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Coordinating 'Ethical' Clinical Trials: The Role of Research Coordinators in the Contract Research Industry

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Abstract

Change in the way new drugs are developed, including the privatization of clinical trials, has altered the arrangement and roles of health care professions. In this article I examine one aspect of this change: the role of research coordinators in the conduct of contract research in the United States. My focus on coordinators highlights the ethical conflicts embedded in clinical trials. I describe the ways in which coordinators experience and contend with the conflict between research and care and show how their construction of ethics is distinct from institutional conceptions formally associated with human subjects research. My analysis demonstrates how the coordinators' focus on ethics is a response to their role conflict and an attempt to reinsert individualized care into the context of research.

Keywords

clinical trials; ethics; human subjects; pharmaceutical industry; research coordinators; role conflict

Introduction

The past two decades have witnessed a radical shift in pharmaceutical drug development. To a large extent, this process has been marked by a change in the location of clinical trials. Prior to 1990, pharmaceutical companies contracted primarily with academic medical centers for the clinical phase of their research and development (Sox 2001). Shifting from more than 80% in 1990 to less than 35% of pharmaceutical contracts today, universities have been increasingly replaced by private-sector, for-profit research organizations, often being run out of private practices (CenterWatch 2005). Moreover, clinical trials are increasingly conducted outside of the United States (Parexel 2005). This process of privatizing clinical trials is driven by pharmaceutical companies' desire to cut costs and to speed up the development of new products (Evans, Smith, and Willen 2005). More broadly conceived, these changes are part of larger corporate trends emphasizing outsourcing, cutting production costs, and maximizing profits that have been described as characteristics of globalization, neoliberalism, and post-Fordism (Castells 1996,Harvey 1990,Smith 1990).

As part of the reorganization of pharmaceutical research, a veritable clinical trials industry has formed. This industry includes companies to support the outsourcing of contracts to independent research sites (*i.e.*, 'investigative sites'), companies to provide a corporate infrastructure for small investigative sites (*i.e.*, SMOs, 'site management organizations'), and companies to provide niche services like recruitment of human subjects and preparation of U.S. Food and Drug Administration (FDA) applications for experimental products (*i.e.*, CROs,

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'contract research organizations') (CenterWatch 2005). Even the review of study protocols is now outsourced to for-profit institutional review boards (IRBs) that provide centralised review of clinical trials (Lemmens & Freedman 2000). Further, many of these companies have a global presence that allows the coordination of clinical trials on human subject populations throughout the world (Petryna 2005).

The new mode of drug development has involved changes in more than the locus and logistics of clinical trials. Pharmaceutical companies are increasingly adding genetic components to studies as a way of banking information they hope will be useful and important in the future (Hedgecoe 2004). In addition, industry insiders report that clinical phases of development are routinely begun before pre-clinical results on animals have been fully analyzed, that clinical protocols are more complicated with more information about subjects being collected over longer periods of time, and that more stringent inclusion-exclusion criteria define which human subjects can be enrolled in studies (Personal communication, interview with physician-investigator, 3/31/04). These modifications to the studies themselves are propelled by the pharmaceutical industry's desire to streamline development, to gather more information about their investigational products for the same or less investment, and to ensure the best conditions for proving the efficacy of their products (CenterWatch 2005). The randomised controlled trial may be considered the gold standard in clinical development (Timmermans and Berg 2003), but this does not mean that the design of this type of study is static or exempt from economic and political pressures (Hess 2000).

Changes in the organization of pharmaceutical research and the subsequent proliferation of a clinical trials industry have produced new professions and roles within the healthcare sector. Although many of these roles are based on more traditional doctor-nurse and doctor-patient relationships, the context of contract research alters older configurations of power and engenders new ethical conflicts within the clinic (Fisher 2005).[1] Some scholars have done empirical studies of the organization of medical research (*e.g.*, Epstein 1996, 2004, Fishman 2004, Gray 1975). Others have shown that ethical conflicts are inherent in clinical research (*e.g.*, Fox 1996, Mueller 1997, Taylor 1992). Yet, to date, only a few researchers have explored the implications of this new mode of drug development (Fisher 2005, Petryna 2005).

In this article I examine one aspect of these changes: the role of research coordinators as part of the clinical trials industry in the United States. My focus on coordinators highlights the role and ethical conflicts embedded in clinical trials. In order to show these dynamics, I describe the ways in which coordinators experience, and contend with, the conflict between research and care as part of their position within the clinical trials industry. Specifically, I explain: 1) what coordinating drug studies entails, 2) how research coordinators manage the conflict between research and care, and 3) how coordinators frame their jobs explicitly in terms of an ethic that is distinct from formal institutional conceptions associated with human subjects research. My argument is that coordinators use ethics as a vehicle through which they can reinsert individualised care into the context of research.

Method

This article is based on findings from 12 months of qualitative research in the Southwestern United States.[2] The purpose of the study was to investigate the relations, structures, and logics produced through the privatization of clinical trials. Using a mode of institutional ethnography

[1]Contract research refers to clinical trials sponsored by the pharmaceutical industry. It is often contrasted with investigator-initiated research, which is generally sponsored by the federal government or private foundations.

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(Smith 2005), I examined the everyday work lives of those in the clinical trials industry paying particular attention to the power dynamics that organise the social relations within that industry. In my work I was particularly attuned to the role and ethical conflicts – of various degrees of intensity – that were described by my informants (*i.e.*, physician investigators, coordinators, monitors, and even human subject volunteers) and observed in their practices (*e.g.*, recruitment of subjects, informed consent processes, and study retention and compliance).

My research consisted of interviews and observation at more than twenty for-profit research organizations in two major cities. Semi-structured interviews with 57 informants were clustered to get the perspective of multiple employees at individual investigative sites (*i.e.*, conducting contract research), including physicians, coordinators, administrators, and patient-subjects. The sites I chose represent a diverse sample of organizational forms, including private practices, dedicated research sites, and large (non-academic) hospitals. My sample also included interviews at two not-for-profit investigative sites. In general, the types of drugs being tested were targeted at a wide range of medical conditions, including illnesses such as allergies, depression, irritable bowel syndrome, and weight loss. A few centers were conducting research on more treatment-intensive illnesses like HIV and cancer. My research also included attendance at industry conferences and the monitoring of publications produced by industry professional organizations.

Apropos to this article, I interviewed 18 coordinators (15 women and 3 men, 16 white and 2 Hispanic) and 3 recruiters (all women, 2 white and 1 African American), who had previously been coordinators. Ten of these 21 individuals were nurses, and one was a physician assistant. Their ages ranged from late-twenties to sixties, with the majority being in their forties. My interviewees also ranged widely in their amount of experience in the industry: from as little as three months to over 15 years. Specific demographic information about the individuals I quote in this paper can be found in the appendix.

Results: Coordinators' Role and ‘Ethics’

The vast majority of coordinators are women (90%), many of whom have come from nursing (60%) or other health-related positions (CenterWatch 2005). Not unlike the work of nursing, coordinators have the task of educating patients about clinical trials, getting patients to consent and enroll in studies, and alleviating patients' fears about medical research (Sandelowski 2000). It is primarily through coordinators that patient-subjects interact with the industry and come to believe that they are being cared for (Mueller 2001). This role is not taken lightly by coordinators because they understand that the quality of their interactions with patient-subjects will determine how well they are able to recruit, enroll, and retain those individuals. At the same time, many coordinators explicitly underscore the profound ethical implications of their work and their relationships with patient-subjects.

In spite of the centrality of their position, coordinators are often overlooked in discussions about the ethics of clinical trials (Davis *et al.* 2002). In many respects, this lack of attention to the work of coordinators is related to the more general invisibility and undervaluation of nursing within healthcare (Reverby 1987, Statham, Miller and Mauksch 1988). As is often the case with nursing (Duffy 2005), coordinating studies has been devalued because it is seen as unskilled women's work, not because the work is seen as unimportant in the quotidian operation of clinical trials. In fact, coordinators are often described as the most important members of clinical research teams (Fedor and Cola 2003).

Coordinating Drug Studies

The job descriptions for coordinators vary widely, yet the basic tasks that are delegated to them include recruiting, screening, and enrolling patient-subjects into particular studies, managing

the regulatory documents like IRB submissions and FDA forms, and sometimes even overseeing the financial end of contract negotiation and fee collection (Woodin 2004). The labour associated with 'coordinating' a study includes two stages: screening/enrolling and maintenance. During the screening and enrolling process, coordinators meet with patient-subjects who have been referred by physicians or have responded to advertisements. At these visits, coordinators go through informed consent forms and answer any questions potential volunteers have about a study. Only after patient-subjects have signed their explicit consent do coordinators complete the screening process by taking patients' medical histories and completing all laboratory work (*e.g.*, blood draws, urinalysis).[3] This information about patient-subjects is then used to determine whether or not they are eligible to enroll in studies based on the specific inclusion-exclusion criteria set by the pharmaceutical companies.

Those patient-subjects who do qualify are then enrolled in the clinical trials. This means that coordinators must follow the explicit instructions for randomizing patient-subjects into the different arms of the studies. During the phase of study 'maintenance,' coordinators ensure that patient-subjects are compliant: meaning that patient-subjects not only take study medications but also attend all study visits and complete associated diaries or other instruments designed to collect data on their symptoms. Coordinators are seen as critical in making sure that the specific details of all the studies being conducted at investigative sites are done according to protocol and on schedule.[4]

One of the main functions of coordinators during study maintenance is retention; it is crucial for the pharmaceutical companies' data that patient-subjects who are enrolled in studies complete them.[5] As a result, there is a strong emphasis placed on the interpersonal skills of coordinators for getting patient-subjects to enroll in studies and motivating them to follow the protocols:

> Compliance and retention can depend on the coordinator … If you respect the patient, you understand that they are taking an investigational medication, if you're flexible enough to work with their schedule, in a good mood, stuff like that, it really makes a difference to people … A lot of people just like to come in and talk. (Coordinator A)

A strong theme in coordinators' descriptions of their interactions with patient-subjects revolves around talking. Coordinators see this type of interaction as what is necessary for individuals to feel comfortable about participating in research studies, and they highlight the importance of establishing strong ties of trust with patient-subjects. This tone is often established from the first interaction coordinators have with prospective patient-subjects. According to informants, a personal tone is critical to recruiting and enrolling patient-subjects:

> I try very hard to be very compassionate and understanding. I listen to them … The way I recruit probably takes a whole lot longer than some, *but I'm a friend of that woman* before she ever walks in the door. And when she does, I'm delighted to say, 'Oh Mary, I remember speaking with you. It's so good to get to meet you now.' (Recruitment Specialist A)

Moreover, the relationships that coordinators build with patient-subjects must be maintained and built upon during the course of the entire study.

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[3]Elsewhere, I critique the assumptions underlying informed consent and the process used by coordinators (Fisher 2005). See also Corrigan (2003).

[4]Coordinators are especially important in light of the problem known in the clinical trials industry as 'phantom investigators.' It is widely acknowledged that physicians have low levels of involvement, that they delegate most details of study protocols to coordinators, and that they are often quite unfamiliar with the studies they are responsible for conducting (CenterWatch 2005).

[5]One of the labor-intensive components of coordinating is the task of documenting everything that happens as part of the clinical trial. Information is written in patient-subjects' charts – called the 'source document' – and then the specific information requested by pharmaceutical companies is transferred to 'case report forms' that are then sent to the sponsoring company.

Emphasis on the interpersonal skills of coordinators and their work of recruiting, enrolling, and retaining patient-subjects results in the job being highly gendered. This gendered component is explicit in what coordinators say about their professional roles. For example, many of my interviewees feel that women are uniquely qualified for coordinating, even without a background in medicine or patient care. They emphasize that women's specific interpersonal skills are critical to clinical trials because the job requires a sensitivity to others' needs that is rooted in women's personal identities. Empathy and compassion are coded here as the domain of women and as the human element to clinical trials.

In short, the value placed on coordinators is often determined as much by their gendered interpersonal skills as by their ability to multitask and to keep studies well organised.[6] Less value is placed on the medical expertise that coordinators have as nurses, technicians, and physician assistants. Their medical knowledge is often seen as incidental to the work they do managing drug studies. In part, their medical expertise is ignored because these prior positions are not seen as *required* for coordinating. Of course, in practice, coordinators frequently make medical decisions and judgments in their interaction with patient-subjects. In the next section I pick up this thread by discussing how coordinators experience the conflict between *clinical research* and *patient care* and how they mobilise a discourse of ‘ethics’ to combat this role conflict.

Resolving Role Conflict through ‘Ethics’

One of the hardest lessons for new coordinators, especially those who are nurses, is that research is not care. Even with training on how to conduct the various aspects of clinical trials, from determining if patient-subjects are eligible for studies, to randomizing the patient-subjects into groups, to documenting all of the details of the study, many coordinators experience a conflict between their job description and their role vis-à-vis the patient-subjects. While I am not the first to notice this conflict (Davis *et al.* 2002, Mueller 1997), my research extends this earlier work by analyzing how the coordinators' construction of specific ethical practices is generated by their interactions with patient-subjects and *not* from their job descriptions, IRB requirements, or formal ethical principles that have been linked to human subjects research.

Most discussions of medical ethics focus on the protection of autonomy through the use of formal measures such as informed consent forms (Beauchamp and Childress 1993), but as with medical interactions more generally, everyday experiences of research ethics are constantly negotiated by the actors in the research setting. It is this informal and constructed sense of ethics that I am engaging here. In order to explain the way ethics comes into play in research settings, I must begin with a description of the way coordinators experience the conflict between the roles of researcher and caregiver.

In one case, a coordinator had been a practicing nurse in the same private practice for decades when the physician she worked with began seeking contracts from pharmaceutical companies to conduct clinical trials. After a few months as a coordinator, she described to me how she keenly felt the struggle to understand her role in research as separate from care and to make this distinction clear to patient-subjects.

> It's just getting that thing in your head that it's *not* a patient-doctor or nurse relationship. It's a *participant-research* [relationship] and making that clear … That, ‘Yes, you're important as an individual, but it isn't a doctor-patient relationship’ …

[6]My interviewees also saw these latter characteristics as inherent, not as skills that are developed through work experience: coordinators either have them or they do not. Moreover, coordinators argue that these are traits that women are more likely to have than are men because they are similarly needed in the management of domestic activities. Here, these skills seen as useful in both coordinating clinical trials and the care of the home are naturalized as feminine.

> [There was a] participant we had that was doing this [study] for psoriasis. It was unfortunate that out of the four people that have [been enrolled in the study], he was the one [whose condition] was the worst and had been getting worse – which was why he came in. Well, we were almost sure he got the placebo. He got no effect … Even though he'd read the informed consent and we'd explained it to him, he didn't understand it well: 'How would they pick me to not get the drug when I'm so bad?' … He still seemed a little dumbfounded by it because you're in a medical setting, *sort of* … We're doing medical tests and they're still expecting medical treatment *appropriate* for their [conditions], even though you've told them otherwise. (Coordinator B)

Coordinators understand that randomization means that patient-subjects who very much need medical treatment might instead receive a placebo as part of a clinical trial.[7] They also understand that a research orientation toward clinical trials (*i.e.*, separating the goals of research from care) is key to the retention of human subjects. As part of the training many receive, coordinators are asked to accept the studies' most important goal for the pharmaceutical companies: drug development. It is, therefore, coordinators' duty to deliver patient-subjects and their data to completion in these studies.

Role conflicts intensify for coordinators as they develop relationships with patient-subjects. As I noted above, building these relationships is often crucial for recruiting and retaining patient-subjects in clinical trials. Conflicts intensify because unlike standard medical care, coordinators are not only allowed but *encouraged* to spend a significant amount of time with patient-subjects. Most coordinators I interviewed emphasized that participation in a clinical trial enabled better care for many patient-subjects because the medical interactions are much richer due to the time spent with coordinators:[8]

> It's really neat too because the length of our studies – we have trials that can go on for years: 3, 4, 5 years – you get to know those people over time … It's more personable, and we don't have that anymore with healthcare, [but] *we're* able to give that to people [in research]. (Recruitment Specialist B)

By creating these direct ties with patient-subjects, however, coordinators become invested in them as individuals. Subsequently, it is difficult for many coordinators to justify putting the interests of pharmaceutical companies before the interests of the sick people coming to their investigative sites for help. Coordinators describe being torn between their obligation to pharmaceutical companies and to patient-subjects: 'Unfortunately, we have some studies right now that are not a good option [for subjects]. For me, it's difficult when I have a conflict between whether this is really the best thing for the subject or not' (Coordinator C).

Because they interact with patient-subjects as individuals rather than as data, many coordinators I interviewed could not fully accept the separation of research and care. In other words, the relationships they develop with patient-subjects add to their experience of role conflicts within the context of clinical research. Through their interactions with patient-subjects, coordinators cannot help but see their role – at least partially – in terms of helping the patient-subjects. In one remarkable case, a coordinator who had 14 years of experience convinced the physician for whom she was working to stop accepting particular studies. In her telling of this story, she had done multiple studies for several different pharmaceutical

[7]The vast majority of pharmaceutical clinical trials are designed to compare investigational drugs against a placebo. Only in the treatment of some illnesses, like HIV/AIDS and various cancers, do pharmaceutical companies use an open-label drug against their investigational products. This is because it is considered easier and cheaper to show efficacy of the new product by comparing it to a placebo.

[8]This sentiment about better care being available through clinical research was also echoed by patient-subjects I interviewed. Each of them made a point to tell me that they felt they had received higher quality care (even when they thought they had been on placebos) because of the attention they received during the studies.

companies on cox-2 inhibitors[9] (*e.g.*, Vioxx®, Celebrex®, Bextra®) and saw the negative effects that this type of drug was having on patient-subjects:

> I finally got to the point where I said, 'No, I don't want to do these studies.' And so I had to talk to Dr. X and say, 'You know these meds? We're supposed to be here helping mankind and these medicines aren't. They're making them worse and [causing] a lot of pain. That's not what we're here for, so I don't want to do these studies. If you want to do these studies, that's fine, but you'll need to find somebody else to do it for you. Because I can't legitimately give people these medications.' (Coordinator D)

Although this type of situation is not the norm in contract research, it does illustrate the extent to which some coordinators will go to minimize their own conflict between research and care. It also reveals the sincerity of coordinators' concern for patient-subjects. Given that the relationship-building in which they engage acts as an extremely effective recruitment and retention strategy, coordinators' interest in patients could serve an instrumental purpose for the industry as a whole. Yet, in the context of their interactions with patient-subjects, coordinators clearly value patient-subjects for more than their enrollment quotas. As a coordinator emphasized, 'It's more than just good PR to have somebody care about you as a person, you know? I mean, that's what we're about. The studies don't matter to me; it's this person' (Coordinator E).

In a sense, the role conflict that coordinators experience surrounding the differences between research and care get played out as a professional conflict between the needs of patient-subjects and the coordinators' obligation to pharmaceutical companies. As such, the coordinators I interviewed have come to describe these conflicts not as intrinsic to their roles but as exogenous ethical conflicts. This interpretation of the conflict between research and care shapes coordinators understanding of what is 'ethical' in the management of clinical trials. Through an appropriation of a formalised concept of ethics, coordinators confer their own meaning of ethics through their everyday practices. Importantly, as the remainder of this section argues, coordinators create their own code of ethics by applying a traditionally feminised sense of right and wrong to the work that they do (Bowden 1997).

Pharmaceutical companies, it should be noted, place little formal emphasis on ethics in coordinator training. The only clear link between the explicit preparation for the job and ethics is embedded in the informed consent process that coordinators learn. Within that context, coordinators are trained to establish what is defined as a non-coercive and informative environment by providing as much time as the patient-subjects need to review the form and by answering any and all questions regarding the studies. Additionally, training often emphasizes that informed consent is an ongoing process rather than a discrete event, and coordinators are asked to review consent forms with patient-subjects frequently, if not at each study visit.

Although these procedures clearly fit into the ethical principle of autonomy that has shaped the federal regulation of human subjects research (Faden and Beauchamp 1986, Wolpe 1998), the pharmaceutical industry has also emphasized that viewing informed consent as a process can facilitate patient-subject enrollment and retention (Getz 2002). In other words, ongoing informed consent can encourage patient-subject compliance. For the pharmaceutical industry, this alternative focus on informed consent as a process effectively removes it from the ethical realm and into a marketing modality.[10] What pharmaceutical companies emphasize

[9]It is interesting to note that this interview was conducted on 1/27/04 before the Vioxx® story broke, so the informant was not merely posturing in response to a scandal.

[10]This marketing use of informed consent is often the subject of panels at industry conferences (*e.g.*, Getz 2002).

as ethical practice at the research site is less related to the treatment of human subjects and more focused on the data that is produced through the studies.[11]

In spite of the limited degree of emphasis placed on ethics in coordinators' training and interactions with pharmaceutical companies, coordinators told me that ethics is much more important to their jobs now than it was five years ago. By way of an explanation, a coordinator who had been in her position for more than ten years told me that early on in her career there was such a high learning curve for conducting studies according to the protocols that nobody had time to consider ethics. She explained that experience has led to a different consideration of her work: 'So it's [still] all about, "Yes, we want the patients in the trials," but your ethics are more involved now. [You ask yourself,] "*Should* this patient be in the trial?"' (Coordinator F).

What this coordinator and many others are referring to when they discuss this new attention to ethics is a concern with the appropriateness of clinical studies for individual patient-subjects. Their interpretation of this normative dimension to their work has very little to do with inclusion-exclusion criteria that literally determine whether or not patient-subjects *can* be enrolled in clinical trials. For many coordinators, they make an ethical assessment on two levels: the study itself and the individual patient-subject.

In the former category, coordinators with whom I spoke were quite adamant that they evaluate studies to determine if they are acceptable for *any* patient-subjects. What guides their sense of what is appropriate is often explained both explicitly and implicitly in popular articulations of the Kantian categorical imperative. For example, coordinators often mention the 'Golden Rule' and view their responsibility towards patient-subjects in personalised tones, thinking about how they themselves would like to be treated in the same situations:

> Recruiting a patient for a clinical trial …, it's just like with everything; it's the same value I use with my everyday life; it's what I raised my boys on. It's to treat other people the same way you want them to treat you, and that is something that I strongly hold dear to my heart even in clinical research. I am not going to say or do anything to another woman that I wouldn't want them to say or do to me. (Recruitment Specialist A)

Similarly, coordinators told me that they should recruit strangers into drug studies only if they would enroll someone from their own families. If they would not do so, they indicate, they should question the ethics of their involvement with that study, 'If I wouldn't put my own mother or father or brother or sister or children in a study, then don't do it' (Coordinator G). The example of the coordinator who notified her physician that she did not want to coordinate any additional studies on cox-2 inhibitors also illustrates a holistic concern about the types of studies offered to patient-subjects.

The second level of coordinators' ethical orientation toward their work involves determining whether or not the clinical trials are appropriate for specific individuals. One of the key ways this manifests is through an evaluation of the severity of the patient-subjects' illnesses. For example, if coordinators feel that potential patient-subjects are very ill, they may decide that a study with a high chance of receiving a placebo is too high a risk for those patient-subjects,[12] especially when there are already effective products on the market for the conditions under

[11] In the last decade, pharmaceutical companies and the FDA have grown increasingly concerned about the perpetration of research fraud: fake patient-subjects, fabricated data, and/or tampering with laboratory results. A highly publicized case of which involved a California doctor who was engaged in severe research misconduct (Eichenwald and Kolata 1999).

[12] Studies have different randomization schedules for the experimental and placebo arms of the clinical trial. For example, studies commonly randomize 25%, 40% or 50% of patient-subjects into the placebo group. In contrast, other studies are designed so that 100% of patient-subjects will receive a placebo at some point during the study.

investigation. One coordinator was particularly emphatic about the appropriateness of studies for individual patient-subjects:

> A lot of people think that research might be a way to go, [but] it's not. If they're too sick, I don't want them in the study. They need to seek help. Even if they can't [access healthcare], we'll pick up the phone and call services … [to] get them pointed in the right direction. (Coordinator H)

When I questioned coordinators about such ethical determinations, many explained to me that assessments of clinical trials were needed to check each study against the broader goal of medical progress and improving the health and welfare of patients. In their view, conducting clinical trials was about the advancement of medicine for the benefit of humanity. Without prompting, few coordinators mentioned the profitability of the pharmaceutical industry. When I questioned them about R&D agendas and the huge profits enjoyed by pharmaceutical companies, all of the coordinators patiently explained to me that the cost of drug development is so high that the pharmaceutical industry is not as profitable as it appears. In their view, pharmaceutical profits are funneled straight back into R&D expenses. In fact, many coordinators told me that working in the clinical trials industry helped them understand the high cost of drugs.[13]

By understanding the clinical trials industry in humanitarian terms, coordinators construct their professional identities with an altruistic mission and apply it to their understanding of ethics. In some respects, their focus on medical progress replicates the conflict between research and care in a slightly different way. On the one hand, coordinators need to minimise their concerns for individual patient-subjects for the potential benefit of society. On the other, coordinators remain focused on the benefits and/or risks to individuals who do participate in the studies. The 'ideal' that is constructed by coordinators is a combination of the two modes: the desire to bring medical progress directly to patient-subjects who enroll in clinical trials.

Thus, for research coordinators, ethical clinical trials are defined quite differently than they are by institutional review boards, federal agencies, and academic or clinical bioethicists. While these latter groups emphasize the autonomy of human subjects as the means of protecting them from research abuses, coordinators adopt an approach in line with more traditional modes of medical paternalism.[14] Whereas institutionalised bioethics is formalised and emphasizes universalism, coordinators cannot affect such detachment and make no pretense of neutrality. In fact, coordinators' understanding of ethics is so contingent and particularistic that they can and often do disagree with each other about which studies are more ethical and what types of decisions patient-subjects ought to make.

What my research suggests is that coordinators respond to the conflict between research and care by individualizing both pharmaceutical studies and potential patient-subjects. They then make determinations about who should participate in which clinical trials. This construction of ethics has little in common with the more abstract goals of protecting the rights and welfare of human subjects, which is the mission of federal regulation. Yet it reinscribes a particular type of care back within the context of clinical trials that is based on a feminised sense of right and wrong and a maternalistic concern with the well-being of individual patient-subjects.

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[13]In spite of persuasive refutations about the cost of drug development (Angell 2004), the pharmaceutical industry's claim that profits are re-invested in R&D has remained salient through the industry's strategic marketing (King 2005).

[14]Elsewhere (Fisher 2005), I draw the distinction between traditional modes of paternalism and what I call *pharmaceutical paternalism* – an organizational instantiation of medical paternalism occurring within private-sector clinical trials. I see this new form of paternalism as characterized by decision-making for healthcare that is no longer made by physicians or nurses for patients or by patients themselves, but rather by pharmaceutical companies for consumers – both patients and their providers. What is best for patient-subjects is defined through the development of study protocols designed to prove efficacy of pharmaceutical companies' new products.

This is not to suggest that coordinators' mobilization of ethics leads to better protection of patient-subjects. Instead, coordinators' explicit attention to ethics suggests a disconnect between the ethical principles that currently guide human subjects research and the needs of patient-subjects who are making personal decisions to participate in pharmaceutical research. Limitations in regulatory oversight cannot be overcome by coordinators alone, but their attention to ethics can help to highlight the structural conditions – intractable diseases, lack of health insurance, need for supplemental income, etc. – impacting upon patient-subjects' participation in drug development.[15]

While this orientation towards clinical trials is clearly laudable, it is also problematic. Of course, it should be the goal of human subjects research to treat study volunteers with respect and care, yet the sense of ethics adopted by coordinators simultaneously serves the profit motive of pharmaceutical companies by adding a softer, maternalistic face to the rigid demands of drug development. Where this distinction matters is when the focus of drug development becomes the quest for market share, which is then repackaged as narratives of medical progress. Just as nurses have traditionally ensured compliant patients within the system of medicine and healthcare delivery (Sandelowski 2000), through their 'sentimental work,' research coordinators are ensuring both current and future consumers of pharmaceutical products.

Discussion and Concluding Remarks

My focus on the role of research coordinators within the clinical trials industry offers a more complete picture of the the way ethics gets constituted on the ground in pharmaceutical research. As this and other scholarship has shown (Mueller and Mamo 2000, 2002), because coordinating is predicated upon the nurse-patient relationship, coordinators experience role conflicts in which their obligation to patient-subjects must be balanced with their obligation to pharmaceutical companies. This conflict catalyzes informal ethical practices as part of coordinators' attempt to reinsert care into research.

My findings have particular relevance for sociological and feminist approaches to bioethics. By drawing attention to structural conditions that provide the contexts for ethical action, including analyses of gender, class, and race, social scientists are increasingly engaged in complementary empirical research to redirect philosophical and clinical assumptions predominant in the field of bioethics (DeVries & Subedi 1998, Holmes & Purdy 1992). As an emerging field, the sociology and, to some extent, anthropology of bioethics have been framed as a corrective to both the abstraction of bioethics and the lack of normativity within the social sciences (Zussman 1997). Scholars who position themselves within this disciplinary framework have criticized bioethics for its lack of empirical material from which ethical standpoints are constructed and have argued for a new bioethics that is rooted in the social sciences (Hoffmaster 2001). In addition, scholars have called for sociological analyses to be relevant for policymaking (DeVries 2004).

My work does more than simply illustrate the conflict between research and care that is embedded in our current system of clinical trials. I have also shown that the negotiation of ethics is an everyday affair situated in the quotidian work of conducting pharmaceutical studies, not just in exceptional cases that generate the ethical dilemmas that provide the case material for normative bioethicists (Chambliss 1996, Winner 1991). As such, my research signals a place were empirical and normative ethics work hand-in-hand. My focus on the significance of the ethics of everyday practice begins where the work of bioethics has, until recently, left off. The exposé of egregious ethical breaches and the policy-making intended to prevent future

[15]Scholars who emphasize the importance of structural conditions to patient-subjects' participation in medical research include Corrigan (2003), Eckenwiler (2001), Elliott and Lemmens (2005), King, Henderson, and Stein (1999), and Zussman (1997).

violations prepared the ground for my study and others like it. My research broadens the field of ethical concern and opens a new and important area to those who claim expertise in bioethics.

Appendix: Demographic Information for Quoted Informants

- Coordinator A: white, female, 25–35, no prior medical training
- Coordinator B: white, female, 40–50, nurse
- Coordinator C: white, female, 25–35, nurse
- Coordinator D: white, female, 40–50, medical assistant
- Coordinator E: white, female, 55–65, nurse
- Coordinator F: white, female, 35–45, no prior medical training
- Coordinator G: white, female, 40–50, no prior medical training
- Coordinator H: white, female, 40–50, counseling background
- Recruitment Specialist A: white, female, 45–55, former coordinator, no prior medical training
- Recruitment Specialist B: African American, female, 30–40, former coordinator, life science background

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