

Re-inscribing Gender in New Modes of Medical Expertise: The Investigator–Coordinator Relationship in the Clinical Trials Industry

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This article analyses the ways in which research coordinators forge professional identities in the highly gendered organizational context of the clinic. Drawing upon qualitative research on the organization of the clinical trials industry (that is, the private sector, for profit auxiliary companies that support pharmaceutical drug studies), this article explores the relationships between predominantly male physician-investigators and female research coordinators and the constitution of medical expertise in pharmaceutical drug development. One finding is that coordinators actively seek to establish relationships with investigators that mirror traditional doctor–nurse relationships, in which the feminized role is subordinated and devalued. Another finding is that the coordinators do, in fact, have profound research expertise that is frequently greater than that of the investigators. The coordinators develop expertise on pharmaceutical products and diseases through their observations of the patterns that occur in patient–participants’ responses to investigational drugs. The article argues, however, that the nature of the relationships between coordinators and investigators renders invisible the coordinators’ expertise. In this context, gender acts as a persistent social structure shaping both coordinators’ and investigators’ perceptions of who can be recognized as having authority and power in the workplace.

Keywords: agency, medical expertise, clinical trials, pharmaceutical industry, doctor–nurse relations

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How are gender inequalities reproduced in organizations serving the pharmaceutical industry? This article examines the emergent professional context of women in pharmaceutical drug development. Drawing upon research on the organization of the clinical trials industry (that is, the private sector, for profit auxiliary companies that support pharmaceutical drug studies), this article specifically explores the gendered relationships between predominantly male physician-investigators and female research coordinators. In this clinical context, research coordinators have significantly more research expertise than do investigators yet, because of the norms surrounding doctor–nurse relationships and the gendered divisions of labour in medicine, the coordinators remain subordinated to the investigators in spite of their significant clinical knowledge about drug development.

Feminist and gender scholarship has aimed to explain and challenge the modes by which women continue to be subordinated to men, even accounting for the considerable advances in opportunities available to women (for example, Lorber, 1995, 2005; Tichenor, 2005). In the workplace gender inequalities can manifest in well-known institutional forms, like the glass ceiling (Padavic and Reskin, 2002; Rosser, 2004), or in regimes of flexible work that often lead to less secure employment and lower wages (Adler, 1999; V. Smith, 1990). These and other workplace inequalities have been described as rooted in the gender subtext of organizations (Smith, 1987), or as the rules and relations that are structured to appear neutral but nonetheless disadvantage women and minorities. Formal and informal mechanisms make up the gender subtext of organizations including how successful management is defined and how promotion schedules are filtered through competency requirements (Hatcher, 2003; Rees, 2004; Rees and Garnsey, 2003). This structural view of organizations enables analyses that illustrate how power operates to maintain and reproduce persistent gender inequalities (for example, Acker, 1990; Benschop and Doorewaard, 1998; D. Smith, 1990).

By examining gender as a social structure that operates at the levels of individuals, interactions and institutions (Risman, 1998), scholars have shown how gendered identities and relations are performed and normalized. For example, Patricia Yancey Martin (2003, 2006) has argued that the formation of gender roles is an active process that is practiced at the group level through everyday interactions among colleagues of both sexes. As part of these dynamics of gender performance, some workplaces encourage women to adopt masculine managerial styles and reward them for doing so (Wajcman, 1998), particularly because those professional identities leave occupational hierarchies intact (Pierce, 1995). In other workplaces women choose to create traditionally feminized gender identities or to impose gender identities on other groups of female co-workers (Brooks and MacDonald, 2000; Kennelly, 2002). In this vein, the work of Mary R. Jackman (1994) and Gail McGuire (2000) illustrates how women who

successfully adopt highly feminized roles subsequently contribute to gender inequality at work.

What is particularly interesting about these scholars' explorations of gender inequality in the workplace is that they highlight the ways in which women exert their own agency to adapt to a subordinate status within their organizations. Barbara Risman (2004) has noted that subordinate adaptation comes with compensatory benefits. For example, she draws upon the work of Michael Schwalbe and colleagues (2000) to argue that women trade power in exchange for particular types of relationships with men in their families. Significant evidence also indicates that similar processes take place in the workplace, wherein women exchange status for relationships with co-workers and supervisors (Schwalbe *et al.*, 2000). Understanding this dynamic is critical for both highlighting and contesting women's continued subordinate status at work.

This article analyses the ways in which research coordinators forge professional identities in the highly gendered organizational context of the clinic. Although coordinators in the clinical trials industry gain much more knowledge through their job responsibilities than do investigators about the process and products involved in pharmaceutical clinical trials, their expertise is rarely acknowledged in the industry. In fact, investigators are commonly given credit for the insights that coordinators have about the products under development. To explain the invisibility of coordinators' expertise, this article shows that coordinators' relationships with investigators lead both groups to devalue the coordinators' knowledge and maintain a rigid gendered division of labour in the clinic. The argument here is that gender acts as a persistent social structure shaping both coordinators' and investigators' perceptions of who can be recognized as having authority and power in the workplace. The coordinators adapt to this gendered hierarchy in exchange for the compensatory benefits they receive through their relationships with the investigators.

The article begins by providing an overview of the division of labour that is associated with conducting pharmaceutical industry studies. In particular, this section describes the ways in which the job of coordinating research is feminized. Then, after outlining my research methods, I discuss the investigator-coordinator relationship by attending to the ways in which gender is practiced (Martin, 2006) and reinforced not only for investigators but also for coordinators themselves. Next, I analyse the specific types of expertise that coordinators gain through their jobs to demonstrate how their skills are perceived through a gendered lens that simultaneously ignores their contribution to pharmaceutical research and development and gives credit to investigators for the coordinators' insights. The focus throughout the article is on coordinators' agency in participating in and contributing to the gendered hierarchy of pharmaceutical research and medical expertise.

The gendered labour of clinical trials

The clinical trials industry in the USA is made up of thousands of for profit clinical investigative sites that range from small private practices to large dedicated research centres. Proliferating in the 1990s in response to the pharmaceutical industry's mode of outsourcing, these companies contract with pharmaceutical companies to test drugs on human subjects as part of research and development of new products (Fisher, 2009).¹ As might be expected, the labour associated with conducting clinical trials is premised on traditional divisions of labour in medicine. Specifically, the roles associated with this work have been pre-scripted along the lines of the doctor–nurse relationship with the associated imbalances in prestige, authority and wages. As with nurses, coordinators are doubly subordinated: firstly, because they tend to be women and secondly, because they are not doctors.

To contextualize and flesh out the gendered position of coordinators, it is important to understand the division of labour for conducting pharmaceutical studies. There are two predominant roles that must be filled: principal investigators and clinical research coordinators. The principal investigators are those individuals with whom the pharmaceutical companies are contracting and who are registered with the US Food and Drug Administration (FDA) as being responsible for those studies. Unlike in much academic research, principal investigators on pharmaceutical studies largely have no role in designing the studies or detailing which patients should be eligible to enroll. Instead, the investigators conduct the specific clinical protocols determined by scientists and project managers in the pharmaceutical companies. As investigators, they are charged with ensuring that the human participants' conditions are being monitored and making clinical decisions about discontinuing participants from studies in cases of endangerment (Ginsberg, 2004). The day-to-day responsibilities of investigators include taking patient histories, conducting physical examinations and signing off on necessary paperwork. In general, the investigators' role in conducting clinical trials does not depart significantly from the activities that they perform as physicians in standard medical care.

The research coordinators, on the other hand, are those individuals who are employed by the investigators to manage the studies that the clinic is hired to conduct. Although their job descriptions can vary considerably depending on the size of the site and the number of studies that they are assigned, the coordinators are generally responsible for enrolling the human research participants, engaging in the informed consent process with the participants, conducting medical screenings and many study procedures, completing all the study paperwork and documentation, and acting as the liaison between the investigators and the pharmaceutical company project managers assigned to studies (Woodin, 2004). Importantly, the coordinators

are the primary providers with whom the human participants have the most contact during clinical trials.

The coordinators' work is very time intensive and requires significant organizational and interpersonal skills. They simultaneously oversee multiple studies and must verify that the specific details of each study are done according to protocol and on set schedules. This involves managing significant paperwork as well as people. For example, coordinators keep track of multiple modes of documentation (the type of paperwork and its submission differ by each pharmaceutical company) and multiple regulatory issues, including paperwork for the FDA and institutional review boards. In addition, coordinators have the responsibility of leading participants through study protocols. This entails motivating the participants to be compliant and to complete often quite lengthy studies. Coordinators are in regular contact with multiple representatives from pharmaceutical companies, and the relationships they have with those individuals often determine whether or not the clinic will receive additional studies from the pharmaceutical companies. Hence, the coordinators must be simultaneously oriented to detail for each study and to the big picture to manage all the studies. According to a pharmaceutical company representative I interviewed,

Coordinators have an extremely difficult job ... They're balancing a lot of things. And in most cases, they're trying to do a good job for their patients [that is, the study participants] ... I mean, it is a very tough job. The coordinator has the hardest job. They have very hard jobs.

Moreover, the coordinators' workload is often intensified by needing to do not only their own jobs, but also often the tasks that should be the responsibility of investigators. The clinical trials industry has dubbed the low levels of involvement of investigators in the studies as the 'problem of "phantom" investigators' (CenterWatch, 2003). In these cases, investigators delegate as many elements of the studies as possible to coordinators, and they merely provide their signatures to the paperwork while the coordinators interact with the participants and conduct the studies. In this context, the work of coordinators is seen as crucial for the success of clinical trials (Fedor and Cola, 2003).²

To understand the division of labour between investigators and coordinators as intensely gendered, it is revealing to look at the characteristics of those who fill these two positions in the USA (Table 1). The investigators are predominantly white men who have medical degrees, which is typical given the demographics of USA physicians more generally. As a point of comparison, 73 per cent of US physicians are men (American Medical Association, 2006), and 82 per cent of US investigators are men. In fact, the differences between these percentages may be due to the tendency for investigators to be slightly older (only 8 per cent are under the age of 40) than are physicians as a group. In contrast, coordinators are predominantly white women who have nursing

Table 1: Characteristics of clinical trial practitioners in the USA

Principal investigators (%)	Research coordinators (%)
Hold a medical degree: 96	Hold nursing degrees: 60
Men: 82	Women: 90
White: 92	White: 88
Age: 41–60 years old: 77	Experience as coordinators:
under 40-years old: 8	two or more years: 85
Certification in internal medicine: 50	five or more years: 54
One year or less experience as investigators: 63	
<i>Source:</i> CenterWatch, 2003.	

degrees.³ Similar to the trends with physicians and investigators, the sex of coordinators mirrors that of nurses, a profession with a representation of 94 per cent women and of whom an estimated 82 per cent are non-Hispanic Caucasian (Department of Health and Human Services, 2004).

What is less expected in the socioeconomic profile of the industry is the amount of experience in conducting pharmaceutical studies that coordinators have compared with investigators. Specifically, more than 60 per cent of the investigators have experience of one year or less, while 85 per cent of the coordinators have two or more years' experience in their positions and half of all coordinators actually have five or more years' experience (CenterWatch, 2003). These percentages indicate that the coordinators may have significantly more practical knowledge and expertise about clinical trials than do investigators. As discussed in more detail below, the coordinators' experience, however, is often not acknowledged or valued as such by the clinical trials industry.

Thus, investigative sites can be said to be modelled on established, traditional medical hierarchies and gendered divisions of labour in which male investigators work with female coordinators to conduct clinical trials. It is, in fact, this parallel (and professional overlap) between coordinators and nurses that provides the foundation for the investigator–coordinator relationships and the delegation of work and responsibility between them. At first glance, little seems to have changed in the hierarchies and relations between doctors and their staff (Strauss, 1985; Wolf, 1988). In this regard, the work of coordinators becomes devalued in much the same way as in nursing (Sandelowski, 2000; Zussman, 1992). Like the rhetoric of nursing, where any *woman* could do the job (Reverby, 1987; Statham *et al.*, 1988), the implication of the feminized nature of coordinating is that there is an under-appreciation for the degree and type of expertise that coordinators have as part of their work.

Organizational and interpersonal skills are seen as innate feminine characteristics borrowed from women's role in the home. The clinical trials industry is no exception in larger trends toward the deprofessionalization of women's work that is often associated with the healthcare sector and is characterized by work intensification and diminished rewards (Radsma, 1994; Speedy, 1987).

Although the investigator-coordinator relationship is premised on the doctor-nurse relationship, it would be a mistake to assume that these relations were the same, even when the investigators are doctors and the coordinators are nurses. Unlike the division of labour between doctors and nurses in standard medical practice, the work of conducting clinical trials is not distributed by different modes of care for the patient-participants. In medicine, patient care could be divided into two types that map onto doctors and nurses, respectively: reductionism and holism. In the first case, physicians are trained primarily to treat illnesses; in the second, nurses are trained to treat people, taking into account clinical problems as well as social circumstances (Fisher, 1995).

In clinical trials, care, as it is traditionally understood as individualized treatment for patients' illnesses, is eliminated from the clinic. The patients are transformed into research participants when they enroll in clinical trials. This means that the goal of their participation is not to make their medical conditions better but to test the efficacy and even safety of pharmaceutical products in development. Participants, unlike patients, never receive individualized care as part of clinical trials. Potential participants, who qualify for studies based on the inclusion or exclusion criteria established by the pharmaceutical companies, can merely elect to take part in the study and follow the strict guidelines of the protocol or they can decline to participate. This move effectively removes the clinical expertise of physicians in their role as investigators. They do not need to evaluate the participants' progress on medication with an eye to altering the course of treatment; instead, they need only evaluate that the participants are not endangered by the studies. As for the coordinators, the ability of nurses to have holistic insights into their patients is not valued or rewarded as such in the clinical trials industry. Clinical studies are significantly more reductive than is standard medical care because the participants are not being treated *per se*; the focus is only on the illness or symptoms in their bodies. This means that coordinators have no basis in clinical trials to evaluate the health and wellness of participants more holistically.⁴

What is different in the context of clinical trials is that the coordinators' expertise is not rooted in 'care' in the same way that it is often framed for nurses (Duffy, 2005; Kuhse, 1997; Tronto, 1993). Instead, the coordinators' expertise is framed as logistical, even managerial. The explicit focus of coordinators' work directs their professional responsibilities to the pharmaceutical companies sponsoring the studies, not the human participants

enrolled in them. In sum, their job is not to care for patients but to manage study protocols and ensure that the human participants are compliant during the course of the clinical trials.⁵

Given that coordinators as a group have more experience working on clinical trials than do investigators as a group (Table 1), it is not uncommon for investigators to explicitly acknowledge the experience of their coordinators when it comes to conducting clinical trials, with some going so far as to say they were trained by their coordinators (Fisher, 2009). Yet, in spite of the coordinators' actual expertise in conducting studies, the old hierarchy of status that privileges physicians/investigators is maintained through the gender dynamics of the investigator-coordinator relationship. As this article shows, the gender subtext to clinical trials work enables the devaluing of coordinators' expertise and the ability of investigators to take credit for the coordinators' insights.

Methods

This article draws upon 12 months of qualitative research examining the clinical trials industry in the south-western USA from October 2003 to September 2004. The project set out to investigate the new relations, structures and forms of logic that have been produced in local clinics through the pervasive outsourcing of pharmaceutical research. This research consisted of interviews and observation at more than 20 for profit research organizations in two major cities. The investigative sites represented a diverse sample of organizational forms, such as private practices, dedicated research sites and large (non-academic) hospitals. The sample also included interviews at two not-for-profit investigative sites. Most of the sites conducted studies to test the efficacy of new products that were targeting illnesses and diseases that already have safe and effective treatments on the market (for example, allergies, asthma, high cholesterol and insomnia). Only one site consistently tested products for life-threatening conditions, such as AIDS or cancer.

The sites were identified using an online database, and all sites in two urban regions of the south-west were contacted to participate in interviews or to consent to participant observation. In 75 per cent of sites in one city and 50 per cent of sites in the other at least one individual agreed to an interview or observation. Participant observation in clinics was focused primarily on interactions between the investigators and participants, as well as between coordinators and participants. Observation at sites ranged from 1-day visits to multiple visits spanning several months. Semi-structured interviews with 63 informants were clustered to get the perspective of multiple employees at individual investigative sites (that is, conducting contract research), including ten investigators (one woman, nine men), 18 coordinators (15 women, three men), three recruiters (three women), nine investigative site administrators

(five women, four men), nine pharmaceutical company employees (six women, three men), and 14 human subject volunteers (eight women, six men). The interviews lasted an average of 40 minutes, ranging from ten to 90 minutes.

Using a mode of institutional ethnography (D. Smith, 2005), this research sought to tap into the everyday, gendered work lives of those in the clinical trials industry to discern the power dynamics underpinning the social relations within that industry. The ethnographic methods were intentionally multi-sited, following practices and metaphors and attending to conflict in organizational cultures (Marcus, 1998). To do so, this research was particularly attuned to the role and ethical conflicts of various degrees of intensity that were described by the informants (that is, the investigators, coordinators and human participants) and were observed through their practices (for example, in the recruitment of participants, informed consent processes and study retention and compliance). In semi-structured interviews, I asked questions about the informants' experiences working in the clinical trials industry, how things had changed over time and what types of changes they would like to see in the future. A qualitative approach to this research was particularly useful in documenting key themes, especially given the dearth of previous empirical inquiry into this domain.

Keeping within a methodology of grounded theory (Glaser and Strauss, 1967), the data analysis relied on the process of coding field notes and interviews for core and emerging categories. One benefit of the arduous process of transcribing my own interviews was that it became part of the first stage of coding and analysing my data. It enabled me to find themes and issues about the clinical trials industry that I had not originally hypothesized. As a result of transcribing each interview while continuing to conduct new ones, I was also able to hone questions and identify other areas in which to ask questions other than those originally planned. After completing the participant observation and interviews, I mapped the major themes to code as part of my analysis, and I combed the field notes and transcripts for insights from informants on those themes. This article is developed from the analysis of themes surrounding the investigator–coordinator relationship.

The investigator–coordinator relationship

With a clinical workforce composed of predominantly male investigators and predominantly female coordinators, it is clear why an older gendered hierarchy has become the model for the new relationship. What is more difficult to explain is that the investigator–coordinator relationship seems to be more traditionally, and problematically, gendered than are contemporary doctor–nurse relationships. Whereas most nurses seem to be savvy and critical about their institutional positions, including their subordination to administrators

and physicians (Chambliss, 1996), most of the coordinators naturalize their positions of less authority through the types of relationships they are actively seeking with investigators.⁶

To begin to explore the ways in which the coordinators actively re-inscribe traditionally gendered modes of interaction, it is revealing to examine what contributes to the coordinators' job satisfaction in the clinic. Through interviews with coordinators, site administrators and pharmaceutical company employees, the most significant factor leading to the coordinators' satisfaction (or dissatisfaction) with their jobs was found to be their relationships with the investigators. As a female site administrator who had previously worked as a coordinator described it:

I think that the physicians make a lot of difference in [the coordinators'] job satisfaction. Physicians that you have the opportunity to work with because coordinators who feel a high level of confidence in the physicians that they're working with and good rapport with them are much happier.

Coordinators who are unhappy in their positions are likely to quit or change jobs. Thus, a high turnover of coordinators has come to indicate a personality conflict or professional problem with investigators. As a female pharmaceutical company employee whose job involved many site visits reported, 'You only see a high turnover at some [investigative] sites, but if you do see turnover, you see it a lot ... It more often really depends on the PI, the physician that they work with, whether or not they like him'.

What elements of the investigator-coordinator relationship lead to coordinator satisfaction or dissatisfaction with their positions? According to my interviews, one of the key factors for coordinators hinges on the degree to which the investigators earn the coordinators' respect or admiration. An example of this was one coordinator who had a photo of the investigator as the desktop wallpaper on her computer monitor. During the course of the interview, she would periodically gesture to his picture:

Personally, I love that my principal investigator is right here on site seeing these patients ... I guess you can tell I'm really passionate about what I do. I have such respect for the doctors that I have the opportunity to work with here. They are first class. But by my choice, I wouldn't work with them if they weren't ... I'm so passionate about this man [the investigator], he's actually, this is his picture [gestures to her computer]. He's my knight in shining armor.

This coordinator's admiration for the investigator positions him in terms of a male medical hero who commands her respect because of his valiant deeds in the arena of medicine.

The most important variable in earning the coordinators' respect and admiration is the way that investigators treat them. Firstly, the coordinators

indicated that they were seeking close and comfortable relationships with the investigators with whom they were working:

I prefer to work with a smaller company, just because I have that closer relationship with the physicians [investigators]. Here we're very small. We are growing, I mean, we started out just with one physician, and now we have, like, four or five. But I have a close relationship with them to where I feel comfortable with them. If I see that something's not going right and it needs to be changed, I feel comfortable telling them. Where I think if it's a bigger office and I didn't have to deal with them on a day-to-day basis, like, if it was just once or twice a week, then I might not feel as comfortable to voice my opinion. So just because it's a small group, we're a lot closer.

Putting aside any possible romantic overtones to both of these last statements, which were clearly present in the tone of their comments, what the coordinators are implying about the relationship when they call it 'close' or 'comfortable', then, is feeling that they are able to give their opinions, especially when they perceive that the studies are not operating as they ought to.

Another aspect that the coordinators often discuss about their relationships with investigators is the investigators' willingness to educate them about medicine and clinical practice. The coordinators who had experienced this type of relationship with investigators felt that it reflected the investigators' respect for them, because the latter were willing to spend time teaching the coordinators about topics related to the clinical studies. The following quote from a coordinator illustrates this point:

Here [the investigators] have spent hours and hours and hours with each new study, every technology, every procedure, they sit down with the entire staff. We're all educated [by the investigators]. If it's a device procedure, 'This is what we do: use this and this is inserted into the vagina and it's clamped like this and we find the fallopian tube'. Whatever it is, we all have, I have had such a tremendous education. Sometimes it boggles my mind, when somebody asks me a question and I know the answer.

Thus, coordinators value investigators who are accessible to them in the sense of being willing to listen to the coordinators' concerns and to 'educate' them about the medical context of clinical trials. While the coordinators clearly find this to be a major benefit to them, the sharing of information goes only one way. Coordinators never educate investigators in the same tone. Instead, as is described in the next section, the coordinators report critical information about the studies that investigators can choose to report to pharmaceutical companies.

The clinical trials industry is not blind to the gendered dynamics at play between investigators and coordinators. Those site administrators and

pharmaceutical company employees who discussed it during interviews talked about it in the familiar terms of the doctor–nurse relationship. For example, a female site administrator explained:

Clinical research is conducted primarily by men physicians — that is changing as the dynamics do, as more and more women become physicians. And most of our study coordinators are women, so we still have that old class of medicine ... There's an old leftover mentality in medicine that has to do with the doctor–nurse kind of relationship, and there are real issues having to do with sexual harassment and prejudices.... There are times when I have to work with my physicians to be kinder and more careful with our staff [the coordinators], and that's one thing that I'm very proactive about.

In her framing of the investigator–coordinator relationship, this administrator describes the tendency of the investigators' interaction to be negative, even so far as exhibiting a valence toward sexual harassment and prejudice in their interaction with the coordinators. From the administrator's perspective, the investigators needed to be taught to be 'kinder and more careful' with coordinators.

While none of the coordinators I interviewed complained of inappropriate or illegal behaviour on the part of the investigators, these types of problems could nonetheless be thought of as the backdrop for the way in which the coordinators perceive the investigators' behaviour. If coordinators come to expect that investigators will not treat them with respect because of status differences based on medical degrees, gender, or other factors, they will then try to gain the investigators' respect as their subordinates. For example, at one site I visited several times, it was apparent that the male investigator did not see coordinators as his peers or colleagues. In an interview with him, he compared himself to his academic counterparts and lamented:

As a man on an island out here, I also don't have that collegial experience, intimate collegial experience.... [It's] not like working next to your colleagues and it's not like working next to medical students who are anxious to learn and all that, so I don't have that aspect.

In his framing, the coordinators are not seen to be even on par with medical students. What is remarkable about this case is that this same investigator had told me earlier in the interview that he had known nothing about clinical research until the coordinators taught him how to conduct the studies. Whereas one might expect that the coordinators would have more power and authority in a situation like this one, that is not what I found. The contrary was the case. During my interview at the same clinic with a senior coordinator who had a background in nursing, the coordinator asked if we could pause because it was lunchtime. After I turned off the recorder, she went on to tell me that she makes lunch for the investigator most days because he never

made himself lunch and instead skipped the meal or ate a take-away. When I questioned her further about this, she said that it was no problem for her because she was going to make a bag lunch for herself anyway, so she simply made double. She said that he had offered to pay her for the cost of those meals, but she would not hear of it because she saw the time spent with him in the break room sharing those meals as compensation.

While this example is somewhat extreme, it nonetheless illustrates that highly trained and experienced coordinators find ways to develop relationships with investigators that cast them in a gendered and subordinate role. Situations like the one at that clinic indicate that some coordinators operate within a feminine frame of mother or wife. Because they are rewarded for this role by the investigators through the resulting relationships, the coordinators inadvertently continue, in hegemonic fashion, to support what the site administrator quoted above calls the 'leftover mentality in medicine'. In other words, the coordinators themselves help to maintain traditional medical hierarchies. It could be that the coordinators want to be treated with respect as feminized individuals because the investigators will not necessarily respect them as professionals or as peers.

The cases in which the coordinators are men provide exceptions that prove the rule regarding the gendered nature of this work in the clinical trials industry. This small group of coordinators has a different outlook on their positions and cultivates different types of relationships with the investigators. In part, the basis on which male coordinators have a different standing from the women in the industry is because they are so rare (comprising 10 per cent of all coordinators). The male coordinators construct their professional identities differently from their female counterparts. They are highly aware of the perception that coordinating studies is thought of as women's work, and they respond to the conflict they experience by emphasizing the temporariness of the position.⁷ According to one male coordinator:

You know, ultimately, professionally, there are future goals obviously. I enjoy the work I do. I love patient relations and I love patient care, but I have higher aspirations.... I want to be here for a while, but I'm going to get as much as I can out of it, learn as much as I can, and then be my own business, start my own company.

As a point of comparison, none of the women coordinators I interviewed framed their jobs as temporary and more often than not the women, particularly those who were nurses, indicated that they felt quite lucky to have found their positions.

The different way in which male coordinators understand their positions influences their relationships with investigators. One manifestation of this is that male coordinators reported that they have more in common with male investigators than they do with the female coordinators. This positioning places them as outsiders among their peers:

It's definitely one of those things where you're kind of working against the tide. A lot of people have their built perceptions and certain constructs about their position as far as men are capable of this, women are capable of this.... I wouldn't say that I'm ever treated differently, but I've been made aware on different levels.... And trust me, the physicians and I had to, more often than not, many times bond to kind of keep me sane.

This reveals that the hierarchy between investigators and coordinators breaks down — at least to some extent — when the traditionally female role is occupied by a man. This may be in part because male coordinators claim to have different professional trajectories from those of the female coordinators. This difference may affect not only the investigators' perceptions of the male coordinators but also the type of relationship that the male coordinators seek with (male) investigators.⁸

Female coordinators do not have the same foundations for camaraderie with the investigators, neither the simple one of sex nor the more intangible one of professional ambition. Thus, an underlying motivation for the female coordinators to form gendered close relationships with the investigators is the belief that these relationships signal that the investigators respect them both as individuals and as coordinators. Given that the coordinators are seeking recognition in very hierarchical ways (that is, they want to be educated about the content of their work or they want to feel needed by the investigators), the gendered dynamic of these relationships is not challenged but reified by coordinators' profound admiration for the investigators.

Coordinators' expertise

The hierarchical doctor–nurse relationship cultivated by the coordinators and investigators also serves to undermine new modes of medical expertise that are developing in the clinical context of pharmaceutical clinical trials. The knowledge transmitted by some investigators to coordinators may indeed be valuable, but the relationship between the investigators and coordinators nonetheless obscures the extent to which the coordinators have expertise that can be mobilized to educate the investigators. This gendered pattern of whose expertise is recognized is particularly striking when comparing the coordinators' and investigators' knowledge about clinical trials.

In general, coordinators are valued by investigators and the broader industry for their 'soft' skills of recruiting and enrolling human participants in studies. Coordinators who are good at their jobs often have highly honed interpersonal skills that can be used to make participants feel comfortable and trust that they will be taken care of during the clinical trials (Fisher, 2006). Importantly, skills such as these are rarely seen as specialized in feminized professions because they are often attributed both by men and by women as

skills that women naturally have (Metcalf and Linstead, 2003). Because the job of coordinating is constructed by coordinators and others in the clinical trials industry as feminized labour, the important non-feminized skills and knowledge that coordinators gain become invisible.

While this is not acknowledged by the clinical trials industry more generally and is rarely acknowledged by investigators, coordinators develop quite sophisticated knowledge in the medical side of the pharmacokinetics of the pharmaceutical products being tested. In other words, coordinators become experts in certain types of illnesses under investigation and they often have profound insights into the effects of pharmaceutical products on the participants being studied. That coordinators themselves undervalue the medical expertise they have indicates the extent to which they value the feminized aspects of their role and contribute to their subordinate status in relation to investigators. This section examines the non-feminized expertise coordinators do, in fact, need for their jobs and the ways in which they nonetheless continue to perform gender in explaining or dismissing their specialized medical knowledge.

During the course of clinical trials, coordinators spend more time with the human participants than any other research staff associated with the clinical development of pharmaceutical products. They are relied upon to deliver the data that pharmaceutical companies are seeking about their products, and they mobilize their gendered interpersonal skills to encourage the participants to be compliant and to report their symptoms accurately and consistently. This view of coordinating is one that matches the job description. What is left unsaid — and what only emerged through directed questions in interviews, which were seeking to tap into the extent of the coordinators' expertise — is that the coordinators are the ones who are able to identify patterns in the clinical effects of investigational products. Through their interactions with participants, they observe patterns that become crucial information for the pharmaceutical companies, the FDA, and even consumers.

Because pharmaceutical companies have expectations about the effects they believe that the products they are developing will have on patients, clinical trial protocols collect specific information about given sets of symptoms and outcomes that are being evaluated. As employees at pharmaceutical companies will readily acknowledge, there can at times be unanticipated outcomes of products that were not identified and planned for during the development of the product. Often these unanticipated effects are negative, but this is not always the case. The most notable example of this is a drug that Pfizer was developing to target hypertension (Leland *et al.*, 1997). Through clinical testing it became apparent that the investigational drug had the systematic side effect of producing an erection in the men participating in the study. Realizing that this side effect could potentially be marketed as the treatment itself, Pfizer began retooling clinical development to target erectile dysfunction in lieu of hypertension. While the history of the clinical

development of Viagra told to date has never specifically credited the coordinators who were part of the process of clinical trials, it seems likely that the coordinators were the first research staff to learn about an unintended, yet profitable, symptom produced by the drug.

Although this present research project did not reveal anything as dramatic as the case of Viagra, there is always information about pharmaceutical products that is produced through their testing on humans, and coordinators are integral to the production of that information. Specifically, coordinators' observations of the effects on human participants of the products being tested operate on two levels: the formal and informal. In the first instance, the coordinators explicitly follow the instructions set by pharmaceutical companies in study protocols and report the data asked for. At the same time, however, they also observe similarities or patterns in physical reactions and events happening among participants.

This expertise that coordinators have, however, becomes gendered through their relationships with investigators. An example provided by a coordinator is indicative of the gender and power dynamic at play:

At the end of the study, [the investigator and I] we'd kind of get together and say, you know, what did you see about this here study? You know, *as a coordinator*, you would list off the different things that you would say [to the pharmaceutical companies]. *That [conversation] really helped the doctor determine the different things he would talk to the pharmaceutical companies about that maybe they're not asking questions about.* [For example,] let's say we're testing a drug, and these people who have chronic headaches, you know, all of a sudden, are not having headaches anymore [and that's a side effect of the drug]. So you know, there's another new indication for this drug that [the pharmaceutical company] maybe needs to look at. The pharmaceutical company may not be able to pick that up from the data [that they request]. I think that if you see anything suspicious about how [a drug] works or how people are reacting to it, you know, things like that, that's a really good avenue *for doctors and coordinators* to talk about. (Emphasis added)

In this case the coordinator reported to the investigator, not the pharmaceutical companies, the patterns she was seeing with participants, and it was he who communicated this information to those companies.

Even though coordinators are the ones who are primarily responsible for communicating with project managers and others at pharmaceutical companies, they are rarely the ones who discuss the unanticipated benefits and risks that might be associated with the pharmaceutical products. Although the coordinator above acknowledges that she is the one to identify potentially relevant information about products because of her interactions with the participants, that information passes through the investigator, putatively to evaluate it and most certainly to get credit for the coordinators' insights. This

pattern was common: coordinators described a desire for their observations about the products and studies to be validated by the investigator before the information is communicated to the pharmaceutical company employees.

On the surface it may appear that the validation that coordinators seek for their insights from investigators is reasonable given that the investigators are technically in charge of the studies conducted at investigative sites. Because coordinators are by and large collecting all the study data, the investigators rarely have any systematic insights about the products they are studying. Recall the industry problem of phantom investigators and the extent to which coordinators must compensate for investigators' low levels of involvement in the studies. One story a coordinator told is illustrative of how coordinators' and investigators' experiences of clinical studies differ. She explained that she and her investigator had done multiple studies for a new type of drug being developed to treat arthritis. After several years she became increasingly disturbed by the negative effects of the drug on participants that she had noticed by working with different products from that classification being developed by several different pharmaceutical companies. Although these studies provided a major source of revenue for the investigative site, she felt compelled to speak with the investigator about the overall pattern she was observing with the drugs:⁹

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 [the investigator] and say, 'You know these meds? We're supposed to be here helping mankind and these medicines aren't... If you want to do these studies, that's fine, but you'll need to find somebody else to do it for you...' After I had talked to [the investigator] about that, he said, 'Hey, you know what, you're right, we're not going to do any more of these studies'. And we didn't do any more of those studies. *You know the doctors don't always work directly with the patients and see everything that's happening in that roundabout way [that coordinators do], so you have to bring that to their attention.* (Emphasis added)

On one hand, this story underscores the profound nature of the expertise that coordinators develop about the drugs they are testing. Because they are interacting so closely with the participants, coordinators have the ability to understand these investigational products in ways that most investigators do not and that pharmaceutical companies cannot. On the other hand, however, the coordinator's version of the story indicates the extent to which coordinators' expertise gets refracted through a gendered lens. Instead of framing her expertise in terms of straightforward, legitimate medical knowledge, it is treated merely as an isolated insight born of feminized care for human participants. In her own story she is motivated by altruism in her desire to help the sick human participants who are enrolled in the studies, and she notices that the drugs are not, in fact, helping them. Of course, this view of herself shortchanges her expertise, but it also integrates her experience into her

feminized identity, which subordinates her knowledge to that of the investigator's. Moreover, at the organizational level, the illusion surrounding coordinators' limited medical expertise is maintained. Even though everyone working in the clinical trials industry is quick to admit that coordinators do most of the work for drug studies, few people admit that coordinators do more than manage the studies.

It should be noted that the coordinators' reports about the patterns they identify do often make their way back through the investigators to the pharmaceutical companies developing products, but that does not necessarily mean that the coordinators' concerns about the products will be acted on. In the case of the coordinator above, she was describing her experience with COX-2 inhibitors (for example, Vioxx, Celebrex and Bextra). One of these drugs, Vioxx, received national attention in late 2004 in response to evidence that this arthritis drug was producing heart problems, including heart failure and death, in patients. Concerns such as those of this coordinator perhaps should have been heeded during clinical development rather than after these products were made available on the market.¹⁰ This story shows both the expertise of the coordinators and the delegitimization of that expertise because they are not given any formal, institutional authority to speak about their experiences during clinical development. Specifically, investigators may be called to testify before panels at the FDA, but coordinators, who are likely to be supplying those investigators with much of their information, are overlooked in the process.

In this section I have argued that the coordinators are not credited with clinical expertise — or, for that matter, financially compensated for it — even though they are the primary producers of information about the pharmaceutical products. In some respects the invisibility of the coordinators' expertise to the coordinators themselves as well as to the broader industry is reflective of the larger historical and institutional trends surrounding women's work and the gendering of labour. Although these political and economic arguments offering reasons why coordinators are not given more respect, authority and financial reward for the work they do are clearly sufficient for explaining their standing in the clinical trials industry, they cannot account for the coordinators' own hesitancy to embrace their expertise and to assert that the knowledge and skills they have are lacking in the investigators. As I have shown, the coordinators are not seeking credit for their insights but they are seeking close and personal relationships with the investigators. That these two things appear incongruent to coordinators is evidence of the gender subtext of the clinic.

Discussion

This article has focused on the gendered dynamic of work in the clinical trials industry. Based on traditional doctor–nurse relationships, the investigator–

coordinator relationship re-inscribes a gendered medical hierarchy into the emergent clinical trials industry. Because that hierarchy dictates that investigators and coordinators are not equals, the coordinators seek to establish relationships with the investigators through which the skills and expertise of the former are subordinated to those of the latter. Moreover, the important insights that coordinators have about the pharmaceutical products under investigation are passed through the investigators to the pharmaceutical companies, thereby shifting credit for that knowledge to investigators.

In the 1960s sociologists discussed what was called the doctor–nurse game (Stein, 1967) in which the role of nurses in the clinic was to be actively engaged in formulating treatment recommendations for patients but to do so in a passive and respectful manner that made the attending physicians appear authoritative and in charge. The doctor–nurse game is said to be obsolete in contemporary medicine because nurses simply stopped playing (Stein *et al.*, 1990; Weitz, 2003), but this is not to say that the power differences between the groups have eroded (Porter, 1992). Within the investigator–coordinator relationship a game is also at work in clinical interactions. In this case, it is not coordinators making decisions in a way that supports the investigators' authority. Instead, the coordinators are downplaying their knowledge and expertise about the clinical trial process and medicine more generally in exchange for a certain type of relationship with the investigators. The coordinators are seeking a closeness with the investigators that can be cultivated by deference and flattery. What is troubling about the rules of interaction is that the coordinators do not seem to perceive it as a game; rather, they buy into the subordinate role they play.

This example of what is predominantly women's work in pharmaceutical drug development serves to highlight the ways in which gender operates as a social structure (Risman, 2004) with effects on workplace authority and power. Not only do women perform gender in order to please their co-workers and superiors (Jackman, 1994; McGuire, 2000; Martin, 2006), but women in feminized fields such as research coordination perform gender in such a way as to obscure their own sophisticated levels of medical expertise. Borrowing from the work of Barbara Risman (1998), gender can be seen to be operating in the clinic on three levels: individual, interactional and institutional. On the individual level the coordinators participate in their own subordination by taking on highly gendered professional identities. At the same time the coordinators' interactions with investigators operate to highlight the investigators' expertise while undercutting the coordinators' own specialized knowledge and skills. Finally, the clinical trials industry contributes to the devaluing of coordinators' work through the uneven social and economic rewards, such as salary, status and recognition, associated with the investigators' and coordinators' positions in the larger organization. In addition, only the investigators are seen as experts about the products studied when concerns arise regarding their safety or efficacy.

The delegitimization of coordinators' work is interesting because of the active role that coordinators themselves play in their own subordination to investigators. Despite the significant progress that women have made toward equality in the workplace, feminized professional identities and the subordinated role that goes along with these identities continue to be rewarded by most industries, the healthcare sector in particular (Bolton, 2005). If women feel compelled to take on subordinate roles to be liked and respected, as is the case with coordinators, it is no wonder that women's work continues to be both undervalued and delegitimized. It seems that in the case of coordinators the compensatory benefits associated with their relationships with investigators matter much more to them than the subordination that results.

This is, of course, not to blame the victims for their subordination but rather to show the degree to which gendered hierarchies are entrenched in the workforce and specifically in the institution of medicine. Coordinators, like many women in feminized jobs, find themselves in a double bind. They must perform a particular gender identity to be accepted in the workplace but this same gender identity traps them in a subordinated position. Gender in these cases operates as both a powerful and constraining social structure because women must perform feminized roles to be accepted in the workplace but these same roles disallow the recognition of their expertise that could bring about institutional change. Thus, the challenge for feminist intervention in the workplace is to minimize the extent to which women's expertise becomes invisible within gendered structures of power.

Notes

1. Outsourcing has been experienced by many industries around the world, and the pharmaceutical industry is no exception. This shift in pharmaceutical research and development is illustrated by the fact that in 1990 over 80 per cent of all pharmaceutical-sponsored research was being done in academic centres and by 2005 only about 30 per cent of contracts were awarded to these same centres (CenterWatch, 2005). In place of universities, private sector for profit clinics have become the dominant site of clinical trials in the USA. This form of outsourcing has also been global, with pharmaceutical companies conducting clinical trials in most countries around the world. For a global perspective on these industry changes see McGee (2006).
2. Given the importance of coordinators in conducting clinical trials, it has been noted that more attention needs to be paid to their work and clinical role in discussions of the ethics of research using human participants (Davis *et al.*, 2002; Fisher, 2006).
3. Coordinators who are not nurses tend to have previously been receptionists or other employees of private practices before the physicians for whom they work started conducting pharmaceutical studies.

4. Although care is not valued in a direct way by the clinical trials industry, it can and does have the indirect outcome of aiding in the retention of the human participants, which is extraordinarily important in drug development (Fisher, 2006, 2009; Mueller, 2001).
5. This is not to say that care is absent from the coordinators' work. On the contrary, it is an important part of their professional identity (Fisher, 2006; Mueller, 1997). The distinction made here is that care is not part of the job description.
6. An organizational difference between the coordinators I studied and the nurses who are often the subject of sociological inquiry is the size of the workforce. Specifically, much of the analyses on nursing have taken hospitals as the locus of investigation, and nurses in these settings have a strong professional identity as a group. Coordinators, in comparison, can be the only one in their investigative site, especially in the private sector, and on average three coordinators work in a facility conducting pharmaceutical studies. Because they work in fewer numbers, coordinators may not develop the same type of collective identity that hospital nurses do. A better comparison might be between coordinators and private practice nurses.
7. During their interviews with me, it was not uncommon for male coordinators to volunteer their sexual orientation. All the male coordinators I spoke with considered themselves to be heterosexual, and they each took the opportunity to mention that the stereotype of the gay male nurse did not fit them. Evidently, they mobilize their heterosexuality as a defensive manoeuvre to assert their masculinity in a feminized professional role.
8. See Simpson (2004) for a more detailed discussion of men's responses to their own and their colleagues' identities in feminized workplaces.
9. Elsewhere I discuss how coordinators consciously construct their own understanding of research ethics, which deviates from more formalized discussions of ethics (Fisher, 2006).
10. This interview was conducted on 27 January 2004, months before the Vioxx story broke.

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