

## Mutual benefit, added value? Doing research in the National Health Service

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**Mutual benefit, multiple value? Doing research  
in the National Health Service**

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## **Mutual benefit, added value? Doing research in the National Health Service**

### **Abstract:**

The National Health Service (NHS) has recently been the focus of government efforts to retain pharmaceutical research in the UK. Efforts to foster new partnerships between health care providers and industry have been framed with suggestions that clinical trials can offer 'patient benefit' within the NHS, cutting across ethical and sociological concerns with the possible tension between doing research and offering care. This paper draws on ethnographic research to explore the sometimes awkward juxtapositions between trial protocols and everyday care, individual health and commercial profit, and thus the distribution of value produced through trials. While researchers appear to find the distinction between research and care useful, at least some of the time, both formal and informal strategies for living with this distinction may have the unintended consequence of making research appear supplementary to rather than simply different from clinical care.

**Keywords:** clinical trials, ethics, National Health Service, clinical researcher

## **Mutual benefit, added value? Doing research in the National Health Service**

Clinical trials are increasingly geographically dispersed, as industry locates research in countries with lower set up costs and more accessible populations than in the major pharmaceutical markets of Western Europe and America (Petryna 2009; Rajan 2006). This research is managed by a new set of commercial actors, contract research organisations (CROs) (Fisher 2006). Yet in the UK, the government has been keen to encourage the continuation and expansion of commercial trials within the state-funded National Health Service (NHS). Most recently it has sought to develop a national infrastructure for 'partnership' working between industry and NHS providers in the name of 'mutual benefit' (Department of Health(DH)/Association of British Pharmaceutical Industries 2008). In this paper I draw on ethnographic data from a number of trial sites to explore the local negotiation of some of these partnerships and benefits. Adding to a literature that has tended to contrast the US and regions such as Eastern Europe, Africa and South America, I introduce experiences from the UK, using observations from different trials shaped by their location in a reasonably well-funded state (i.e. socialised) health care system.

### **The multiplication of value?**

The idea that the UK government should help commercial companies access NHS patients as research subjects can be seen as an extension of the state's longstanding involvement with the fortunes of the pharmaceutical industry

(Abraham 2009). Recent research policy asks NHS providers to act almost as CROs, bringing together different actors to ensure efficient recruitment for trials funded by industry as well as medical charities or the state. Rather than promoting this activity purely with reference to the economic benefits to the national community, the call to site research studies in the NHS has increasingly been justified through an appeal to the 'benefit' for patients and staff in the combination of research and care, a multiplication of value through clinical trials.

This tendency to soften the distinction between research and clinical work can be traced through research policy discussions over the last decade. For example a report published in 2003 by the Academy of Medical Sciences suggested that 'the major beneficiaries of research and development within the NHS will undoubtedly be the patients... It is recognised that patients involved in clinical trials benefit from the application of the rigorous protocols that are a necessary function of this scientific culture. The same culture also improves the performance of health care professionals,' (Academy of Medical Sciences 2003, p18). A report from industry and academia, funded by the government to consider 'bioscience' as a sector, added to this discussion of multiple beneficiaries, calling for 'mutually advantageous collaboration between the NHS and industry for patient benefit' (Bioscience Innovation and Growth Team 2004, p5). The working group set up to consider ways of implementing this team's recommendations about clinical research, under the rubric 'Research for Patient Benefit,' argued that '[trials] will be of benefit to both patients and staff [in the NHS] since they have a common desire to

reduce uncertainty about the best existing treatments and to evaluate new approaches...’ Furthermore, from the perspective of patients, the authors claimed, ‘it is notable that participation in a trial ensures the best possible standard of care and an assessment, under carefully supervised circumstances, of whether there is a better treatment ready to be introduced,’ (Research for Patient Benefit Working Group, 2004, p11). Once again present as well as future patients – and staff – were described as receiving something of value from the research enterprise.

Such policy language cuts across an assumption in ethical discourse that clinical work is distinct from experimental work because of their different aims. In this model one is understood to focus on ameliorating individual suffering, while the other seeks knowledge for the collective. This distinction has led to regulatory frameworks to protect the individual, who must be given information about the uncertainties involved in research before making an autonomous decision to participate. Procedures for seeking such ‘informed consent’ are intended to counter what became known as the therapeutic misconception – the belief among research participants that professionals are acting in their individual best interest (e.g. Lidz et al 2004). Thus the current NHS application for review by a Research Ethics Committee requires that the chief investigator of any project should clarify the ‘risks and burdens’ attendant on trial participation, and set out how these will be shared with participants in consent forms and other documents. Applicants are advised that ‘Recruitment material should make few, if any, therapeutic promises, there should be no coercion or unacceptable inducement,’ (IRAS 2009, p7).

Empirical social science also reveals concerns about the combination of research and clinical care. Sociologists have tended to see these as producing competing demands on health professionals (Fox 1959, Merton 1976), and expressed doubts about their ability to manage such conflict, particularly if clinicians receive direct payments for recruitment to commercially funded studies, as is common in both North and South American health care systems (Lakoff 2005; Fisher 2009; Petryna 2009). In one recent UK study, staff in a specialist genetics clinic reported other concerns relating to the potential distortion of either clinical services if research funds were used to fill gaps in normal provision or of scientific agendas if research teams become too involved in clinical care (Hallowell et al 2009). As a result professionals in this study described a number of strategies designed to separate research from clinical care including: not passing back all information generated in the process of research; raising the question of research with patients at different times or in different places from those associated with healthcare delivery; or using different staff members to coordinate research activities.

Despite such concerns, empirical research also shows that clinical staff in research roles frequently believe that participants receive benefit from trials, for example through additional monitoring and attention (e.g. Fisher 2006). For example, Easter et al (2006) drew on interviews with staff and participants to describe 'the many meanings of care' within research, including physical and emotional support. Taking part in trials may represent a realistic route to

access services if provision is limited for particular countries or patient populations (Petryna 2009; Timmermans and McKay 2009; Timmermans forthcoming). This paper draws on ethnographic data to explore concrete experiences of the distribution of research and care in the UK's National Health Service. What purchase is there for the concept of 'mutual benefit'? How far do both formal and informal aspects of trial organisation in the UK help clinical staff manage research roles, and what are the implications for present patients?

### **Situating trials in the NHS**

The ethnographic work that informs this paper comes from three trials located in and around a single NHS Trust, but testing different interventions. Data were collected from participant observation of all three trials and interviews with research staff in each setting. My involvement intensified over the period of data collection between 2002 and 2009 as my work became more collaborative, moving from 'participation' in the same spaces and activities as (patient) participants, to active engagement with discussions of trial design and organisation in conversation with researchers. This period also saw changes to the field of clinical trials, as government expressed support for the sector through the provision of funding, and more importantly tried to streamline bureaucracy. A key example of this was the development of an Integrated Research Application Service to standardise procedures for applying for approval from individual NHS Trusts and ethics review committees (quoted above), alongside templates for agreeing and reporting on 'partnership' between the NHS and industry (DH/ABPI 2008).



Data about the effects of such initiatives on actual trial activity are confused. Though the UK's share of the global clinical trials industry has continued a gentle decline, industry continues to spend between £1 and £2 billion on clinical trials annually (Kinapse 2008), supplementing lower levels of funding from the government or medical charities (estimated at just under £1 billion between 2004 and 2006, UK Clinical Trials Collaborative 2006). The ratio of industry to charitable/NHS research seems likely to continue in the order of 2:1 (DH 2005), but there has also been much recent encouragement for co-funding arrangements. There is no single register offering a comprehensive listing of all trials recruiting in the UK across the period, but a portfolio held by the National Institute of Health Research indicates that in 2010/11 more than 2500 trials were ongoing, and that more than 470,000 patients had been recruited in 2009/2010.<sup>i</sup> The cases considered in this paper can thus offer only brief examples from a large, diverse and evolving sector<sup>ii</sup>: illustrating a large 'commercial' pharmaceutical trial, a smaller trial of innovative technology funded by charitable money, and a trial of organisational interventions being researched through co-funding arrangements. Despite these limitations, and their diversity, my observations reveal shared strategies, both informal and formal, for distributing value, or benefit, through and with clinical trials.

### ***Making space for commercial research***

*Sometime in autumn 2002: I enter the hospital site on foot from the tube station and peer at a map to try to locate the*

*Department of Clinical Pharmacology, where I will meet with my contact, a researcher on a major pharmaceutical trial. Finding the building, I am admitted after pressing a buzzer labelled with the name of the trial, looking like a logo. I follow signs to an internal door sporting the same logo and am met by the researcher. He takes me into a small room that I think I hear him calling 'the feeding room'. 'This is where we give people breakfast,' he explains. 'Some of the tests mean they need to come here fasting, but we give them something before they go.' It is warm in the room, and as I take off my coat I make small talk. 'I had forgotten how warm hospitals are!' 'Strictly speaking this is not a hospital,' he comments quickly. (Research note, undated).*

This brief record of my first contact with the world of clinical trials stays with me as an example of the mindfulness with which my fellow researchers approach their work and its definition. At the time, the clinic is one of approximately ten centres gathering data for a major multinational study, funded by one of the biggest pharmaceutical companies in the world. Though the site looks like a hospital ward to me – curtained bays, a single desk staffed by nurses, weighing machine – the investigators clearly distinguish the place from therapeutic settings. Commercial funding helps make this spatial strategy possible by funding a kind of clinical trials unit formally affiliated to a university rather than the hospital. This institutional separation is reflected in arrangements for recruitment to the trial and the use of medication within it.

Like many other pharmaceutical studies, the trial has recruited from patients in primary care. Individual family practices are asked to suggest people who might be suitable, who are then invited for screening. No patient can be enrolled if his or her general practitioner (GP) does not subsequently think it is appropriate. Monitoring and the prescription of trial drugs take place in this clinic, though records are sent back to the GP throughout. In addition GPs may continue to prescribe whatever additional drugs they think appropriate during the course of the trial (which will continue for several years). This arrangement appears to reduce conflicts of interest, since formally speaking the provision of ongoing care is located in primary practice, while the work of research is able to operate on a separate level. The existence of the trials unit makes this concrete by providing a space and staff distinct from either the family practice or hospital.

Nevertheless, different types of care giving are important in both the formal design of the trial and its everyday organisation. There is no suggestion that this common condition should go untreated, even given the ongoing involvement of GPs, so the protocol includes the prescription of drugs to all participants.<sup>iii</sup> The comparison is thus between two different treatment modalities, which are themselves quite complicated. These may well go beyond the kinds of medication regimens attempted in general practice, so that entry into the trial may appear as a kind of referral for specialist intervention, although the regimen is adjusted according to protocol rather than staff expertise. This protocol based care is available to all participants.

Staff members also behave as if they are offering something of value to participants, an impression which is supported by some more subtle aspects of the setting. The pills used within the trial are brought and taken from the clinic in branded carrier bags. These rattle seductively and I come to associate them with the 'goodie bags' distributed at children's parties. One member of staff refers to the trial site in these terms as she refills a water machine with plastic cups one morning. A participant asks, 'Having a party love?' She replies, with a smile, 'It's always a party here!' The comment is indicative of a particular atmosphere at the trial site, which is frequently characterised by lively banter.

In contrast to the US trial site observed by Petryna (2009), who saw physicians handing pills through a glass window, visits to this site are protracted and in many ways personal occasions, as commercial funding gives staff extra time. Thus when participants arrive they are greeted cheerfully by name and summoned into curtained cubicles for a detailed discussion of how they feel, any side effects or symptoms, and various measurements and tests. This 'personal' concern manifest in the ward is continued with the offer of breakfast before participants leave. In a large well-appointed kitchen, staff members are able to make tea and coffee, toast bread, and supply butter, marmite and jam according to participants' preferences. There is a clear feeling that this is a kind of hospitality, and the offer is made repeatedly, almost coaxingly. Participants who refuse are teased: 'Mr Smith doesn't like our breakfasts!'

Yet though the room where these breakfasts are consumed appears to have a domestic air, in contrast to the institutional curtains of the ward, there are some features on my first visit that strike an odd note. On the ward, the paper folders for each participant appear only in small piles set out for each clinic, while the work of data management is kept apart or 'backstage' (Goffman 1959). In contrast the 'frontstage' of the breakfast room speaks to a degree of tension between the different tasks of the trial, for its tables and chairs are used for meetings as well as hospitality. There are files in a bookshelf and stacked precariously on the windowsill, and one marked 'RIPs,' catches my eye, an ominous presence amongst the potted plants. On the longest wall, opposite a blue sofa, is a large white board. This board was covered with a large sheet, which I connected with the RIP file. The researcher explained that the team had been looking at some early, blinded comparisons between the two trial arms. The graph under the shrouding sheet showed divergent lines, representing the two treatment modalities. The implication was that this information had to be covered to allow the regular use of the room.

While the work on the ward contained a clear spatial separation between the staged 'clinical' encounter and the work of accumulating information, echoing the separation between the responsibilities left with GPs and those taken on by the trial staff, the breakfast room contained a more uneasy combination. At the same time, these facilities and the branding evident on the door and on the carrier bags handed out to patients spoke of the resources brought into the Trust by the contract with a pharmaceutical company running an

international study. My second site looked very different, proceeding by self-consciously rejecting the commercial route for innovation and celebrating its location in the resource-strapped NHS.

### ***Side-stepping the market***

My second example comes from a trial of an innovative therapy entirely funded by charities, with support in kind from the hospital trust in which it is located. Despite these characteristics, it builds on my first example in illustrating both how NHS trials are intended to operate apart from service delivery, and how both formal and informal aspects of trial organisation complicate any such separation. Though the investigators had long-standing relationships with commercial firms in this field they described this trial as apart from the market, with reference not only to the source of capital but also the abandonment of intellectual property rights in the products of the research and the recruitment of NHS patients.

*'Industry, that might have been a route, but I think it became clear early on, we weren't talking about a product... The whole purpose of this isn't to come out with the Nobel prize, but more than anything to provide for a desperate group of people, which is a group we've been steered towards from an ethics point of view... Our research philosophy here to some degree is the no-option patient, partly because not many people consider them. Most of the trials that industry brings here are [in] selected patients, where they want their [device] to work.*

*The people we increasingly saw were the ones with no option, and it was nice to target that group' (Interview with clinician researcher 31/08/07).*

Here the trial was set apart from the production of cultural capital ('the Nobel prize') for the investigator as well as economic value for industry vested in 'a product'. Though the choice to focus on patients with no further treatment options was linked to external advice that it would be easier to get ethical approval in this group, the speaker ended with a statement about the satisfaction that it gave staff to engage with patients ignored by the market.

As proposed in the reports quoted at the start of this paper, the trial design effectively offered 'protocol based' treatment to all those enrolled. Yet the insistence that this group should be defined by having 'no further treatment options' had a number of important effects. This focus on people who must be formally defined as having no alternatives fed a sense among research staff and participants that the intervention constituted a kind of 'last stop' treatment. As part of consent procedures, participants were asked to confirm that they understood that they had no further therapeutic options, in several cases raising concerns about their life expectancy that they had not discussed with their usual clinicians. This resulted in interaction with other NHS staff receding into the background, as potential participants focussed on the chance of improvement represented by the trial, and defined their interests as being permitted to enrol.

The statement in the inclusion criteria that participants must be 'stable on optimal therapy' also connected the practices of recruitment with ongoing care. Though intended to ensure that they really did have no other therapeutic options, and that any improvement could be linked to the experimental intervention, it had the practical consequence that a fairly thorough assessment carried out at an initial screening visit frequently resulted in changes to treatment plans *before* recruitment. Needing a formal definition of optimal therapy the research team referred to international guidelines, but these did not match the experience of many who attend screening. As a result researchers engaged in delicate negotiations with their usual clinicians to increase or modify their existing treatment, getting involved in therapeutic decisions before enrolment.

Yet as in my first example, and as suggested in the literature, 'care' is not just a matter of therapeutic intent. A culture of good relationships was celebrated among research staff as linked to the location of the trial in the NHS in general, and in the hospital where they worked, a tertiary centre with strong links to the local community and a loyal staff. There was no special site for the activity of research here, and participants were lodged on one of the main wards when they visited for the intervention.

*One of the trial participants is coming in for the intervention today. He will stay about a week. I walk with one of the research nurses to check that a bed is ready for him upstairs. It is a small Victorian hospital, and the ward is at the front. It*



*has a large picture window, but is otherwise quite dark, cramped and a bit shabby. She comments, 'When people come for the intervention sometimes they say things about the hospital, because they expect something all shiny and white, and you know, this is the NHS! But once they're here, they get to know us. Everyone's very friendly here, everyone knows everybody else and it makes for a good atmosphere' (Fieldnotes April 2006).*

Like the pharmaceutical study, this trial was defined as different from everyday care because of the 'good atmosphere' created between staff and patients. With the exception of the two principal investigators (both senior physicians) the research team used first names and made a point of developing jokey, even affectionate, relationships with participants over the time they spent in the hospital. The extra time available for such interaction was presented as an advantage of doing nursing work in research rather than on the wards.

*'The main thing that surprised me is that I've got more patient contact than I used to, than I expected' (Conversation with nurse researcher, fieldnotes July 2007).*

Researchers were careful not to suggest that such enhanced contact is necessarily beneficial for participants, and were often worried about the strain on them of the journey to the trial site. But it was unusual to see a need to

separate the 'caring role' from the pursuit of research. In one exceptional case this did appear important because of the risks of the experimental procedure (*not* the benefits accruing from usual care). A participant had been in the hospital for several days having tests in preparation for receiving the intervention or placebo. His blood chemistry appeared to have been adversely affected across the stay in hospital and he might have been further endangered by elements of the procedure. In this situation, staff diagnosed a potential conflict of interest, between looking out for him as a patient and their wish to get an additional subject into the trial by administering the intervention, a situation complicated by his wish to go ahead. Rather than refer back to the patient's original doctor, the lead researcher sought a resolution through delegation at the trial site, appointing a slightly junior doctor as the clinical lead, who would collect information on the participant's current condition and move towards a decision grounded in the therapeutic relationship between doctor and patient. As a result, the procedure was cancelled.

Though this was a rare event, the initiative to 'stage' or 'reinvent' a clinical role spoke in some sense to the degree to which care had been handed over from the patients' own doctors during the process of recruitment. Though formally the architecture of the NHS had separated the care offered by these doctors from the research, its location in a specialist centre, and the use of the protocol helped create the idea that participation might confer therapeutic benefits distinct from the additional time and engagement with patients, even before any effects of the experimental intervention. The conditions for this came from an ethical framework that suggested that the most experimental

treatments should be tested on people with nothing to lose (and implicitly, nothing else to gain), but also gained traction in the shared environment of the NHS.

### ***Elaborating services in partnership***

If my second example shows a case of research coming after regular therapeutic resources are exhausted, my third appeared to insert additional resources into the NHS prior to the offer of treatment. The trial followed the drug study described in my first example coming out of researchers' sense that participants did well because of the kinds of enhanced contact described above.

*'We built up a lot of trust in the time doing [the big drug trial]. Local GPs are very suspicious of big Pharma, and often rightly so. But with us they saw that their patients were well managed, and that they liked coming to the clinic. We were able to spend time with them, and as [their health improved] the GPs could see the benefits. So everyone was getting something,' (clinician researcher, fieldnotes, September 2008).*

Such narratives echoed policy discourse about the shared benefits accruing from clinical studies. Yet the absence of direct commercial funding for large drug trials (in the increasingly competitive international environment perhaps) informed a new approach. This investigator secured an educational grant from two drug companies for a trial of interventions to improve practice in a

particular clinical area. Here education and/or decision support systems for GPs were the object of the experiment. The study explicitly set the provision of training in communication with patients (developed through the experience of the more leisurely trial interactions described in my first example) against a protocol-based approach to up-titrating or altering medication, implemented through electronic case management by researchers making suggestions on patient records held in primary care.

The study seemed to offer a concrete example of the multiplication of value proposed in recent government policy. Industry provided some funding and hoped to benefit from the increased use of the drugs used in the traditional pharmaceutical study. General practitioners got advice from specialists on treating a common condition, and the primary care trust hoped to meet government targets and community needs in that area. Yet this arrangement appears to presuppose benefit for the patients of practices enrolled in the study. To get agreement for the fact that different practices were to receive different types of intervention or none (in the control arm), the research team drew on arguments, familiar from the first Medical Research Council trials in this country, that in a situation of scarcity, randomisation is a fair way to distribute common resources. If the trust could not immediately implement improvements across the entire community, then an ethical case could be made for implementing them in randomly selected practices as part of a controlled comparison. The knowledge produced here served as an additional form of value to the improvement in treatment that was assumed to follow from either education or protocol or both.

This organisational justification for the trial made little mention of any risks. Indeed the study was formally defined as 'service improvement' and thus avoided full ethical review. In addition, both formal and informal accounts emphasised that the study did not disturb the therapeutic relationship in primary care.

*'We don't see the patients during this period [of the trial], they're your patients, your relationships, we don't interfere with that,'*  
[quote from presentation at GP practice.]

Yet the researcher also grounded his recommendations in his specialist knowledge. For example in educational sessions he made frequent reference to 'more than 7000 patient years' of experience (accrued in trials), and a wish to pass on 'tips and tricks' that worked for him in building relationships with trial participants.

Even more strikingly, the research team deflected concerns about the co-funding arrangements for the trial by presenting themselves as uniquely able to manage competing priorities. Their experience on research trials made them advocates of additional medication in this field, but they were independent of any particular pharmaceutical product or company and where possible would recommend a generic not a branded product. However they also advocated developing the field against a backdrop of concerns about prescribing costs in the NHS. In this sense they developed a narrative about

both industry and government interests with the idea that both present and future patients need protecting from both sides. Though GPs remained the immediate care-providers this carved out a role for the researcher in managing the social relations surrounding service change.

## **Discussion**

The examples used above are only snapshots of the very diverse therapeutic and economic landscape of clinical trials in the NHS, which according to policy makers is being transformed through efforts to increase the UK's share of pharmaceutical research worldwide. However despite these limitations, my examples offer evidence of formal and informal strategies for living with what may be awkward juxtapositions between experimental protocols and clinical care, individual health and commercial profit.

I started this paper with excerpts from recent policy that proposed a kind of multiplication of benefits around NHS research. I also noted that some theories in both ethics and sociology appear to signal the dangers of such claims, in the name of either the vulnerable participant or the conflicted researcher. Interview studies with people who actually carry out research give some support to both sides in this debate. For example such workers may describe efforts to separate care and research (Hallowell et al 2009) but also frequently talk about their belief in the benefits that research participants may receive (Easter et al 2006; Fisher 2006). In seeking to build on and extend this literature with observations of some of the practices that make up NHS trials, I want to draw on work by Mol (2002) that makes multiplicity a topic in

its own right.

In her ethnographic study of atherosclerosis Mol proposes that disease itself is 'multiple'. Within a hospital different practices – focussing either on patients or different parts of the body (arteries viewed in angiography, amputated limbs) – effectively produce different definitions of disease and different solutions. This 'incoherence' is not a problem in medicine, which unlike science does not need to produce 'universal knowledge' but is practical in its focus. 'Incompatibilities between objects enacted are no obstacle to medicine's capability to intervene – as long as the incompatible variants of an object are separated out... Distributions separate out what might otherwise clash,' (Mol 2002, p114-50). In describing the enactment of atherosclerosis through practices, Mol identifies a number of possible forms of distribution, for example across the patient's journey between diagnosis and treatment, or across a patient population in which some people receive one treatment and others receive different interventions. These distributions are often implicit. Yet there may also be attempts at coordination: a form of 'adding up' for example where either one diagnostic test is given greater importance than another, or the accumulation of results triggers an intervention; or 'calibration,' contained in attempts to make diagnostic tests comparable. I want to propose that the different kinds of care furthered in both clinical and research work and the possible benefits arising from such activities, are also both distributed and coordinated. Building on these observations I consider how far the specific boundary between research and care appeared important in the trials I studied, even as policy appeared to undermine it, to explore the contribution

of different formal and informal attempts at either coordination or distribution, and to draw attention to the effects of these attempts for the experience of staff and patients.

(i) *Maintaining a boundary?*

Current ethical frameworks tend to proceed by formally distinguishing research from care, such that research requires additional ethical review, institutional permissions and audit. The idea of a boundary between research and care also appeared important in more informal descriptions of trial work, which tended to stress the ongoing responsibility of the usual caregiver for ethical concern with the individual patient. In each case described here, potential participants were unlikely to be known to researchers before screening, but instead were identified by general practitioners or specialists in different parts of the NHS. Sending a patient to be considered for inclusion in a trial was not understood as passing over therapeutic responsibility. Indeed, the need for these doctors to give their permission for their patients to participate in research appeared to give this therapeutic relationship primacy, and it was also generally expected to continue alongside the research encounters (an arrangement known as *partial entrustment*, Easter et al 2006), or in the case of the third trial to be the only actual contact with patients (researchers were explicitly kept out of the consultation room).

Moments and spaces where research and care appeared in conflict were uncomfortable, but were relatively rare. Indeed as in other studies, different and additional forms of care appeared everywhere in my observations. Such



personal attention in the trial setting should perhaps not be assumed to be 'surplus' (c.f. Easter et al 2006), but may be fundamental to researchers' ability to enrol patients and other clinicians in their projects. As noted by Timmermans (forthcoming) and Fisher (2009) good relationships with participants are critical for recruitment, retention and compliance in both commercial and non-commercial trials.

Yet the emphasis on the enhanced 'atmosphere' of a research project appeared the reverse of an ethical concern with research as a poor substitute for care. Instead a further boundary was invoked between the particular risks of commercial research, and non-commercial research. Here NHS values might be offered as an alternative or counterweight to corporate ones, as in the second example where accounts of the features specific to this trial acted as 'interferences' with 'the market model' of development (Mol 1999). But they could also be brought to the table in negotiating collaboration with commercial interests as in the third example in this paper. As proposed in policy discourse, the NHS as a 'caring context' brought something valuable to the practice of research, just as research was imagined to bring something to the NHS, and its existence appeared to bridge a gap between the interests of individual patients and the collective goals of research.

(ii) *Strategies for distribution or coordination*

To the extent that regulation involves setting out differences and relationships between the activities of research and care, one might think of it as an attempt at coordination in Mol's (2002) sense of the term. One way of making such

comparisons is by assigning different intentions to different roles within an organisation, so that the research role is clearly distinguished from care-giving, yet this use of intentions, rather than activities, has been criticised as confusing for patients and staff (Hallowell et al 2009). In the genetics clinic studied by these authors, care and research were often closely intertwined – yet as in my case this did not result in staff abandoning the distinction. Instead they described informal ways of maintaining a boundary, supplementing the regulatory focus on informed consent with practices that look more like *distribution*. As noted in my introduction these included at least three strategies: treating information from research as categorically different from clinical information, which should be fed back to patients; separating research from care in time and space, for example by discussing research in separate consultations; or using different personnel to further science or deliver care.

The first strategy, withholding information from research participants, was the least common one in the examples presented here. Clearly there is likely to be some unevenness in the flows of information between staff, patients and study sponsors. In my first example data showing the early outcomes of the trial population were hidden, if imperfectly, from participants. Yet participants might often be asked to accommodate additional information about their condition, for example during regular monitoring visits. In the second the formal request for informed consent also embodied a demand for participants to absorb prognostic information as part of the trial, information that was at least sometimes unwelcome.

In contrast all three trials observed used both temporal and spatial distribution to divide 'research' from 'therapy'. Therapeutic responsibility was generally located in an institution acting as the usual care provider, while research was located at a specialist centre, to which potential participants were sent, though as we have seen in the third example an extra level of protection was claimed from the fact that patients never interacted directly with research staff at all. Where patients did attend research sites they encountered professionals engaged in activities of screening, enrolling, intervening and monitoring, but not formally speaking providing therapy. To the extent that other forms of care were important, as noted above, these appeared to be further, and more informally, distributed at the local level. For example in the first trial the curtained cubicles offered sites for expressions of concern and more clinical interaction, away from the management of trial data. This personal concern was supplemented by the offer of breakfast as a kind of fringe benefit of participation in the commercial trial.

Distribution of activities among staff was also a theme in my data. The sites I observed employed staff explicitly defined by their research role, especially nurses, though clinicians were more likely to combine roles as a 'clinical investigator'. Yet all staff emphasised their ability to move between research and different kinds of care, and were generally unselfconscious about offering therapeutic advice in certain encounters, for example before enrolment. In other words, staff claimed to manage the combination of roles at a personal level in the context of the temporal and spatial distribution of activities. The exception to this pattern was the use of a junior member of staff to carry

therapeutic responsibility in my second example, where more formal coordination was attempted at the research site. The need for this spoke of the failure of the spatial and temporal distributions described above.

My data on the everyday work of carrying out trials largely confirm arguments about the potential value of informal distribution strategies for managing different activities in particular institutions (Hallowell et al 2009), though some appeared more useful than others in the examples given here. Yet in combination for formal coordinations, such informal strategies may also have unintended consequences, particularly if we consider the ways in which people think about the potential benefits of trials.

*(iii) Making research supplementary*

One might argue that the research teams observed in this research were free to engage in their own informal negotiations between scientific investigation and care giving because real therapeutic responsibility was located elsewhere. Bracketing the therapeutic relationship in this way appeared to have an ethical effect, presenting clinical care as safe from the interests of pharmaceutical companies, government or indeed individual researchers in doing trials, as well as the epistemic effect of increasing the relevance of the research against service variation (Will 2007). Yet this separation could also appear to make research 'supplementary' to the basic provision of care.

This effect was particularly clear in this second trial discussed above, where the attempt to enrol patients with no other treatment options meant that they

were focussed on the trial as offering *at least the chance* of improvement, and a site for accessing some form of 'treatment' (those with untreatable conditions become the NHS equivalent of the uninsured). Furthermore, the delicacy of negotiations around the designation 'stable on optimal therapy' in this case meant that participants had good reason to feel that they had been offered a second opinion and chance at new treatment through the trial.

Though the use of social and clinical inclusion criteria and informed consent procedures are intended to make explicit the potentially greater risks and particular agendas of research trials, in situations where recruitment operates along the same pathways as referral within the NHS as a whole (primary care to secondary care, or one hospital to another) the conditions are created for this 'calibrating' logic to be confused, and the trial to appear as an offer of additional even superior advice and treatment.

The vision of the trial as 'supplementary' might be confirmed by the extra time and money available in the research setting. Even formal discussions of trials might imply that research participation included some additional benefits as a kind of quid pro quo for the unknown risks of the experimental intervention, and that randomisation was not only a statistical matter, or way of disciplining professionals (Marks 2000, Chalmers 2005) but a moral technique for distributing potential benefits. Such effects also fitted with staff discussion of the interaction they enjoyed with trial participants. An emphasis on this contact was also observed not only in the time spent in consultations, but also expressions of hospitality. The importance of these practices should perhaps

make us cautious about assuming that any benefit to trial participation is purely down to the application of a protocol.

## **Conclusion**

Despite the new language of partnership in clinical research, and a long history of alignment between the UK government and commercial interests in this sector, health policy is also increasingly concerned with cost containment in the NHS. In 2005, a Parliamentary Committee recommended a major institutional step to address this perceived contradiction, proposing that the then Department for Trade and Industry take responsibility for furthering the economic potential of drug companies located in the UK, while the Department of Health allowed itself to focus more clearly on the pursuit of value (House of Commons Health Committee 2005, p6). Such a separation strategy has not been adopted around clinical trials, which have been marked by the rhetoric of mutual benefits and multiplying value, and, most strikingly, by the suggestion that 'present patients' as well as future ones have something to gain from participating in research.

Since the publication of the Research for Patient Benefit report, a number of academic studies have attempted to test this claim empirically. The most recent meta-analysis finds very little effect on outcomes in either direction, i.e. little evidence of either benefit or harm (Vist et al 2008), in fact the authors claim that this increases the generalisability of trial results across unselected populations. Despite this epistemic interest in reducing the distinction between research and ordinary care, it remains a key principle in ethical discussion

and thus in the regulatory framework for trials. In so far as these are documented in protocols and ethical reviews, I have proposed that these represent particular attempts at coordination between different activities, but ones which more often proceed by 'adding up' than by conscious calibration.

Though my observations confirm the importance of different kinds of care-giving for the researcher, the everyday practices of research also represent attempts to distribute and thus distinguish activities to various degrees. Such strategies may be important when they draw attention to the uneven distribution of value that may surround a particular research project. Yet where current frameworks and practices make research appear 'supplementary' to clinical practice there appears some risk of ignoring the real impact of the separation between primary care clinicians and researchers (who appear to have specialist knowledge). When trials are inserted into referral patterns within the NHS, boundary work may not have the desired ethical effect of flagging the risks of research, but rather make trial participation appear more desirable. More research could be done to investigate this tentative proposal in other trials, and other settings.

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<sup>i</sup> [http://www.ukcrn.org.uk/index/clinical/portfolio\\_new/P\\_news.html](http://www.ukcrn.org.uk/index/clinical/portfolio_new/P_news.html) accessed 10<sup>th</sup> July 2010.

<sup>ii</sup> The trials described in this paper were not chosen to illuminate questions about the distribution of benefits specifically, but rather to investigate the broader organisation and scientific justification for trials in very different fields, and to compare apparently 'routine' research and research claiming to represent methodological innovation. Observations of the first trial took place over a few months during my doctoral research, while participant observations and interviews relating to the second and third trials took place over two years during postdoctoral work. Fieldnotes quoted in this paper therefore come from a number of different periods of observation. Quotes from these fieldnotes are necessarily paraphrased, but those from interviews are verbatim from transcripts.

<sup>iii</sup> See also Timmermans (2010) though placebo trials still dominate the field of US research, as discussed in Fisher (2009, p189).