration, federating data from different locations and delivering these data to anyone within a community, irrespective of location. Medical data have traditionally been worked with very differently, typically at a more local level, and the process of ethical approval reflects this is in some respects. In order to engage in research with data from many sites it was necessary for the project to obtain approval from a Multi-centre Research Ethics Committee (MREC). Each participating NHS Trust would then have to approve this MREC decision, and could also ask for other information regarding the way

that the project would be governed. The process was a complex one that perhaps because of the nature of the project, even researchers with prior experience in the medical domain found difficult to manage.

> "Another interesting thing was trying to keep track of where the process had got to and whether we'd got ethics on various sites... There was some sort of system, but it didn't always work, and this sometimes took a long time to show up in the MREC." [050318:1400-36]

This ethical approval process was of considerable concern to the project's researchers. There were worries relating to the duration of the process, which stretched over much of the project's two year duration. However, there were also more substantive concerns. The innovative and technological nature of the project was somewhat distinct from the type of work more usually submitted for review by the ethics committees. It was felt that due to the complexity of the technologies involved, domain specialists with a sound understanding and experience of the technologies and their operation could assist the necessarily more generalist assessment of projects by ethics committees."

> "It's a question of whether the people [on the ethics committees] have the right skills and the right information to make a rational judgment, about the balance between protecting the patient and allowing research to progress. What is a reasonable risk, and risk analysis, often people don't have the right skill sets to do it." [050317:1400-317]

It seems unclear whether the difficulties raised by researchers relating to the process of ethical approval, are merely organisational or whether they are indicative of a more fundamental tension between medical ethics and new technologies. Either way, understanding the nature of these ethical concerns and how they may change will be a valuable source of insight in the development of future legislation.

3. Clinicians

While ethics committees have a strong degree of control over research and its conduct, ultimately it is the clinicians who physically hold the patients' data. Clinicians may see themselves as "custodians" of these data [050317:1400-103] controlling their use on behalf of the patient. It is the clinicians with whom researchers must deal in order to acquire data, and they consequently have a great deal of power to control how those data are distributed and used. However, over and above protecting patients, they may also see these data as "their asset", as having value, as that they have expended effort developing, and as a consequence may seek to protect [050317:1400-13].

The eDiaMoND project gathered data from four different breast screening clinics. Standard contracts were drawn up which would assign any IP resulting from the use of these data to the project. Once ethical and administrative concerns had been satisfied, three of the four clinics were happy for these data to be entered into the system on these terms. However, the fourth clinic successfully renegotiated its contract. Under its new agreement, it would retain any IP associated with these data or their use. From its perspective, there was no reason why, if a commercial product was later created by the project or its partners, they should effectively have to "buy back" the data they had initially provided [050318:1400-204]. In renegotiating its contract, the clinicians demonstrated a significant power over the medical

data for which they were custodians.

Also of concern was the organization of the acquisition process; how medical data held in the clinic would be digitized, and then securely leave the clinic and transferred to part of the project's Grid infrastructure. Acquiring these data was therefore not a straightforward process. The majority of the data had to be scanned from film, and their associated medical record typed in and anonymised by a technician. But there were exceptions; some of the cases were acquired, not by scanning, but from direct digital x-ray machines. Furthermore, some of these data were specially selected, and then "annotated" by a clinician, so that cases could be used for training purposes. In order to complete this time consuming work, both clinicians and technicians had to be paid. From a legal perspective, the mechanisms through which these data were acquired, and the details of the employment that enabled their acquisition, may greatly affect the legal status of these resulting data.

Moreover, trusts, like the NHS, have the power to set up licensing agreements, and could potentially profit from data they provide. Many of the researchers were unconcerned by this, after all they had no interest in developing products. But in common with other ambitious projects, eDiaMoND was significantly dependent on commercial support. Thus the ability for institutions to establish equitable licensing agreements within a clear legal framework may be essential to ensuring adequate investment for the successful development and deployment of such technologies.

4. Researchers

The interviews used for this work have thus far been conducted with members of the eDiaMoND team and have included a range of participants: technologists, managers, social scientists, university research officers, and commercial employees. However, while these roles may have been diverse, through their connection to the project, each interviewee had a strong link with research activities. In the reflections they provide, the researchers' control over these data was often played down. Instead those seen as having control were: patients, clinicians, or ethics committees. Researchers highlighted the fact that they had been provided with data for a strict purpose, and for a fixed duration.

> **Interviewer**: "Well what about the data in your database, do you own that data?"
> **Interviewee**: "The cautious assumption we've made is that we don't own it, but we're licensed to use it; in some cases an explicit licence from [one site], and in others and implicit license. ...but we don't believe that we have the right to go and sell it, and we can't do anything above the two years of the project anyway." [050317:1400-239]

Rather than having control, one researcher described their role in the project as mere technical custodians of those data.

> "We were quizzed by [one NHS region] on our security, we had to go and present, they wouldn't take our word for the fact that we'd keep the data securely, we had to show them the architecture, which VPN, how are you're encrypting it, so you are almost like a technical custodian, but not in terms of legal stance, you don't seem to have any rights over it." [050317:1400-396]

In this sense, while the researchers' control over data seems minimal, their responsibility for their control is considerable. Grid technology, in common with any other Information

Technology, must be maintained and has with it an associated risk. It was made clear that the eDiaMoND project would be liable should anything go "wrong" with their technology [050317:1400-409].

> **Interviewee**: "The other big problem for us, with regards to the epidemiological stuff and collecting mammograms is that our connection with [the epidemiologist] didn't really materialise... Although she was happy for us [here] to digitise them for her, she wasn't particularly excited about the idea they would go into some Grid database that might be accessible, you know, you never know quite what's going to happen to the data at the end of the project. She felt quite, it's obviously quite valuable data, and she'd like to keep control of it, I suppose."
> **Interviewer**: "Do you think that's protecting all the effort she's put into acquiring that data?"
> **Interviewee**: "Yeh, yeh, I think that's exactly it. Having put in all that effort, I guess she feels that she wants to have sole right to publish anything." [050401:1400-65]

Clinicians, who may have direct access to patients and their information, quite commonly conduct research in this field. In providing others medical data carefully gathered for their own research, tensions may arise between collaboration and competition. These tensions are often resolved at a contractual level. For example, a clinician's research data may be licensed for use by another research group, but only on terms that ensure the resulting work will not compete with the clinician's own research.

Obtaining data for research is therefore not only a matter of ethical approval, patient consent, and collaboration with clinics, but may also be a matter of research politics. It is clear that data that have been carefully selected and developed should be protected. But the idea that valuable research projects might be blocked by political concerns seems somewhat undesirable.

Discussion

From the current interviews with researchers, they have tended to undermine their control over any data they may hold. However, from the public's perspective things may appear differently; how, for example, can the public know that their data are being treated responsibly? University spin out companies are now commonplace; academics may also be managing directors; the line between academic research and commercial development is perhaps not as distinct as it once might have been. Consequently, concerns relating to the use of data may seem justified.

Digital Rights Management technologies may address these matters, as may clarity relating to legal rights, responsibilities, and relevant penalties. Ultimately, however, no matter how tough the enforcement, the public is still dependent on individual researchers to act ethically and responsibly with their information.

> **Interviewer**: "Is there a feeling that [the Principal Investigator] is more or less responsible for everything?"
> **Interviewee**: "In that strict accountability sense, I guess that's what the [clinical governance] document's suggesting, I guess he is in a strict sense. But working locally, we feel responsible for doing things in a proper way, and in accordance with the ethical approval that we've got." [050318:1400-106]

This sense of responsibility is perhaps reflected in the 'honorary' clinical appointments that were granted to the academic researchers who were handling medical data. However, while a sense of responsibility is no doubt important, ethical action may be, as one researcher put it, a matter of "common sense" [050401:1400-264]. Providing data for research is therefore more than simply a matter of licensing, it is also a matter of trust (Jirotka, forthcoming). In their individual day-to-day actions, each researcher is entrusted with the responsible treatment of the data they use. Indeed, one of the beneficial aspects of current localized arrangements is the way this trust might be built: patients can meet face-to-face with clinicians; clinicians can meet face-to-face with researchers; and projects must be given ethical approval at a local level. In attempting to refine the legislative structure that may facilitate innovation in e-Health, it will be vital to ensure that locally established networks of trust may continue to flourish.

The type of technology proposed by eDiaMoND, with its potential shift from local control toward global accessibility, presents both opportunities and tensions. By enabling new kinds of research and collaboration, new technologies may significantly benefit health care. However, this must not be done at the expense of patients' privacy, or in a way that might damage the mechanisms through which researchers may demonstrate themselves trustworthy. By making valuable data more mobile, research progress may be maximized. But researchers must still be allowed to adequately protect their work, and industrial partners to establish fair licensing arrangements. Successful distribution of data on a national and international level requires clarity as to the rights and responsibilities of those who provide and use these. The definition of legal structures for the ownership of IPR will play a vital role both in clarifying concerns and enforcing compliance.

Summary

By examining the issues raised by eDiaMoND, the IMaGE project seeks to investigate and extend notions of IP protection for collaborative computing environments, and more widely for other types of innovative research and development projects. The lack of clarity clouding these concerns may be a significant barrier to the future success of ambitious research packages like eDiaMoND and the theories and models of ownership developed by this project may therefore be critical. The research will consider both the purely legal aspects of ownership and protection, and the broader social implications for medical practice, scientific research, and industrial innovation. In this way, it promises to make a distinct contribution not just to the development of collaborative medical diagnosis systems, but also to help facilitate the process through which other innovative technologies may find their place within society.

While existing models for the protection of patient privacy and confidentiality are adequate for addressing the concerns for which they are designed, such models do not address issues of IP ownership. More importantly, they do not balance the patients' needs with those who collaborate to provide medical diagnosis, training and research, or those commercial investors who fund the research and development projects and require a high level of certainty as to the ownership and control of the rights in those data generated, manipulated, transferred and shared in such projects. Ownership of IPRs in medical data will need to be resolved by assessing and potentially changing the balance of responsibility for, and control over, data and the rights inherent in those data. In the result, the goal will be to ensure society derives maximum benefit from these resources, while respecting the rights of those who may have a stake in the use, distribution and commercial exploitation of such resources.

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References

eDiaMoND Homepage, available at "http://www.ediamond.ox.ac.uk"..

BBC, National Breast Scan Library Proposed, available at "http://news.bbc.co.uk/1/hi/health/2326667.stm".2002.

Boseley, S. (2004) Breast cancer; the relentless rise. The Guardian, January 15th

Taylor, J. (2001) Presentation given at UK e-Science Meeting, London, July.

Foster, I and Kessleman C (1998) The Grid: Blueprint for a New Computing Infrastructure

Geldman, A. (2002) NHS staff: the issue explained. The Guardian, June 26th.

Hartswood, M., Procter, R., Rouncefield, M. and Slack, R.. Performance management in breast screening: a case study of professional vision and ecologies of practice, in *special edition on Human Error and Medical Work, Journal of Cognition, Technology and Work.*, (4)2:91-100. 2002.

Hartswood, M., Procter, R., Rouncefield, M., Slack, R. and Soutter, J. The Work of Reading Mammograms and the Implications for Computer-Aided Detection Systems, in *Proceedings of the Seventh Medical Image Understanding and Analysis Conference*, pp 89-92. 2003.

Jirotka, M. Procter, R. Hartswood, M. Slack, R. Simpson, A., Coopmans, C. and Hinds, C. Collaboration and Trust in Healthcare Innovation: the eDiaMoND case study. Submitted to the *Journal of Computer Supported Cooperative Work*