



Protecting Patients—Managing Persons

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This paper is based on my experience of applying for ethics approval from two different Local Research Ethics Committees (LRECs) in the context of fieldwork with people suffering from multiple sclerosis (MS) in the Manchester area. I argue that LRECs are a form of audit intended to remove relationships from the decision process and to change practice. By focusing on the category of ‘informed consent’ and how it is conceptually and bureaucratically constructed, I analyse the ways in which ethics committees are able to preserve the notion of individual choice while at the same time defining its parameters. In so doing, ethics committees interfere with the efforts of people, such as the ones I worked with, to become productive in culturally-specific ways, for instance by being involved in research. I conclude by reflecting on how the removal of the relational dimension of research through bureaucratic technologies, such as ethics committees, affects anthropologists.

The following paper is based on my experience of twice applying for ethics approval from Local Research Ethics Committees (LRECs) during my fieldwork in northwest England. My first application was ‘deferred’ which, given the graveness of the committee’s concerns, was tantamount to a rejection, but my second attempt with a different committee and a different project was passed after some revisions.¹

I consider ethics committees in general, and the two I had dealings with in particular, as one of many contemporary manifestations of audit. This observation implies that ethics committees are not merely descriptive techniques, but Foucauldian technologies intended to affect change (Power 1999; Shore and Wright 2000; Strathern 2000). By focusing on the notion of ‘informed consent’ and how it is conceptually and bureaucratically constructed in the context of ethical approval, I analyse the ways in which ethics committees are able to protect the concept of persons as individuals, while simultaneously allowing for their management. I will conclude with some brief reflections on the implications for anthropological research.

The research context

My doctoral thesis was concerned with the relationship between productivity and personhood in the lives of people who had multiple sclerosis (MS). It was based on fieldwork in three fieldsites in the Manchester area: a therapy centre, a yoga-cum-

¹ Unless attributed otherwise, all quotes come either from written communication with the two ethics committees or from the forms prepared for them.

lunch class, and a course for people with MS intended to improve their skills of managing their illness. While the first two sites were in the voluntary sector, the last one was part of the UK National Health Service (NHS).

MS is a disease of the central nervous system with around 85,000 sufferers in the UK (MS Society 2004). It damages the myelin sheath—the protective coating around nerve fibres—in a process referred to as demyelination. The myelin sheath ensures the reliable and fast transmission of nerve impulses and where it is destroyed, the impulses become increasingly weak and erratic, interfering with muscle control and a variety of sensory activity in all parts of the body (Robinson, Neilson and Rose 2000). It is impossible to predict which nerves are being damaged, in what order and at what rate. Some of the symptoms from which the people I worked with were suffering included balance problems, spasticity, muscle weakness, pins and needles, feeling too hot or too cold, bowel and bladder problems, incontinence, impotence, loss of sensation, pain, fatigue, mood swings, slurred speech, blurred vision, and blindness.

The first time I applied for ethics approval was at the beginning of my fieldwork. As I put it in the LREC application form, my intention was to find out if ‘being a person with MS in Britain change[s] the kind of person you are and if so, in what ways’ by conducting fieldwork in the MS day clinic at a major local hospital. I had spoken to the senior specialist nurse in charge of the clinic and other services for people with MS, and she had been friendly, patient and encouraging. In fact, it was her suggestion that I talk to the patients at the day clinic who she said would do ‘anything to alleviate their plight’. All that remained to be done before I could start fieldwork was to obtain approval by the relevant ethics committee, or so I thought.

My supervisor put me touch with another anthropologist and going by her experience of applying for ethics approval in the mid-1990s, this was a time-consuming, but surmountable task. However, when I read the relevant application form, I wondered if procedures had not become more formalized and rigorous since then. There were 19 pages, eight sections, 37 questions, plus an interview topic guide, invitation and information letter for ‘research subjects’ and consent form: all 16 copies thereof to be submitted to the committee in time for its next monthly meeting. My heart sank even further, when I studied the questions more closely:

Study design (e.g. RCT, cohort, case control, epidemiological analysis)

- | | | | |
|--|-----|----|-------|
| 14 (a) Human subjects | yes | no | [...] |
| iii) What is the primary end point? | | | [...] |
| v) What is the statistical power of the study? | | | [...] |

24 Please indicate whether the study involves any procedures which:

- | | | |
|-------------------------------|-----|----|
| Involve taking bodily samples | yes | no |
| Are physically invasive | yes | no |

Are designed to be challenging or disturbing

(physically or psychologically, to any degree) yes no

How was I to make an ethnographic study involving participant observation and informal interviews with a small and unspecified number of participants fit into these categories? The obvious, but decidedly unwelcome, answer was that this was an endeavour akin to squaring the circle and that I was unlikely to succeed. Nonetheless, I tried and delivered my stack of applications.

The anthropologist I had turned to for advice during the preparation of the form had assured me that it is rare for ethics committees to ask applicants to attend their meeting, so when I received a letter inviting me to ‘discuss certain aspects of the study’ with the committee I was surprised, but optimistic, that this would give me a chance to present the research outside the restrictive categories of the form. Yet, when answering the questions of the ten committee members assembled around the large conference table, I quickly realized that the committee and I had very different ideas about what ‘valid research’ looks like.

A week later, I received a letter from the committee informing me that it had deferred its decision pending issues such as:

‘The Committee felt that there was a lack of justification of the use of such a vulnerable group of patients. In fact, had the researcher chosen a different groups, such as dyslexia sufferers or diabetes patients, they would not have needed to deliberate as long.’

‘The Committee understands the norms and methodology of qualitative research, but remained unconvinced that the outcome would be unbiased, or that the data could be analysed effectively, therefore lacking analytic evidence.’²

Given the nature of the committee’s concerns, this deferral was *de facto* a rejection. I propose that my experience with this ethics committee was no mere technicality, but instead was indicative of wider social, historical and political changes in the UK, such as the rise of audit (Power 1999 and Strathern 2000).

Why ethics committees are a type of audit

There are three reasons to consider ethics committees a form of audit. First, because of the historical time-frame of their emergence. Second, because they automate management. And third because they are intended to change practice.

In the UK, the British Medical Council first reported on the responsibility of researchers for the well-being of their subjects in 1963 (Alberti 1995). In 1967 the

² At the end of my first year, and only a few weeks before I met the committee, my research proposal had been assessed by two members of the Department of Social Anthropology at Manchester University and passed. Hence the committee’s assertion to know ‘the norms and methodology of qualitative research’ should not be read as an ‘objective’ judgement concerning the quality of the proposed research, but represents at best a rather sobering commentary on the public understanding of social anthropology.

Royal College of Physicians recommended that all hospitals should establish ethics review boards on an informal basis. However, it took 16 years for guidelines to appear from the Royal College of Physicians on how these ethics review boards should function and another five years for such guidelines to be published by the Department of Health in 1984. A further two years passed, before LRECs became mandatory for every health district. By then Britain had already been ruled for seven years by a Conservative government under Margaret Thatcher, which considered the norms of the market to provide the regulatory blue-print not only for the activities of the state itself, but also for the conduct of individuals. Audit has further proliferated under New Labour, because Tony Blair's government continues many Conservative policies and shares important ideological paradigms with its predecessor. Examples are an emphasis on individual responsibility and government schemes such as private-public partnerships or public finance initiatives in transport, housing, healthcare, and education.

Audit has its roots in financial management, but as a term and a practice it is sufficiently difficult to define to allow for its application outside accountancy. Audit's slipperiness of meaning did not only permit it to spread beyond its origins, but also opened up the possibility to use the word not descriptively, in terms of what it is, but normatively, in terms of what could or should be (Power 1999: 5). This is an ideological rather than ontological perspective, which lends audit a political dimension (Porter 1995 and Strathern 1997).

Audit aims to cut out the relational dimension of management and 'automate' it by making people self-managing, through, for instance, the use of forms. Previously the site of management was between people; with audit management is located within people. Whereas one can talk back to a manager, this is not possible with a form, as I found out with my first application. Even though I met the committee in person, this had no influence on my application and in fact had been carefully designed not to.

Automated management requires standards, procedures and protocols that ensure that even variety appears only in prescribed forms. Richard Wilk has written of 'structures of common difference' which 'celebrate particular kinds of diversity while submerging, deflating or suppressing others' (Wilk 1995: 118). He used the term in the context of analysing the transnationally imposed 'standards' of beauty applied in beauty pageants in Belize, but the idea itself can be transferred to almost any kind of standardizing technology, such as when the first ethics committee expressed its concern about a perceived lack of objectivity in my research proposal. The committee had pre-defined notions of what 'research' was on the basis of which it would then 'impartially' judge any application. However, what was missing was an 'impartial' discussion about what constituted 'valid' research in the first place.

Paying attention to the role of 'objectivity' is crucial if one wants to understand how audit operates, because the case in favour of audit is made not only in bureaucratic, but also in moral terms. In contrast to 'expert' knowledge, which will inevitably be subjective and lack 'fairness', so the argument goes, objective assessment by audit is 'indifferent to difference' (Herzfeld 1992). Not only can it be 'fair' and 'objective', but also 'transparent': everyone can know the rules by which he or she is being judged. In that sense, audit is presented as a more democratic and more equal

alternative to 'elitist' and 'secretive' 'expertise'. But as I pointed out above, this is a projection rather than a reality.

The whole of anthropological methodology is premised on resisting the habit of objectifying persons and reducing them to certain narrow 'research-focused' criteria. Hence, any attempts by ethics committees to de-personalize the relationship between anthropologists and those they work with has profound consequences. In order to illustrate and support this argument, I will focus on the concept of informed consent, which is central to the committees' definition of ethical research. This will eventually allow me to shed some light on the ways in which the notion of informed consent is conceptually and bureaucratically managed, by asking what happens to the patients whom ethics committees have been set up to protect?

What constitutes informed consent?

Informed consent occupies an important position in the codes of ethics developed by the American Anthropological Association (AAA) and the Association of Social Anthropologists of the UK and the Commonwealth (ASA) (American Anthropological Association 1998 and Association of Social Anthropologists of the UK and the Commonwealth 1999). Both organizations stress that consent has to be obtained in advance of the research and be meaningful to the people it is asked from. The AAA and ASA understand consent in research as a process that has to be renegotiated over time. While the ASA does not specify ways in which consent can be sought, the AAA explicitly states that '[i]nformed consent for the purposes of this code, does not necessarily imply or require a particular written or signed form. It is the quality of the consent, not the format, that is relevant (American Anthropological Association 1998).' That consent is a process and does not always need to be given in writing contrasts starkly with UK ethics committees' understanding of what constitutes consent and how it is to be obtained.

The work of researchers employing anthropological approaches in medical settings has established that an interpretation of consent as 'once given—always valid' can be deeply problematic as Julia Lawton found during her fieldwork with terminally ill patients at a hospice in Cambridgeshire (Lawton 2000 and 2001). How, Lawton wondered, was she supposed to gain meaningful consent from people who on their arrival at the hospice were frequently distressed, confused, sedated or comatose? Moreover did consent gained in the prescribed way remain valid through the last stages of terminal illness (Lawton 2001)?

Similarly, Katherine Owen discovered in her study of severely learning-disabled women in the UK, who were living in a locked ward, that formal procedures were not the end of the researcher's ethical concerns (Owen 2003). The women with whom she worked were, due to their diagnosis, legally assumed not to have the capacity to make an informed choice. Under these circumstances, proxy consent is usually sought and in Owen's case the institution's consultant psychiatrist and the relevant LREC made this decision. Yet, as she discovered, official consent does not necessarily imply actual consent, because the women found many ways to express their willingness or their reluctance to talk. They ignored Owen's questions, remained silent, walked

away when she approached, or turned their faces to the wall, thus forcing her constantly to negotiate their cooperation.

In terms of the format of consent, each time I applied for ethics approval I suggested that ethnographic research cannot proceed without first gaining and then maintaining the consent of all parties involved. Yet, on the occasion my application was approved, the committee made it clear that it required *written* consent. Their insistence on explicit and formalized consent illustrates how bureaucratic technologies, such as forms and signatures, are applied in order to remove the relational dimension from the research process.

Trust is an example of a 'subjective' element of research rendered obsolete by formalized consent. By the time I began work in the NHS, I had already spent several months as a volunteer in two other fieldsites and had got to know over a third of the people I was to interview about their experience of attending an illness management course. As I discovered, the time I had spent making sandwiches and fetching cups of coffee, lending a steadying arm, pushing wheelchairs, or simply chatting had not been wasted.

Although according to the logic of the ethics committee, all participants had given their consent and consequently all interviews should have been of a similar quality, in my experience, this was not the case. The qualitative difference between the interviews with those I already knew from my previous fieldsites and those I only met for the NHS research was striking. The richest, most detailed, frank and most conversation-like interviews were all with people with which some degree of familiarity and trust had been allowed time to grow.³ Which goes to show that trust cannot be established by a signature on a piece of paper. Rather it needs to be developed as part of an open-ended and ultimately unpredictable process of engagement.

Informed consent and personhood

Ethics committees' conception of informed consent also exposes some central assumptions about the kind of person able to give or withhold it.

As Lawton's and Owen's experiences show, the existence of an individual able to make rational decisions is essential to the functioning of ethics committees. Who is considered to be a rational agent has always been subject to change. Men without property, women, or members of minorities have all found themselves excluded from this category at some time in history on the assumption that they lack the 'natural' ability to make 'rational' choices. In an age of New Reproductive Technologies and genetics this axiom has not disappeared, but instead has been reconfigured as an element of individual choice (Strathern 1992). One of the consequences of this process is that persons no longer exist 'naturally'. Instead they have to be constantly

³ The blurring between the category of 'researcher' and 'volunteer', or 'participant' and 'observer' in fieldwork raises its own ethical conundrums (Lawton 2001).

generated by the choices they make and are increasingly held responsible for aspects of their lives that previously seemed to be outside their control.

For instance, Irene,⁴ who regularly attended the Yoga Lunch, was convinced that with MS she had to fight for every little thing, down to wanting to see the consultant neurologist rather than the specialist nurses during a recent visit to the hospital:

'You know what, I said [to the neurologist] I've had this disease six years and you know what I've had for it? He said: "What?" I said: "Squat. Nothing." [...] Yeah, it's very, very hard work to see who you actually want to see and get what you want.'

Irene feels responsible for ensuring that she receives what she is convinced she needs. As Celia Lury has succinctly put it, since the late 20th century society is no longer characterized by the dictum of 'I think, therefore I am', but rather by 'I can, therefore I am' (Lury 1998). This new paradigm opened up a deeply disturbing possibility for the people with MS I worked with. What would happen, many asked themselves, if they were no longer 'able to do', would they cease to 'be'?

As Bridget, who had been living with MS for many years, explained to a young woman who had only recently been diagnosed:

'She is me two years ago; [...] very negative and the only thing ever that would help would be her walking again. [I'm] saying to her: "But Penny, what do you want to do? Sit in a wheelchair 'till you're 50 and then get cured and wonder what you could have done with your life?"'

One way to 'do something with one's life' was to become involved in medical research, and some people, such as Teresa, had actively tried to be recruited:

'I made sure that the MS Nurse knows I definitely want [beta-interferon] and I'm not going to stop asking for interferon, I just keep on. I know that I probably won't get it, but I want it on my notes and I'll keep on asking. And I've told her, I want to be considered for any research, or whatever, trials.'

Iris, another participant with MS, had requested to be part of a trial run by a specialist hospital in a nearby town about the effects of cannabis on spasticity, but had, when we spoke, not heard back from them. In the early days of her illness, Christine, who was now severely disabled, had been involved in scientific trials, and Bridget's friend Dawn remembered how eager Bridget had been to take part in drug trials, even if they 'seemed really dodgy and had horrendous side effects.' Judging by my experience there was little cause for Dawn to be concerned, because it seemed very difficult for the people with MS I met during fieldwork to get on any trials. With the exception of a few people who were involved in a comparative relaxation/reflexology study, no-one I knew or even reliably knew of was currently involved in any trials of new drugs or high-profile areas of research, such as stem-cell therapy.

There were certain practical arguments that accounted for this discrepancy between the willingness to participate and the actual acceptance rate. Applicants might not

⁴ The names of all research participants mentioned in this article are pseudonyms.

have had the 'right' kind of MS, or the 'right' kind of symptoms, or their illness was too far or not far enough advanced. But the sense among people with MS in the Manchester area that the really important research was happening elsewhere, suggested that such practical reasons were not the whole story.

When one day a middle-aged man from London visited the Therapy Centre and joined in the conversation, he caught everyone's attention by letting on that he was involved in all sorts of drug trials, such as the trial for a new cannabis-derived pharmaceutical product which was about to start. His remarks prompted Dave, one of the regulars, to ask pointedly if we in the north were the poor relations, who were missing out on all the new drugs being tested that would be offered to people with MS down south? Teresa expressed similar sentiments, when I was talking to her:

'I get a magazine, MS Matters it's called, and they refer to different trials. I was getting quite frustrated for a while, 'cause everything seems to happen in London and anywhere else but Manchester.'

Dave's and Teresa's comments suggest their awareness of the relative importance of various locations, in Gupta and Ferguson's sense, in the context of medical research (1997). Official discourse, however, attempts to minimize the significance of such differences, because they would indicate the existence of 'subjective' relationships and threaten the 'objectivity' of medical research. This form of ideological blindness had important consequences for the ability of many people with MS to be productive in certain culturally-valued ways with all the disquieting implications in terms of personhood that I have already outlined. However, this did not mean that the participants ceased to be productive *per se*, but that they found it increasingly difficult to appear productive as autonomous individuals, as the example of Gary illustrates.

When Gary was first diagnosed with MS he was only five years away from retirement and vowed to make it through the last years in the job 'unchanged'. He told no-one—including his wife—that he had MS, not even when the distances he was able to walk shortened significantly and he 'kept falling over.' Gary's determination to remain the same and his family's and work colleague's collusion by failing to notice 'obvious' changes is intriguing in a number of ways. First, because they exemplify how many of the people I met during fieldwork were engaged in generating a form of normality they had previously taken for granted. Before their diagnosis persons were simply a fact of life, but with MS people had to think about what being a person and being 'normal', an attribute they valued highly, implied and this compulsory reflexivity changed things by making them explicit (Strathern 1992: 44). Second, because Gary's example illustrates how his agency—his ability to be productive as an individual—becomes more and more visibly reliant on the cooperation of others, which in turn casts doubt over the location of Gary's agency. For instance, when Gary's wife, Veronica, accidentally learned of his diagnosis she did not confront him, but waited for him to come clear, even though this 'caused a bit of a strain' in their marriage. Veronica ostensibly treated Gary 'as if she didn't know', but the collaborative effort that went into maintaining his person(a) cast doubt over its authenticity.

In order to generate themselves as individuals, Gary and other people with MS drew on distributive forms of agency, which in turn undermined their efforts at presenting themselves as such. As I have pointed out, informed consent is always defined as an exercise of individual, rather than collective, choice. At the same time, profound transformations in the ways Euro-American persons are conceptualized in hegemonic terms have increased the urgency for many of the people I met to be productive in culturally-specific terms. Theoretically, taking part in scientific research was one potentially useful thing that they could do so. In practice, ethics committees' assumption that all persons were individuals allowed for the management of persons, while simultaneously preserving a semblance of choice. In so doing, ethics committees undermined the efforts of those it intended to protect to conform to hegemonic notions of personhood. Ethics committees thereby contributed to an experience of loss and failure quite unconnected from any physical decline that was a common feature in the lives of those I met in the process of this research.

Conclusion

In this paper, I have not been concerned with the question of what constitutes ethical research. Rather, I have analysed how ethics committees, as a form of audit and hence of bureaucratic technologies, serve to generate what can be described as the fantasy, in the sense of Navaro-Yashin (2002), of the individual by filtering out the relational dimension of agency. As a discipline concerned with relationships, the proliferation of bureaucratic techniques surrounding academia and academic research has important consequences for anthropology. Indeed, my first experience of applying for ethics approval would suggest that the capacity of anthropology to conduct research in the NHS is becoming increasingly restricted. More cheerily, my second LREC application was successful because I was able to draw on relationships within the organization, such as collaborators willing to meet up personally with the committee chairman in order to speed up final approval, suggesting that most people are aware that there is no escaping relations, whatever the regulations say. However, some change in terms of who anthropologists are able to work with has certainly occurred. Whereas in the past, it was the elites that remained inaccessible, ethics committees to some extent succeeded in redistributing the access to particular 'groups' of people that are deemed too vulnerable, too dangerous, too unrepresentative, or any other possible characteristic in order to merit research, by removing their right to choose, thereby raising the spectre of censorship in all but name and establishing beyond a doubt the political nature of bureaucratic technologies.

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Susanne Langer completed her PhD in Social Anthropology at the University of Manchester in autumn 2004. She conducted fieldwork in the northwest of England with a group of chronically ill people and their families and friends. Her thesis explores the ways personhood, productivity and ideas about normality become entangled and entwined in people's lives. Susanne is also interested in theories of value, ideas about health and healing, anthropological approaches to the study of bureaucracy, and methodology in qualitative research. She is currently turning her thesis into papers and presentations and can be contacted at susanne.langer@12rowan.org.uk.