

Volunteer human subjects' understandings of their participation in a biomedical research experiment

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Abstract

The paper focuses on how volunteer human subjects in research understand their own participation in experimentation. We ask how they view their own role, the experimental setting, and how they articulate their understanding of the researcher–subject relationship. The empirical basis of the study is participant-observation and qualitative semi-structures interviews with volunteers in an experimental setting far removed from the more commonly studied randomised control trial (RCT), namely, the early stage testing of a prototype instrument for breast imaging. Analysis of this empirical data leads us to conclude that research subjects do not conform solely to one or other of the models of the researcher–subject relationship suggested in the literature. Rather, the interaction needs to be considered as a social situation which volunteer subjects actively negotiate in real time. They move through multiple roles and identities as part of the navigation through unfamiliar social territory, in order to establish a relationship in which they can feel socially comfortable and appropriately valued.

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Introduction

The practice of allowing participants in experiments a voice in the conduct of research has received growing attention in recent years (Epstein, 1996; Goodare & Lockwood, 1999; Williamson, 2001). This trend, largely focused on the clinical trial, is to allow patients or their representatives a voice at the planning and management level. Significant inputs have been to research priorities, trial design, choice of outcome measures, and cooperating in recruitment (Entwistle, Renfrew, Yearley, Forrester, & Lamont, 1998; Hanley, Truesdale, King, Elbourne, & Chalmers, 2001).

A different perspective on the participant's voice is to focus on how volunteer human subjects¹ understand their own participation in research. Much of the work here has been primarily geared to address concerns of trial managers about recruitment and retention of subjects for clinical trials (Ross et al., 1999). More recently, there has been increasing use of qualitative methods to probe research subjects' understandings, with a particular emphasis on their construal of concepts

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¹The British Psychological Society changed its terminology from 'subjects' to 'participants' in January 2000 (British Psychological Society, 2000). Official guidance on research governance has however defined 'participants' as "patients, users, relatives of the deceased, professional carers or members of the public agreeing to take part in the study" (DoH, 2001, p.20). To avoid ambiguity we have therefore retained the old terminology, in conjunction with 'volunteer' or 'patient-volunteer'.

central to the design of the randomised controlled trial (RCT) and the implications for informed consent and trial management (Edwards, Lilford, & Hewison, 1998; Snowden, Garcia, & Elbourne, 1997). In our study, by contrast, we have chosen a research setting (the early stage clinical testing of a prototype diagnostic instrument by a UK university-based group) which, while recruiting human subjects to participate in research with a practical clinical aim, is significantly distant from the more familiar comparative, interventionist clinical trial. The tests can offer no health benefit to any of the volunteer research subjects. Furthermore, the tests are undertaken in a university research laboratory, not a hospital and conducted by non-clinical scientists, not physicians. This setting has the merit, for our purposes, of avoiding or mitigating some of the complicating factors of more typical clinical trials (such as understanding of randomisation or equipoise) and enabling us to focus primarily on the experience of being a human research subject. How do volunteers view their own role, their relationship with the researchers, and the experimental setting? In particular, we are interested in the way in which volunteers articulate their understanding of the researcher–subject relationship.

In pursuing these questions we do of course acknowledge that volunteers are a heterogeneous population and the research situations in which they may find themselves are equally diverse, with different demands, constraints and benefits. The spectrum of experimental clinical studies ranges from Phase III clinical trials offering desperately ill patients the chance of access to a potentially life-saving drug to studies of normal human physiology with no therapeutic aim. Likewise, there is a significant difference between volunteering for an experiment that takes an hour and one that involves months as a subject. All these will affect volunteers' attitudes and reactions. The broader social setting will also have an influence: our work took place in the UK where a comprehensive National Health Service (NHS) provides access for all to free medical care, and was sponsored by non-commercial interests (charity and research council funds). The experience of the subjects and the researcher–subject relationship will inevitably be shaped by this context.

The research experience and the researcher–subject relationship in the literature

The science laboratory has become a familiar site for ethnographic investigation by sociologists and anthropologists interested in the social process involved in knowledge production (Knorr-Cetina, 1995; Latour & Woolgar, 1979; Lynch, 1985), yet we found that the experiences of human volunteers in the research process have remained curiously invisible in the social studies of

science literature. Similarly, while an extensive academic literature exists on the doctor–patient relationship (Stevenson, Cox, Britten, & Dundar, 2004; Williams, Weinmann, & Dale, 1998), there is little detailed study of the interaction between researchers and volunteers.

Where social science has made human subjects in experiments a topic of research, the focus has most often been on researchers' responsibilities (the bioethics literature) or volunteers' motivations to participate and the implications for clinical trial management. More recently, some in-depth studies relating to RCTs have more directly explored the subjects' experiences of participating in research. These various approaches are discussed below.

The bioethics approach

The bioethics literature focuses explicitly on the moral imperatives that should govern human experimentation and the duties and rights that apply (Lock, 1995; Vanderpool, 1996), and as such exerts significant influence on both the research relationship and the volunteer experience. This work has been prompted historically by cases where scientific experimentation has resulted in harm to participants (Goodman, McElliot, & Marks, 2003; Lederer, 1995; Moreno, 2001). Academic bioethics, together with its more practical manifestation in codes of conduct and regulatory oversight (National Commission, 1978; Nuremberg Code, 1949; World Medical Association, 2002), reflects genuine concern over the potential for the researcher to do harm to the human subject, and for this reason places responsibility solely on the shoulders of the professional.

From a social scientific perspective this material is however somewhat lacking because, rather than making the relationship between researcher and subject the topic of empirical research, it generally assumes that the researcher is a clinician, and the researcher–subject relationship is thus superimposed on a doctor–patient relationship. This inhibits separate characterisation of a researcher–subject relationship and concentrates attention on those aspects of volunteers' understandings that concern the doctor–researcher distinction (see for example Appelbaum, Roth, Lidz, Benson, & Winslade, 1987; Featherstone and Donovan, 2002). But across the spectrum of clinical research studies, researchers may or may not be clinicians, volunteers can be patients or healthy, and the experimental setting may be different from sites of medical encounters and lie outside the context of the volunteer/patient's personal health care.

A further limiting assumption of much of this literature is that the volunteer has no ability to contribute to the experiment except as passive research material rather than contribute to outcomes as a quasi-collaborator, which we would regard as a matter for empirical investigation. Recent guidance issued in the

UK on research governance in health and social care (DoH, 2001) advocates public participation, but remains in the established ethical-protective mould as far as participants in experiments are concerned, apparently reserving more active participation to ‘patients/users, their relatives and organisations representing them’ (para 1.11)

The trial management literature

The literature relating to clinical trial management provides insights on volunteers’ motivation likely to be relevant in broader research contexts than the controlled clinical trial. Studies of trial participants have shown opposition to payment of research subjects (Russell, Moralejo, & Burgess, 2000) and altruism as a frequently mentioned motivation for taking part, though in some cases coming second to self-interest (Edwards et al., 1998). This is broadly consistent with Titmuss’ view of volunteering for research as a gift relationship (Titmuss, 1971), and Mead and Parsons’ construal of the research subject as sharing researchers’ goals of contributing to knowledge or the public good (Mead, 1969; Parsons, 1969). Some recent studies of cancer patients however show perception of personal benefit as the leading motivation (Johnson, Williams, Nagy, & Fouad, 2003; Wright et al., 2004). Volunteers may expect to gain in terms of alleviation or cure for their illness, or simply by obtaining more information (Gray, 1975). Financial reward (including access to free health care in countries without a comprehensive national health system) can also be a motivation for entering experiments, as evidenced by an emerging cadre of ‘professional guinea-pigs’ in the United States (Weinstein, 2001) and websites advertising trials as earning opportunities in the UK and internationally (e.g. www.gpp.net). Overall, motivation to participate in clinical trials may thus be understood as the volunteer’s drawing up of a ‘personal balance account’, influenced by personal and contextual factors (Verheggen, Nieman, & Jonkers, 1998).

Linked to motivation, a particular concern of this literature is with barriers to recruitment (especially to RCTs). Anxieties about additional demands on time, about the uncertainty inherent in the trial situation, and (in particular) a desire for more information are barriers most frequently reported by patients (Ross et al., 1999), alongside fear of illness and limited understanding of medical research in general (Stevens & Ahmedzai, 2004).

This management-orientated literature thus provides insight into the preferences, anxieties and expectations that volunteer human subjects may bring into a research study. Though some are specific to particular kinds of clinical research (particularly the RCT) others seem likely to translate into a variety of experimental settings and correspond to some of our own empirical findings.

Studies of patient-volunteers’ understanding

A further group of studies, straddling both ethical and trial management interests, provides in-depth qualitative investigations of patient-volunteers’ understandings of the research design of RCTs and the implications for their welfare and for ‘informed consent’ (see for example Appelbaum et al., 1987; Featherstone & Donovan, 2002; Lidz, Appelbaum, Grisso, & Renaud, 2004; Snowdon et al., 1997). Though this work is directed to exploring problems of controlled trial design, the qualitative methodology brings out issues of trust, sensitivity to being used as ‘a guinea pig’, and the struggle to make sense of participation (e.g. Featherstone & Donovan, 2002; Corrigan, 2003) that emerge also in our own fieldwork.

Methods

Research setting

The setting for this study is the early clinical testing of a new method for diagnosis of breast cancer, using radiation at optical wavelengths (i.e. lightwaves, rather than X-rays or ultrasound radiation) to generate an image of what is inside the breast and thus locate and identify any abnormal growths. This method has potential advantages, in terms of image discrimination and patient safety, over existing methods of investigation. A team of medical physicists at a leading UK university has developed a prototype optical imaging system, and this paper reports on the first series of tests on human volunteers, undertaken to establish the quality and consistency of images obtained, and the robustness and practicality of the system in operation. The tests are carried out in a university research laboratory by the non-clinical medical physics team. Each volunteer undergoes two consecutive breast scans using the prototype equipment, and technical data is recorded by the computerised system. Imaging is not ‘real time’, so volunteers do not see the images resulting from their individual scan.

Participants

Volunteers are women aged between 20 and 75, though predominantly in the younger age groups, in a range of occupations from manual to professional. Over a period from mid-2001 to early 2004 the new technology was tested on three healthy volunteers (recruited through personal contacts) and 18 patient-volunteers with pre-diagnosed breast conditions. The patients are recruited by two collaborating consultants at the nearby teaching hospital which is formally linked to the university. These patients, who are undergoing

treatment under the NHS for a variety of breast conditions (mostly benign), are asked by their consultant if they would like to take part in the research, which offers no direct benefit. Of those who volunteered all but three patients had conditions that were non-malignant and non-life-threatening (eg fibroadenomas). A small honorarium (£40 sterling) is paid to volunteers.

The written information given to volunteers concerning the breast scan invites them to participate in a 'research study' to see how well a new method of making images works. It emphasises that there are no known or foreseeable hazards associated with the use of light for imaging and explains that volunteers should not expect any direct benefit to themselves though there could be benefits to future patients if the device proves successful. It also makes clear that their decision on taking part or not will in no way affect their medical care. A separate information sheet refers to a related study running alongside the imaging studies to get volunteers' views on their experience and ask for suggestions for improvements to the system which could benefit future patients.

The research team consists of the lead medical physicist and his two research assistants, none of whom had previous experience of working with patients, and two social scientists collaborating on the aspects involving volunteer input. In relation to the social scientists, the natural scientists in this research are simultaneously collaborators and research subjects, while our own position as social researchers is to ask volunteers (for our study) about their experiences of being volunteers (for a different but related study). Such relations have demanded a high degree of reflexivity on the part of the social scientists (Barbour & Huby, 1998; Boynton, Wood, & Greenhalgh, 2004; Woolgar, 1988) and although full discussion is beyond the scope of this article, this engendered continual reflection on our identity as social researchers and the epistemological status of the knowledge that we were producing.

Data collection and analysis

In an addition to their normal testing protocol, we agreed with the medical physicists that data collection on instrument performance should include qualitative input from the volunteers on their experience as quasi-users, obtained through participant-observation during laboratory scan sessions, and qualitative semi-structured interviews with the volunteers afterwards. Scan sessions lasted up to 40 min and audio taped interviews took between 30 min and an hour and half, most lasting about 1 h.

All the healthy volunteers and 15 of the 18 patient-volunteers were interviewed for this study by the first author [NM], normally immediately after their scan. The interviews covered prior experience of health research, expectations, anxieties (via a neutral enquiry about

'your feelings'), practical elements of the scan process (what worked, what could be improved), comparison with other methods, overall evaluation, motivations, attitudes to this technology and how it might rank as a healthcare priority. We aimed to explore both volunteers' experience and the contribution they might make, given encouragement, to the development trajectory of the technology. Thirteen scan sessions were observed by NM, audio taped where feasible, and unstructured notes taken as a supplement to the interview material. Further semi-structured, qualitative interviews were conducted by the second author with the medical physicists to provide an insight into researchers' expectations and assumptions regarding the researcher–subject relationship.

Analysis followed standard qualitative methods. The interviews were all transcribed and the transcripts were read through in order to provide an overall impression of the information, and then to develop a coding frame based on themes emerging from the interviews. Methodologically, the formulation of categories for the coding frame was influenced by approaches within discourse analysis (Gill, 2000), acknowledging that the volunteers' accounts actively construct, rather than simply describe, their identities as volunteers (Burman & Parker, 1993; Potter, 1996). The transcripts were then coded.

The interviews produced a broad range of data providing, for example, insights into the scope and limitations of volunteer input to the future development of the technology and perceptions on priorities. We focus however, in this paper, on the subject–researcher relationship as viewed by the volunteers.

Results

In this section, we initially set the scene by describing, from the perspective of the participant–observer, the typical sequence of events when a woman arrives for a scan. We then discuss volunteers' accounts of their own role, developing a categorisation of the multiple identities volunteers call on in the course of the research encounter, and relating these to the social anxieties that surfaced quite frequently in the course of volunteers' accounts.

Setting the scene

On arrival at the Medical Physics Department the volunteer sits down with one or two of the investigators, receives explanations about the research project, asks any questions she may have, and confirms her consent to taking part. She is taken to the laboratory, where she changes into a gown, sits in front of the apparatus, and, leaning forward, positions her breast in the aperture

ready for the experimental scan. One of the team assists with the positioning; another is at the console of the instrument. She will need to hold the position without moving for some 7 min. The lights are turned off, and the scan starts in darkness. During the scan, the researchers report periodically on progress: a conversation may spring up. At the end of the scan: lights on, volunteer rises, an opportunity for the researchers to expound the technology and for questions and comments from the volunteer. Usually a second scan is performed after a short break. After this the volunteer gets dressed again, receives thanks and that would normally be the end of her participation. In our case, she is then interviewed about the experience.

Volunteers' conception of their own role

Though volunteers' accounts of their experience provided insights into how they view roles and relationships in research, their main focus was on managing the novel social encounter in which they find themselves taking part. Their concern was less with the researcher–subject relationship in the abstract, and more with the relationship as an aspect of managing a new kind of social situation for which there are no familiar and agreed rules.

The repertoire of roles

Volunteers referred to a range of roles and identities as they navigated their way through an unfamiliar and potentially unsettling social setting. Their conceptions of their role may be broadly categorised as: 'giver', 'patient-beneficiary', 'client', 'collaborator' and 'guinea-pig'. In the following, names have been changed to preserve anonymity; 'h-v' and 'p-v' after the pseudonym denote healthy volunteers and patient-volunteers, respectively.

The giver

Virtually all volunteers saw themselves at least in part in the role of giver. In many cases this conformed to the altruistic gift relationship envisaged by Titmuss (1971) motivated by a desire to serve the public good, though mediated and modulated by context and personal history (Small, 1998). To be of service to other, future cancer patients was most often mentioned, sometimes relating specifically to women with breast conditions similar to their own, for example

I know there's not a lot of information about women with cyclical breast pain—and anything which might shed some light on it... [Abigail, p-v]

Though Abigail was young enough (20–30 age group) possibly to hope (as some other volunteers frankly acknowledged) that she might be among the future

beneficiaries of the new technique, she reinforced her choice of the role of giver rather than potential beneficiary through a consistently professional and detached demeanour at scan and interview.

Others focused on helping medicine or research to progress, for example, Ida, another patient with non-malignant growths, commented:

...if five minutes of my time is going to help perhaps some doctor or the research to progress, I guess that's a good answer for me. [Ida, p-v]

Another, who was reluctant to accept her honorarium until she knew it came from sources outside the NHS (UK National Health Service), related her participation more explicitly to her personal experience and gratitude for the care she had received:

Without sounding too above myself, I feel I'd like to help basically. So, you know, NHS people have helped me a lot, and if I can research for them, then it's no skin off my nose, is it? [Yasmin, p-v]

Both Yasmin and Ida contrast the smallness of the demand the research made on them with the large potential for public good, but nevertheless took satisfaction in the gesture they were making. Implicit also in Yasmin's comment is the idea of paying what was felt as a personal debt. Several volunteers linked their altruism to personal bereavement or experience of illness, for example this healthy volunteer:

I have lost 2 friends to cancer, and I think it's important that if you do have an opportunity to either give money or time or whatever, to try and do something to help. And I feel now that at least I've done something, it doesn't make me feel—like they died for nothing. [Edith, h-v]

This sense of adjusting some private balance sheet and the construction of themselves as making a gift without seeking or expecting a direct return, seemed to imbue the volunteers with a certain confidence in their position, a sense of personal empowerment. One volunteer (who had very recently undergone chemotherapy for malignant disease) noted explicitly the difference in power relationships:

It was fun, actually. ... it's not like going to a medical appointment, because it's research. ... You want something from me more than I want something from you. That's the point. [Aurelia, p-v]

Though reference to altruism might be expected as the conventional response, we suggest that the role of altruistic giver serves here as just one way of accounting for their participation; a way moreover which provides also scope for both satisfying personal goals and establishing a relationship of equals with the researchers.

The patient and potential beneficiary

At the same time as presenting their position as ‘giving’ to research, some patient-volunteers found it difficult always to separate the experimental scan from their ongoing programme of clinical care. In the three cases where this was most visible, despite articulating clearly their understanding that the technique was unproven and that the scan would not be of benefit to their own condition, they still struggled to separate their anxieties and hopes as patients from their role as research subjects. Thus one young volunteer with non-malignant ‘lumps’, when asked about her thoughts before the test, said:

Nothing much: I was just hoping, you know, to get like more information on my lump. A help for decisions I have to make. [Alice, p-v]

But when asked later in the interview how she would describe the procedure said:

‘Something interesting’ It will be good if it could help, could actually—because right now it is at the research level.

And she later developed this further to identify the potential advantages of the experimental system:

if it had been tried in tests and it worked, I would say, if you can tell the lump might be developing into something cancerous.

Another volunteer (with a similar condition but a few years older (age-group 30–45) and more openly anxious) provides an account which illustrates the tension between such expressions of hope and a clear understanding that the experiment could provide no immediate benefit:

I sort of was interested just to know if mine had as well [i.e. if her ‘lump’ had shown up on the experimental scan]... I don’t know I mean, I know it’s not going to give me any diagnosis, or anything like that, it’s just -I suppose I just wanted to know that it works. And I suppose, also to put my mind at rest that I’m, that I’m right that I have got some [growths]. But alright, you know, I know that they are not malignant but it’s also something that just says—But that’s not, but I know that’s not the basis of the experiment. So it’s just, it’s a little difficult [Aileen, p-v]

This dual thought process differs from the ‘therapeutic misconception’ identified by Appelbaum et al. (1987) as these volunteers were by no means unaware or unappreciative of the research-only nature of this intervention. Nor are they, as in the situations described by Snowdon et al. (1997) and Featherstone & Donovan (2002), struggling with a difficult concept like randomi-

sation. There may however be an implicit scepticism about the official dictum that images from an unproven technique could never contain information of value, that allows personal hopes to surface briefly. This, along with their anxieties about benign conditions turning cancerous, brings elements of the ‘patient’ role into the experimental situation.

Additionally, some of the volunteers did refer in interviews to the scientists as doctors. This does not necessarily imply that these volunteers were falling into a traditional patient–doctor relationship. Indeed, the volunteer quoted at length above also remarked “I suppose that you are aware that [team leader] isn’t necessarily the same type of doctor as the one you normally see. But things like that—it didn’t bother me”.

We read all these reactions as evidence of an ongoing struggle to ‘place’ the volunteer-subject experience in relation to the more familiar patient/treatment experience.

The client

A more generalised version of the doctor–patient relationship—the professional–client relationship—did however appear to form part of volunteers’ understanding of the experimental situation. The analogy is necessarily a loose one, volunteers had not engaged these professionals to act on their behalf and serve their interests, rather the contrary. Volunteers had nevertheless entrusted their well-being to the researchers for the duration of the experimental session. The researchers thereby assumed a fiduciary responsibility, in the discharge of which the volunteers expected them to show a level of professionalism, attentiveness and consideration. It is worth noting, for the sake of symmetry, that such expectations engendered a degree of anxiety on the part of both subject and researcher. As the team leader explained in interview:

I’m just thinking about my own attitudes, I’d never done anything like this before. I suppose I was fairly apprehensive the first time we did a scan, I was apprehensive about such things as their security, how they react to the laboratory.

One simple way in which the team maintained a professional performance—which volunteers often singled out for mention at interview—was to give frequent progress reports during the 5–10 min-long scan on how near it was to completion (e.g. ‘we’re a quarter way through; half-way’ etc). It was important to volunteers to be assured of this professional attention, and they were critical if it appeared to be lacking. For example, Alana, a mature woman (31–45 age-group) with mastalgia (breast pain) who had been largely silent during her scans commented at interview:

I think ... the doctor [should be] more talking to you; to reassure you, that you are OK, or in a good

position, or you are doing something or not [Alana, p-v].

One of the healthy volunteers, a professional woman herself, and confident in engaging with the team during the scan session, nevertheless made a similar point:

...there was a conversation—a slightly more casual conversation—while I was actually doing the second test. And then I actually felt then, that's not quite so comfortable. And that's something about the professionalism of the whole thing, and I was more comfortable when I knew that it was more focused. [Madeleine, h-v]

Volunteers here appear to be invoking well-known social conventions for professional–client relationships as one of a number of possible supports in an uncharted social situation.

The collaborator

Some aspects of volunteer accounts initially suggest that they also regard their role as collaborator. On the other hand, an expressed desire to 'do well' at their scan and their readiness to make their contribution at interview might alternatively be interpreted in terms of the need to put up a creditable social 'performance' rather than making a collaborator's contribution to the achievement of the research goals (Goffman, 1971)[1959]. All volunteers nevertheless did appear to take on a personal responsibility for the fulfilment of two tasks: (1) to provide a 'good' scan result; and (2) to make practical suggestions about how the experience, and particularly the patient–machine interface, might be improved.

Concern about quality of scan results was evident in the kind of reassurance sought during scan sessions: for example, Yasmin, who maintained a conversation about the technology with the lead physicist throughout her scan, used a brief lull in the conversation to ask:

Is everything all right? ...I'm paranoid in case I mess up on it [Yasmin, p-v]

Not all volunteers were as readily interactive as Yasmin at the scan sessions, but made similar points in the course of the interview, such as this from one of the older (over 60 age-group) volunteers:

although you have got to keep still you haven't got to keep absolutely immobile like if they are taking an X-ray. So maybe that could be said to people. You know, if you do have to move slightly, it won't mess it up, you know. [Edwina, p-v]

Again, a volunteer whose scan had to be aborted (because the equipment was insufficiently adjustable to suit her physique) took this as a personal failure, saying, with a mixture of ruefulness and exasperation, that she

felt cross with herself for not having been able to find a satisfactory position. She reverted to this theme towards the end of the interview, and finally offered to return to try again when we had made planned modifications to the equipment.

Likewise, volunteers took seriously the invitation to make suggestions for improvements, and as well as commenting carefully on their own experience, offered both practical and imaginative solutions to the perceived problems (such as providing cushions, or repositioning the apparatus so the volunteer could see what was going on). And, considering the brevity of the experiment, many also showed a strong sense of engagement with the project. This was usually in the form of expressing their support for this kind of research and hope for the team's success; but also included expressions of enthusiasm like 'I was just very thrilled to be involved.' [Aileen, p-v] or 'It was interesting. It was in with the engineers; and ...he showed me the computer screen, how it worked.' [Alice, p-v]

All accepted with alacrity the offer of receiving feedback on the progress of the project, and a number offered to return for a further test scan.

The guinea pig

One further notion that needs to be mentioned is the 'guinea pig'. The actual term was only used once in relation to this experience, by a volunteer who said:

I didn't feel like a guinea pig [Aileen, p-v]

But a degree of anxiety about being the object of research was acknowledged by many interviewees. This appears to be a reflection of how ethical considerations with respect to their own safety enter their understanding of the subject–researcher relationship. They read the information sheet (in some cases very carefully) and listened to the oral briefing. But where there were matters of risk on which they did not feel qualified to make a judgement, their levels of trust expressed in interviews were often high; thus Ida (quoted previously in relation to the role of 'giver')

...that's the first thing I have asked my doctor: is this any crazy order of energy involved; is it something really that it could be quite dangerous for the future, and he reassured me that it's nothing like this—it is just a simple strong light who can kind of read inside. And I was satisfied with this answer. [Ida, p-v]

Or Norah, awaiting mastectomy, and the oldest volunteer to take part

What are you going to say to me?—it's perfectly harmless. You wouldn't be doing this if it wasn't, wouldn't you—I mean, would you? [Norah, p-v]

Similar levels of trust have been noted in the literature among volunteers for controlled clinical trials (e.g. Corrigan, 2003; Featherstone & Donovan, 2002). Volunteers were, nevertheless, aware that more formal ethical safeguards operated and sometimes expressed appreciation of particular provisions (e.g. vetting by independent committees; right to withdraw without giving a reason). Their focus when interviewed however was less on the physical challenges or possible hazards of the experimental procedure and more on a punctilious professional–client relationship, as already described, or on other person-to-person interactions that made them ‘feel part of the team’ [Edith, h-v]. For example, the woman who ‘didn’t feel like a guinea pig’ also commented:

I didn’t feel like I was shoved away in a box or anything. [Aileen, p-v]

This focus—on not being treated like an object—was therefore expressed as both a resistance to the dehumanising rubric of ‘guinea-pig’, and emphasis on reassuring signs that pointed to their participation as human volunteers, such as formal ethical approval, feeling part of the team, and acknowledging the scientists as professionals.

Thus we argue that volunteers’ invocation of a range of roles reflects the importance of establishing themselves as *human* volunteers (either as giver, client, collaborator), and resisting aspects of the encounter that suggested otherwise. The roles are also important as an aid to managing the human relationships involved in being a volunteer for this kind of experiment. All the roles identified carry within them some elements of a set of social rules or conventions for that situation. While volunteers usually maintained a calm front during the scan session, the discourse of many at the one-to-one interview indicated that being a human volunteer breeds a number of anxieties about possible social embarrassment. When encouraged to reflect on their experience there were three themes that arose spontaneously—among the more reticent as well as the more forthcoming of the interviewees—namely: (i) an equal (or greater) focus on being mentally rather than physically comfortable during their scan (though comments on being comfortable made during the actual scan session related exclusively to physical comfort); (ii) concerns about feeling isolated or ignored (for example the remark about not feeling shoved away in a box quoted above); and (iii) anxiety about undressing, as one volunteer put it, ‘getting my kit off’. The last in particular was sufficient of an issue for the volunteers for many spontaneously to include the relative privacy of the optical scan (compared to ultrasound or mammography) as a major criterion for the general

acceptability of the technology, putting it on a par with safety and painlessness.

Our characterisation of volunteers’ conception of their role is of course not exhaustive, nor are we suggesting that any one model must dominate or that roles are mutually exclusive. Nor do all volunteers migrate through all roles, or use them in similar proportions. We argue that, in order to navigate a novel, socially uncharted, situation, the volunteers—each differently—invoke a repertoire of roles to help to make sense of their experience and construct and sustain a relationship with the researchers.

Discussion

Any discussion of our findings must start with reiterating the point made earlier about the diversity of research settings in which volunteers take part in research, and the significance of local context in shaping volunteers’ experience and the relationship between researcher and researched. The setting for our fieldwork plunged volunteers into a situation of intimacy with strangers where the familiar doctor–patient relationship was ruled out as a pattern for conduct and they had to shape their own social rules as they went along. This, with other contextual factors such as the non-therapeutic nature of the research, is likely to have influenced the volunteer perspectives reported in our findings.

Formalised accounts of experiments generally overlook that using human subjects in research will in many, though not all, cases necessitate a personal encounter between researchers and researched. In these circumstances being a volunteer becomes a social achievement established through interaction with the researchers and experimental set-up, as evidenced by the volunteers who wanted to do things properly and not ‘mess up on it’. A consistent finding in this study was a concern among volunteers to establish an appropriate workable relationship (as giver, patient, client etc.) that would contribute to the success of the project. This eagerness to contribute was, at the same time, balanced by an expressed desire to be socially ‘comfortable’ in a highly unusual setting. The theme of social comfort took priority in interviews over physical comfort during the scan. Among these volunteers, uncertainty about role and the appropriate social framework, and hence the norms of behaviour and relationships to expect, can create anxieties that rank with or exceed those caused by the physical challenges of the experiment. The process of establishing a workable relationship involves active negotiation, testing, adaptation and resistance in any specific situation. The particular problem for participants in the research encounter is the uncertainty about mutual expectations and the kind of performance the situation requires.

Our findings also underline the distinction between patients and volunteers. Despite the tendency in academic literature and formal ethical guidelines to regard the two categories as synonymous, it is clear that these volunteers generally separated their identities as patients from the research setting—also invoking other categories such as client, giver and ‘not guinea-pig’ when referring to the subject–researcher relationship. Indeed, when the interviewees spoke of themselves as patients or the researchers as doctors, there was an evident tension between this reference and their clearly expressed understanding that the experimental scans could not provide medical benefit to the subjects.

Similarly, our findings challenge bioethics-based assumptions about the subject–researcher relationship. The bioethical literature and attendant regulatory structures discussed earlier assume a passive research subject in need of protection. While this approach has proved a beneficial assumption for protecting the well-being of volunteers, it also claims to ‘speak on their behalf’ thus reducing the input of volunteers to the experiment to that of research material. Volunteers in this study rejected this passive role, referring to themselves in terms that we have classified as patient-beneficiary, donor, client and collaborator, and at each point emphasised their participation as *human* volunteers while actively rejecting their participation as objects or ‘guinea-pigs’.

Our work fills in some gaps in the management-oriented literature on characteristics and preoccupations of volunteers, within the context of a particular kind of clinical study. Participant understandings can be expected to vary in different situations. For instance, other participants motivated primarily by financial reward, such as the ‘professional guinea-pigs’ mentioned earlier, might be expected to frame their relationship with the researchers in terms of labour relations. Participants in trials of novel treatments that offer the possibility of a direct health benefit may find the distinction between patient and volunteer roles (and between treating physician and researcher) more difficult to sustain. Wherever a research encounter occurs however, the social situation at its heart, and the anxieties and negotiations that go with it, are likely to be a constant feature in the experience of volunteers and those researchers in the front line.

Conclusions

Analysis of existing writings relevant to the researcher–subject relationship and our empirical research on volunteers’ experience lead us to conclude that the interaction cannot be characterised by any single model. Research subjects do not conform solely to one or other of the models of researcher–subject relationship sug-

gested in the literature, such as patient, donor, collaborator, employee. Even within the accounts of a single encounter volunteers may describe their own understanding of their relationship with the researchers in different ways, invoking a number of roles. In particular, the researcher–subject relationship is not a mere facsimile of the more intensively studied doctor–patient interaction. Additionally, the multiplicity of roles invoked suggests that the assumption prevalent in the literature, that researcher and researched share a common understanding of what they are both doing, needs challenge and further exploration.

On the basis of our empirical data we suggest that it is more productive to consider the interaction as a social situation, which has to be negotiated in real time in the course of each research encounter. A successful outcome to this negotiation—in terms of a mutually agreed relationship—is important both to the volunteers and the researchers, and for the successful conduct of the research. Volunteers’ accounts emphasise their participation as human volunteers and actively resist the passive role of ‘guinea-pig’. The relationship is no mere abstraction for the volunteers, it forms an essential component of their handling of a potentially anxious and embarrassing situation. Invoking and moving between multiple roles and identities is part of the process of navigation through unfamiliar social territory and active negotiation of a socially satisfactory researcher–subject relationship.

When considering how these findings relate to other experimental settings, the balance of power would be expected to vary according to the nature of the research or trial and the nature of the participants. A healthy volunteer, for example, is in a different situation from a patient looking for access to a potential treatment and this is likely to affect the researcher–subject relationship. The relationship between researcher and subject is likely also to vary according to the benefits available: a simple economic transaction requires a less personal and nuanced relationship than interactions based on an uncertain benefit to a sick subject’s health or the intangible, but nonetheless expected, benefits of satisfying an urge to altruism, that were a factor in our study.

Finally, returning to our introductory comments about research partnership, our empirical work indicates a high level of engagement of volunteers with the research goals and the technology. This underlines the potential—given the right mechanisms—for research subjects to contribute (as quasi-collaborators) to the outcomes of research by (a) contributing from their experience (regarding for example workability of the protocol or factors affecting volunteers’ compliance/performance) and (b) by active engagement leading to a closer kind of collaboration (e.g. influencing design criteria to take account of patient concerns like personal privacy). Consequently, our findings suggest that the

outcome of the negotiation about the relationship at the point of human contact may have consequences (both positive or negative) not only for sustaining the relationship between researchers and volunteers, but also for the scientists' ultimate research outcomes.

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