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Recruitment Practices and the Politics of Inclusion in Cancer Clinical Trials

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Abstract

Since the 1993 NIH Revitalization Act, researchers with federal funding have been required to include ‘minorities and women’ in their clinical trials, and inclusion in research has come to be seen as an important strategy for reducing health disparities. Based on ethnographic research in oncology clinics in an academic medical center and a public hospital over a period of two years, this article examines how the NIH inclusion mandate is playing out in the context of oncology clinical trials. We argue that while individual patients are recruited to particular trials by individual providers, recruitment processes are shaped by the structural inequities in the US health care system that create differential access to medical facilities with different and unequal research infrastructures. Given the heterogeneity of clinical trials, research infrastructures and the US health care system, the meanings of inclusion in research are multiple, and inclusion by itself, does not ensure equity.

Key Words: Clinical Trials Recruitment, Health Disparities, Cancer, Race, Bioethics
Introduction

In recent years, clinical research has grown more commercial and global, and in the US, more focused on enrolling ethnic and racial minorities. The US National Institutes of Health (NIH) Revitalization Act of 1993 mandated inclusion of “women and members of minority groups and their subpopulations in clinical research” supported by the NIH. The law requires “culturally sensitive and appropriate outreach” to facilitate inclusion, and called for sufficient sample sizes to allow “valid analysis of whether the variables being studied in the trial affect women or members of minority groups…differently than other subjects in the trial” (Public Law 103-43, p. S. 1-14; USDHHS 2002). Steven Epstein (2007) argues that the NIH mandate is part of a larger cultural and political shift in common sense about appropriate medical research subjects. The “inclusion and difference paradigm” as Epstein aptly calls it, reflects two fundamental changes in who should be included in research: first, that researchers should emphasize including all groups in research rather than protecting the socially vulnerable; and second, that biological difference between groups should be directly examined rather than extrapolated from a “standard” subject. Thus, in the context of this biopolitical paradigm, the definition of who should be included in biomedical research has shifted away from an individual or universal subject to groups defined by race, ethnicity, and gender.

By requiring clinical researchers to explore differences in how racially and ethnically defined populations respond to new treatments, the Revitalization Act suggests that inclusion of these groups is an issue of research quality, wherein socially defined categories of race and ethnicity are valid markers of biological differences. This “alignment of categories used in biomedicine, identity politics and bureaucratic administration” (Epstein 2007:278) raises concerns about the re-emergence or persistence of race as a biological category. The US federal government describes its race/ethnicity categories as social, but the requirement for biomedical researchers and clinicians to “import these social categories into explicitly biological or genetic
contexts” creates “a structural situation in which social categories of race and ethnicity may easily become confused and may be conflated with biological and genetic categories in day-to-day practice” (Kahn, 2006:1966). As one critic of the Revitalization Act argued, "the legislation’s emphasis on potential racial differences fosters the racism that its creators want to abrogate by establishing government-sponsored research on the basis of the belief that there are significant biological differences among the races” (Brawley 2004:293). Indeed, the FDA’s 2000 approval of BiDil, “the first race-specific drug” ¹ was enabled by the FDA’s requirement beginning in the 1980s that “subjects in clinical trials of pharmaceuticals” be classified by Office of Management and Budget (OMB) race/ethnicity categories (Roberts 2006:528).²

The Act’s emphasis on race, ethnicity, and gender also elides the significance of other social differences such as income and education, as well as the institutional structures that produce and reflect such differences (Epstein 2007). In the US, the intertwining of race and class stratification overall and in healthcare specifically is well documented. People of color are over-represented among the poor and uninsured, and thus disproportionately seek care in public ‘safety net’ hospitals and clinics (Hasnain-Wynia et al., 2007; Haynes et al.1999) Recipients of Medicaid, the state funded insurance for the poor, and the uninsured (more than 40 million across the US) typically obtain treatment at these safety net hospitals and clinics. These healthcare settings, where typically two thirds of patients are minorities (Regenstein and Huang 2005), are economically squeezed by state and federal budget cuts, and by neo-liberal reforms aimed at accountability, productivity and efficiency (Horton 2006). US health care is thus highly stratified and segregated along multiple dimensions of race, class, ethnicity, migration status etc. (Hasnain-Wynia et al., 2007; Kressin, 2005). Efforts to reduce and eliminate disparities are legion in the US, including an NIH Institute focused on minority health and disparities and an explicit goal to

¹ See Kahn 2006 for an analysis of Bidil and race.
² At the time of the FDA requirement there were 15 categories. Currently the OMB includes five race categories (American Indian or Alaska Native; Asian, Black or African American; Native Hawaiian or Other Pacific Islander; White) and two ethnic categories (Hispanic or Latino and Not Hispanic or Latino).
have eliminated health disparities by 2010 (USDHHS 2000; Epstein 2007). Health disparities research focuses on social conditions such as health literacy (Nielsen-Bohlman et al 2004; Kutner et al 2006) and on biological factors such as genetic differences (Kressin 2005) that may contribute to differences in morbidity and mortality. Still, much health disparities research blurs “the extent to which the disparities are the result of the unequal distribution of resources, ...and the extent to which they are the result of inherent characteristics of individuals defined as ethnically or racially different” (Lee et al. 2001:33).

Inclusion in clinical trials is increasingly considered a “vital prerequisite to eliminating [health] disparities” (Bruner et al. 2006), a premise that we explore here by examining recruitment to cancer clinical trials in both a public hospital and an academic medical center. In response to the Revitalization Act, researchers have increased their efforts to include “hard to recruit” (Wendler et al 2006) subjects, with some commercial firms focused on minority recruitment per se. Research funding depends on it, and a huge literature on how to overcome “barriers to minority recruitment” by addressing minorities’ reluctance to participate in trials has developed over the past 15 years in health services and medical journals (e.g. Ford 2008; Hussain-Gambles 2004). But the Act’s focus on outreach and the “barriers” literature focus on minority willingness to participate both bear scrutiny. Katz and colleagues (2008) recently refuted a long-standing belief that African Americans were less willing to participate in research due to the legacy of the Tuskegee study. In a review of 20 studies reporting the enrollment of more than 70,000 individuals, Wendler and colleagues found that US racial and ethnic minorities are not less willing to participate in research, and as a result concluded that “efforts to increase minority participation in health research should focus on ensuring access to health research for all groups, rather than changing minority attitudes” (Wendler et al., 2006:0201).

The “science of recruitmentology” (Epstein 2008) is flourishing in public health and medicine, but critical social sciences such as anthropology, science studies and bioethics have
tended to focus less on the policies and practices of US-mandated minority recruitment. Rather, these disciplines have engaged other questions: the globalization of clinical research and attendant ethical, economic and cultural questions (Adams 2005; Lakoff 2007; Molyneux, and Geissler 2008; Petryna 2009, Sunder Rajan 2006, Whitmarsh 2008); the pharmaceutical industry as a commercial, political and ethical actor (e.g. Biehl 2007; Dumit n.d.; Fisher 2009; Petryna, Lakoff & Kleinman 2006); randomized controlled trials as a form of evidence (Abraham 2007; Wahlberg and McGoey 2007), and the consent process, particularly the concept of therapeutic misconception (Applebaum 1982; Brown et al 2004; Corrigan 2003; Gikonyo 2008; Lidz, et al 2004; Sankar 2004; Timmermans and McKay 2009).

Nevertheless, the critical social sciences have furthered our understanding of how social and institutional structures shape minority inclusion. Adriana Petryna (2005; 2009) examines the structures regulating ethical research practices in the context of international health crises, such as AZT trials in Africa, and argues that an “ethical variability” emerges wherein regulatory regimes and international ethical guidelines are adapted for commercial advantage rather than for the genuine protection of research participants. This ethical variability facilitates the incorporation into clinical research of populations who often have no other sources of healthcare. In an examination of clinical research in the US, Jill Fisher argues that “the expansion of pharmaceutical trials in the private sector can be seen as addressing two problems in US health care: decreasing revenue for physicians and decreasing access to treatment for patients” (Fisher 2009:2). The result, Fisher shows, has been that low income and uninsured Latino men in the Southwest and African American men in the East now make up the majority of subjects in US based industry-sponsored trials that require healthy subjects. Similarly, Timmermans and McKay (2009) argue that lack of healthcare options can make particular kinds of trials appealing to particular categories of people. Their study analyzes Phase III clinical trials for methamphetamine

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3 These trials caused significant controversy in the 1990s. See for example, J Arras and R Crouch R (1998) and Petryna (2009:34-37).
dependency at an academic medical center, and finds that due to limited access to health insurance and the particular structures of care for addiction, trial participants concluded that the clinical trial was the best source of care for them (presenting challenges for the concept of therapeutic misconception). In each of these cases, structural issues—the changing ethical and other regulatory regimes governing global pharmaceutical trials, changes in global capital flows, and the structure of the US health care system, particularly the lack of equal access to healthcare within a neo-liberal economy, and the structure of care for particular conditions/diseases—facilitate a division of clinical research labor by nationality, class, race, gender and disease.

In this article, we extend the discussion of how institutional structures shape clinical trials practices by demonstrating how the inequities in the US health care system and access to care intersect with research infrastructures to shape access to particular kinds of clinical trials for particular kinds of patients. We discuss how different kinds of trials and the clinical context in which cancer patients are invited to participate may accord different benefits and burdens to patients who choose to participate, and also to the providers who attempt to recruit them. We further contribute to the anthropology of clinical trials by examining the meanings of inclusion in clinical trials primarily from the perspective of those responsible for the inclusion—the providers. And we do so in the context of public and academic medicine, rather than private, pharmaceutical industry trials where most ethnographic research on clinical trials has been conducted.

From the perspective of the critical social sciences, the NIH inclusion mandate may be understood as a specific, local response to US concerns and configurations surrounding health disparities and equal rights. This frame suggests the need for an ethnography of clinical research practices in non-commercial sites, e.g. academe and the safety net, where attempts to increase minority participation in cancer clinical trials takes place. Epstein (2007) recognized that medical providers did not universally embrace the inclusion and difference paradigm, but the Revitalization Act permits no such subtlety and, except when justified by the science, inclusion is
universally mandated. In this article, we ask: How is the NIH mandate playing out on the ground in public hospital and academic center cancer clinics? In these contexts, is inclusion in clinical trials a means to reduce health disparities or facilitate health equity? We argue that the heterogeneity of clinical trials, research infrastructures and the US health care system produce varied practices and meanings of inclusion. While individual patients are recruited to particular trials by individual providers, recruitment processes are shaped by structural inequities in the US health care system that create differential access to medical facilities with different and unequal research infrastructures. Thus, “inclusion” abstracted from the context of specific recruitment practices cannot ensure equity.

In what follows, we describe our two research sites, Social Hospital and Davis Center – including the types of trials offered to patients at each site – and our methods. We then juxtapose two stories of recruitment, one at each site to highlight the sites’ contrasting participatory logics. At Social Hospital, we tell the story of an attempted recruitment of a low socioeconomic status (SES) Chinese immigrant to a Phase III randomized chemotherapy trial. At Davis Center, we describe a high SES white man who chooses to participate in a Phase II chemotherapy trial while trial “shopping.” These case presentations are analyzed in the two sections that follow “Recruitment in Clinical Context” and “Inclusion and Relations of Exchange,” where we also present data from additional clinical observations and interviews with providers. Our analysis focuses on how clinical context shapes recruitment practices and how in these different contexts, inclusion involves particular relations of exchange that differ from the one implied by the NIH mandate’s redress for inequity. In concluding, we consider how varied meanings of inclusion may impact goals of increased health equity and reduced disparities.

Research Contexts and Methods
For two years (2005-07), we conducted ethnographic fieldwork in cancer clinics at Social Hospital, a public county hospital and Davis Center, an academic medical center. We directly observed provider-patient interactions during treatment discussions and recruitment and enrollment of patients onto clinical trials, and conducted in-depth interviews with the providers we observed who were variously engaged in the clinical trials process including: oncologists, surgeons, fellows and residents, nurse practitioners, clinical trials coordinators (CRCs), and patient navigators. We attended tumor board meetings, training and educational events about clinical trials for CRCs and navigators, and committee meetings of a Davis Center-based “minority task force.” The first author conducted fieldwork in the clinic, and observations reported in the first person are hers.

Our research sites reflect the social stratification and the associated segregation of healthcare in the US. Like many hospitals that make up the healthcare safety-net in the United States, Social Hospital is publicly owned and serves many patients with no medical insurance, on Medicaid, the publicly-funded medical insurance program for the poor, or on Medicare, the federal insurance for the elderly and disabled. It is affiliated with a nearby academic medical center (Davis Center), whose faculty and staff provide clinical and teaching services. The Davis Center is a cancer center within a large academic medical center. Compared with the Davis Center, the patient population at the Social Hospital was highly diverse with respect to race, ethnicity, and language. At Davis Center, nearly 69% of patients are white, while at the Social Hospital cancer clinics 70% of patients are people of color (with 33% Asian (primarily Chinese and Filipino), 21% Latino and 16% African American) and nearly a third of patients do not speak English. Insurance status, which reflects the differences in income and employment of

Patient navigators were only present at Social Hospital. They are employed to help patients obtain treatment, access benefits and community services, and to facilitate provider–patient communication via language and cultural translation. A charitable foundation supported the navigators, the CRC, and other cancer services at Social Hospital and explicitly sought to improve access to cancer clinical trials.
patients at the two sites, also differs substantially. At Social Hospital, 32% of patients are uninsured and the nearly all the rest are on some form of publicly funded health insurance or coverage (e.g. Medicaid, Medicare, County coverage, jail etc.) In contrast at Davis Center, more than half (54%) are on private insurance, 28% are on Medicare and only 11% are on Medicaid.

Social Hospital established an interdisciplinary surgical and medical oncology breast clinic in the early 1990s for patients with non-metastatic breast cancer and other breast disease and also had a general oncology clinic for treatment of metastatic breast and all other cancers. This article relies on data from the Social Hospital breast clinic because it had a more active clinical research program than the general oncology clinic at the time of our research. We conducted observations of 77 patient-provider appointments, including 66 discussions of clinical research, (including tissue banking) and interviews (recorded and transcribed) with nine providers whom we had observed in practice. Providers included attendings, fellows, nurse practitioners, clinical trials coordinators and patient navigators.

At the Davis Center, we observed 85 provider-patient interactions, including 39 discussions of clinical trials in two cancer clinics. Although clinician investigators in both Davis Center clinics actively recruited patients for research, one clinic had a well funded research core that supported clinical research coordinators (CRC) with expertise in regulatory matters, sponsor contact, and patient management as well as two nurse practitioners (NPs). The other program had few core resources, so investigators depended on financial support from individual studies and relied on two NPs for research support. We conducted eleven interviews with providers (MDs, CRCs, NP research nurses) including eight formal (recorded and transcribed) and three informal during fieldwork (notes taken) that we had observed in practice. Interview topics with providers in both sites included discussion of ‘shadowed’ observations, patient care responsibilities, activities related to clinical trials and general views of medical research, and personal and
professional background. All recorded interviews were transcribed verbatim by professional transcribers. The two authors conducted content analysis of fieldnotes and interview transcripts.

Appropriate Institutional Review Boards approved all research procedures for this study. In accord with our IRB approved protocol, all proper names are pseudonyms, and we have changed some potentially identifying characteristics of research sites and individuals to ensure confidentiality. We obtained verbal informed consent from all patients and providers prior to all observations and written informed consent prior to all interviews. Unless otherwise noted, quotations are from interviews. Interviews were conducted in the provider’s office or a private conference room at the hospital.

Institutional Access to Clinical Trials

Offering clinical trials is a central to the mission at Davis Center, but not at Social Hospital. During our fieldwork, Social Hospital accessed trials through the National Cancer Institute’s (NCI) Clinical Trials Support Unit (CTSU), which provides basic data management and logistical support for clinical research at resource-poor institutions. CTSU paid approximately $2000 per patient enrolled, but this was not enough to support the Social Hospital trials program, which had to support its lone clinical trials coordinator (CRC) with a private grant. Social Hospital had not always been part of CTSU. In the late 1980s, with Davis Center support, the hospital was a full member of an NCI cooperative group. By the mid-1990s, however, the relationship with Davis Center changed and Social Hospital downgraded to “affiliate” cooperative group member. As an affiliate, Social Hospital only had a limited menu of trials. This created recruitment challenges, as the hospital’s diverse and mostly under-insured patients were best suited for only a few, selected trials; soon, the hospital failed to reach its enrollment quota and had to close the trials program. Shortly before we began our fieldwork, Davis Center received a negative evaluation from NCI regarding the diversity of the patients it
recruited to trials, and in response it sought to increase recruitment at Social Hospital. Dr. Taylor, the director of the Social Hospital oncology program and a senior attending physician, wanted to offer trials to her patients, and so championed the Davis Center “outsourcing” strategy and obtained the foundation grant to support Social Hospital efforts. At the same time CTSU created a new program to make cooperative group trials more easily available. When asked how she decided which trials to open, Dr. Taylor replied,

The most obvious thing was to look at the CTSU list. In other words, what do we have available? And basically to open a broad range of trials, as broad a range as possible. Some of them we knew we would probably never get anybody to [enroll in] because they were just way too complicated and involved a lot more effort on the part of the patient… One of the trials, for example, that we had open was modified to require some extra studies, and…those extra studies aren’t paid for by Medicaid and I can’t justify doing it so we -- and [the Davis Center] didn’t -- just didn’t want to, so we agreed to drop our participation in that trial.

Dr. Taylor believed recruitment for many CTSU trials would be “a total flop” at Social Hospital because patients lacked adequate insurance, did not speak English as a primary language, or had schedules that precluded participating in complex studies. As of May 2010, Social Hospital changed course again as budget cuts led to changes in the CTSU program. The trials program at Social Hospital shut down for a year and then re-opened under a new relationship with Davis Center, which funded a CRC position and allowed Social Hospital patients access to Davis-based trials.

Throughout its history, Social Hospital has offered access to Phase III clinical trials, which typically are randomized comparisons of different drugs, treatment protocols, or drug combinations. Phase I trials (focused on safety) and Phase II trials (focused on drug efficacy) are less-frequently randomized but usually entail greater risk; these trials often are tests of new
compounds to treat cancer and usually restricted to patients for whom standard therapies are no longer effective. Phase I and II trials are often investigator initiated, with industry collaboration, and thus are more likely to be offered at an academic center, whereas Phase III trials are often multicenter trials sponsored by an NCI cooperative group whose purpose is to develop and conduct large-scale trials in multi-institutional settings. (Pharmaceutical companies sponsor all phases of trials.) Thus, patients at Social Hospital typically only were offered Phase III trials while patients at Davis Center had access to Phase I and II trials as well as Phase III. Different trials infrastructure at Social Hospital and Davis Center – and the differential access it provided to patients at each institution – are crucial for understanding how recruitment and minority inclusion played out in the two settings as we see in the following case studies.

**Recruitment at Social Hospital: Dr. Rao and Mrs. Lee**

The Social Hospital breast clinic operates for only four hours, one afternoon a week, during which 35-45 patients have appointments. It is an interdisciplinary clinic providing both surgical and medical oncology services, and is held in the surgical ward whose nurses felt burdened by the clinic’s “extra” personnel (e.g. navigators and the CRC). Nurse practitioners and a rotating cast of medical fellows, residents and students provided much of the clinical care; three attending physicians oversaw their work but often missed clinic due to other obligations. The exam rooms opened on to a single crowded and chaotic hallway. Fellows, residents and nurse practitioners consulted attendings in the hall; the clinical trials coordinator, interpreters and patient navigators waited there to be called in to an exam room; and patients walked to and from the waiting area or stood in their skimpy gowns when they got tired of waiting alone in the exam room.
One day while shadowing Ana, the clinical research coordinator (CRC), I tried to stay out of everyone’s way in the crowded hallway as I listened to her explain two clinical trials for which she thought a patient was eligible to Dr. Rao, the junior attending in the clinic (who nonetheless was experienced in the clinic as she had been an oncology fellow there before becoming an attending.) Ana had to make sure eligible patients were invited to participate in available trials. She and Dr. Taylor, the senior attending and the director of oncology at Social Hospital, met every Friday to review charts and prepare for the week ahead. Providers saw patients randomly—they simply picked the next chart from a big pile on a shelf in the hallway—so Ana had to make sure she caught up with any provider who picked up a chart of one of the eligible patients. Timing was critical: most trials required patients to enroll before they began treatment, so Ana had to make sure she saw patients during their first visit after surgery.

On this day, Ana had summary sheets for two trials and Dr. Rao was reading them, seemingly for the first time. Dr. Rao was unclear of one trial’s goal; she thought it seemed like a step back in science. She also wanted to make sure that the trial would not preclude a hormone therapy she knew the patient needed. She asked for the protocol, but Ana did not have it with her.

Dr. Rao then consulted Dr. Taylor who explained the differences among the many arms of the two trials. With Dr. Taylor’s help, Dr. Rao decided to offer the patient one of the trials, and Ana and I followed her into the exam room. Dr. Rao introduced herself and then me and Ana to the patient Mrs. Lee, who was there with her husband and her daughter. Mrs. Lee and her husband did not speak English. The Cantonese interpreter had yet to arrive, so the daughter, who looked about twenty years old, began translating.

Dr. Rao began by introducing the concept of research: “there is a standard way we give chemotherapy, and the way we find out if one therapy is better than another, is through

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5 As noted in the methods section, clinical fieldwork was conducted by first author Joseph.
studies…” She said, “we have a study if you are interested in being part of one.” The daughter asked, without translating for her mother, “do we have to do it?” Dr. Rao replied, “no, it is a personal choice—if you want to be part of helping cancer care overall, and it might help her as well.” After consulting with her mother, the daughter said, “no, she doesn’t want to do it.” Then Dr. Rao explained the standard treatment: eight chemotherapy treatments every two weeks over a period of four months. The patient asked some questions about the length of her treatment and side effects and the doctor patiently explained—now through the medical interpreter who had arrived—all the details of her treatment. After they discussed scheduling, Dr. Rao left to set up Mrs. Lee’s first chemotherapy appointment.

Ana and I followed Dr. Rao out into the hallway where she immediately turned to Ana and confessed: “I don’t feel like I did a good job explaining the trial, I didn’t know what to say. They discussed the trial for a few minutes, and then Dr. Rao asked Ana to help her re-explain the trial. Back in the exam room, Dr. Rao through the interpreter told the patient and her family that she wanted to tell them more about the trial. She explained that the trial had four arms, struggling to make clear that the patient would only have to be one of them, but that she did not know which one because the trial is randomized. She explained that the treatment was similar to standard treatment, but the dosing and timing differed on each arm because the study was trying to figure out which worked best. She would get the same medications, but might have fewer side effects. This piqued Mrs. Lee’s interest, but then Ana added that depending on which arm she was assigned to, the treatment could take longer than the standard treatment. Unhappy with this possibility, Mrs. Lee decided she did not want to participate. At a point in the discussion when the patient seemed like she might be interested in participating, her daughter asked Ana if she had something she could read about the trial. Ana said she had the consent form, but warned that it contained more information than she would want. The daughter asked if she had it in Cantonese; Ana did not (consent forms were rarely available in other languages), but the
daughter said she would like it anyway, and reiterated that, even after her mother had definitively said she would not participate in the trial.

Given the scope of our study (we did not interview Mrs. Lee), it is impossible to know the precise reasons Mrs. Lee declined to participate. The prospect of a longer course of treatment on trial seemed to provide the rationale for declining. Many other patient factors may have contributed. For example, what prior familiarity did Mrs. Lee have with clinical research? And if any, was it negative, positive or neutral? What was her orientation to risk? What other demands in her life, such as work to support her family, might have made her less inclined to spend the extra time in treatment the study might have required? What level of trust did she have in the medical profession and the particular doctors she faced that day? While these and other patient factors are clearly pertinent, and have been explored extensively in the “recruitmentology” literature (Epstein 2008) and to a lesser extent by social scientists (e.g. Abadie 2010; Dixon-Woods & Tarrant 2009), the focus of our research was on how the clinical context and institutional structure in which Mrs. Lee was asked to participate created the conditions of possibility for particular kinds of inclusion and relations of exchange. Mrs. Lee’s invitation unfolded amidst the typical chaos percolating in the Social Hospital breast clinic as well as that clinic’s focus on clinical care not clinical research. Inadequate interpreter services made for difficult communication, as it did for approximately one-third of patients in the clinic. The interpreter, who arrived halfway through the initial discussion, had no familiarity with the trial and, probably, no training or familiarity with clinical research in general. The trial was a complex multi-arm study designed to examine subtle differences in how the same chemotherapy drugs were delivered—a difficult randomized trial to understand in the best of circumstances. Furthermore, Dr. Rao herself knew little about the study. She learned of it from the CRC and Dr. Taylor’s explanation in the clinic hallway only minutes before discussing it with the patient. And she had read only a summary rather than the full protocol. Dr. Rao’s suggested motivation for participating -- “helping cancer care overall, and it might help her as
well” -- included an abstract kind of altruism to improve science, and a vague allusion to potential individual benefit. Thus the clinical context and research infrastructure in which Mrs. Lee was invited to participate in the trial created particular conditions of possibility for inclusion and exchange. We discuss these conditions of possibility further below, but first, we present an example of recruitment at Davis Center, which brings these dynamics of inclusion and exchange into relief.

**Recruitment at the Davis Center: Dr. Chen and Mr. Smith**

Before I accompanied Dr. Chen into the exam room, he told me that Mr. Smith was here – accompanied by his wife – after being newly diagnosed with pancreatic cancer specifically to learn about Dr. Chen’s Phase II clinical trial. In the exam room, Dr. Chen began this first meeting with the Smiths with questions about work and family. Mr. Smith described his work with high tech companies, his daughter who had just started at an elite prep school and his son who was applying to East coast colleges. Turning to health, Mr. Smith shared a dramatic story of his cardiac arrest a year earlier and the more recent symptoms that had led to his diagnosis of metastatic pancreatic cancer. He offered his recent CAT scans to Dr. Chen who mounted them in the light box and explained how to read the images as he examined them himself for the first time.

Transitioning, Dr. Chen said, “well, you both seem extremely bright.” He acknowledged that Mr. Smith had already talked with two other oncologists and read about various trials and treatments, and that he had talked with Dr. Chen’s research nurse, and read the lengthy trial consent form. He told Mr. Smith that, “someone like you—in good shape, young—should do a clinical trial.” He described his study as Phase II and not randomized, explaining that he had developed it at the Davis Center in collaboration with a pharmaceutical company who supplied the drug. He concluded by saying that he did not feel that it was an “ethical dilemma” to offer
this trial because it was not randomized, and did not involve a placebo. Thus, Dr. Chen implied that placebo or randomized trials would not be ethical to offer to someone in Mr. Smith’s situation, perhaps a reference to the other trials that Mr. Smith had investigated.

Mr. Smith commented that as an attorney, Dr. Chen’s consent form was “not written in a reassuring way.” Dr. Chen replied that the language was required by the University’s Institutional Review Board and that ended the discussion of the consent form. A long discussion then ensued about various trials in the US and Europe that the Smiths had read about, the various drugs being tested, and how they worked biologically, how much was known about them, and other cancers for which they had been FDA approved. Mr. Smith asked if going on Dr. Chen’s trial would require him to forego the option of taking the standard treatment at a later date, adding, “it’s an opportunity-cost issue.” Dr. Chen assured him that he would still be eligible for the standard treatment later, and that he wanted them to make a decision with which they were comfortable.

Demonstrating his consumer expectations, and perhaps an awareness that he was a desirable trial participant, Mr. Smith asked what kind of “handholding” he would have during the trial. Dr. Chen explained that he would see him at the start of each 28 day cycle, and a research nurse would be available by phone at all times. Mr. Smith concluded that participating in the trial was “close to a no-brainer.” Dr. Chen expressed concern about Mr. Smith’s plan to continue working, warning that his treatment had to come first, “particularly if [he was on] a study protocol.” After a brief discussion about how soon Mr. Smith could start, the appointment ended.

The discussion between Dr. Chen and Mr. Smith seemed a meeting of equals: a provider including a patient on his trial and a patient shopping for the best treatment. They needed each

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6 Providers at both Social Hospital and Davis Center were somewhat dismissive of consent forms’ capacity to provide relevant information that would facilitate truly informed consent. Rather sometimes consent forms were described as legal documents that protected the institution rather than the patient and included required information that did not help the patient understand what participation would mean to him/her.
other, and both stood to gain. Dr. Chen was an apt salesman for his study. He knew it well, as he had designed it and was the lead researcher. While recruitment of patients to one’s own study might seem like a conflict of interest, this practice was routinely approved by the Davis Center IRB, and appears to be standard practice in academic medical centers where investigator initiated studies are routinely carried out.7 (We also observed cases where the provider did not necessarily want an eligible patient to participate, if for example, he thought the patient might not be likely to comply with the requirements of the trial or had co-morbidities that would make tolerating the treatment more difficult.) Mr. Smith was a savvy consumer, having shopped around and done substantial research, including beginning a relationship Dr. Chen’s research nurse and reading the consent form prior to meeting the physician.

When comparing Mr. Smith with Mrs. Lee, it is clear that they were differentially prepared to be “included” in clinical trials. They brought different levels of what sociologist Janet Shim has termed “cultural health capital,” or “the repertoire of cultural skills, verbal and nonverbal competencies, attitudes and behaviors, and interactional styles, cultivated by patients and clinicians alike, that, when deployed, may result in more optimal health care relationships” (Shim 2010:1). Yet, beyond such patient characteristics, Mr. Smith’s case, like Mrs. Lee’s illustrates important factors related to the research infrastructure (e.g. the research staff, the providers’ prioritization of research; the type of trial offered) that created the possibility of particular kinds of inclusion and relations of exchange.

Recruitment in Clinical Context

The different patient populations at Social Hospital and Davis Center, illustrated by the cases of Mrs. Lee and Mr. Smith reflect the segregation and inequities in general access to care

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7 The issue of potential conflicts of interest for physicians who take on a dual role of clinician and investigator with a given patient raises important ethical considerations whether or not the clinician has designed the trial him or herself (e.g. see Bramstedt 2004; Hales et al 2001).
as well as access to the research infrastructures at different types of hospitals, such as the public and academic hospitals where we conducted our research. Particular research infrastructures and cultures in the clinics shaped possibilities for patients’ engagement with healthcare and clinical research. Key among the factors shaping patient engagement was that the providers tasked with “inclusion” were differently prepared for and inclined to complete the task of recruitment (e.g. the provider learning about the trial minutes before presenting it to the patient vs. the investigator presenting his own trial with substantial support from his research nurse). Few providers at the Social Hospital breast clinic knew much about available trials. Some were too pressed for time, others did not deem it a priority, and many rotated through the clinic too quickly to bother learning. Providers at Social Hospital, who were typically overextended could be understandably disinclined to focus on trials recruitment, and sometimes pro-actively avoided it. As one Social Hospital nurse practitioner explained:

Honestly, it’s a pain...It slows everything down… You can spend 45 minutes talking about a trial and you basically have maybe discussed possible options for treatment…then you come out and there’s 40 more patients left to see.

This NP argued that teaching and research should take a back seat to patient care. “I feel like the care of the patient is compromised for the opportunity to teach...[doctors will say] ‘he’s learning, it’s a learning moment.’ And I’m like no, it might be a learning moment but they have a patient and the purpose is for them to care for the patient.” These sentiments were common at Social Hospital, which attracted providers inspired by its mission of caring for the medically underserved. In contrast, Dr. Taylor, the director of the clinic who championed the clinical research program at Social Hospital, believed trials were part of the full range of care and that as
a teaching institution it was important to put people on trials and to show trainees how to do it.

Dr. Rao also saw herself as a “big proponent”:

I know that all of our literature comes, you know, most of it’s coming from clinical trials, so how else can we learn something? Yeah, plus I just, at the [Social Hospital] I feel like people are missing out because so many clinical trials are done with Caucasians and I think we really need a general, a more general view, ‘cause you never know what differences will come up with other ethnic groups.

Despite her support of trials-based evidence and the need for minority inclusion, Dr. Rao did not have time to learn about which trials were available for her patients at Social Hospital. Dr. Taylor and the CRC Ana were thus the only staff that knew which trials were open at Social Hospital. Ana confessed that she was responsible for so many protocols – 26 in all – that she could not stay on top of all of them, especially because eligible patients rarely were seen in clinic. When an eligible patient appeared, it required a great deal of work for her and the providers to get up to speed.

At Davis Center, research was central to the mission with investigator-initiated studies held in particularly high regard. Providers knew their own studies intimately, and they tended to have excellent and detailed information about all studies in their clinic. Research support staff was numerous, well trained, and tightly integrated into the recruitment process. Mr. Smith’s case illustrates common practice at Davis Center where patients can speak with a research nurse at length and read consent forms prior to their appointment with a physician. This infrastructure tended to pre-select motivated patients for participation and then help develop strong rapport and relationships between doctors and patients. This mutual vetting process helped identify the “good study patients” like Mr. Smith: healthy aside from terminal cancer, well-informed, easy to communicate with, motivated, with strong social support, and able to comply with the study
regimen) (Joseph & Dohan 2010). Given the risks and demands of clinical trials participation itself, providers viewed the vetting process as appropriate. As one oncologist put it,

Cancer treatments are I think more risky than a lot of other treatments and so it’s even more important that people have a stable social situation and good network of support, and the ability to stay in touch and be responsible about staying in touch. Because you could kill someone very easily if they decide to not call us back or not get the labs done or a lot of those things. And so it really to me comes down ultimately to safety issues and so people who have marginal social situations I think it’s often not safe to put them on clinical trials.

This example illustrates the logic of inclusion at Davis Center which thus went like this: There are few patients at Davis who belong to ethnic/racial minority groups; this is unfortunate because diversity is important; we should recruit at a place like Social Hospital which has a large ethnic/racial minority patient population; but, participating in clinical research can be dangerous and demanding; patients at Social Hospital do not have the resources they need to participate safely (e.g. a “stable social situation and good network of support”); moreover, we need patients to be adherent to study protocols so that studies reach completion; thus while we should include diverse patients on trials, patients at Social Hospital are not good study patients.

Social Hospital had its own logic of inclusion. Some providers embraced inclusion, and they included any patients who were eligible, willing, and from whom they could obtain informed consent. But other providers rejected trials in the name of protecting vulnerable patients or focusing institutional resources on clinical care. Dr. Taylor championed clinical research at Social Hospital while acknowledging that her hospital’s marginalized patients often lacked resources such as “cultural health capital” (Shim 2010) they needed to participate. Thus, she aimed to open trials at Social Hospital with protocols that demanded relatively little of
patient participants and could be performed with the limited resources public insurance would provide.

From the perspective of providers conducting the recruitment/inclusion at both Social Hospital and Davis Center, the equity premise of the Revitalization Act played into the participatory logic in different ways, and the clinical context shaped providers’ orientation to and practices of inclusion in clinical trials in each clinic.

**Inclusion and Relations of Exchange**

Comparing the experiences of Mr. Smith and Mrs. Lee and the logics of inclusion at Davis Center and Social Hospital highlights the forms of negotiation and exchange between patients and providers and among providers that take place during clinical research. The burdens patients and providers are asked to take on, and the benefits they may reap are distinct and potentially unequal depending on where trials are fielded and recruitment is conducted.

At the Davis Center, Dr. Chen’s trial offered a potentially life extending treatment, that might be better, if only marginally so, than the standard of care. Yet Dr. Chen did not discuss the trial in terms of ‘hope’ or the greater good of advancing science and medicine. Rather, the trial was discussed as an obvious treatment choice among several; a rare commodity that Mr. Smith could access only through the Davis Center because it was an investigator-initiated trial. The doctor conversed with the patient using a literally and figuratively shared language. At Social Hospital, Dr. Rao offered the trial as an option that might benefit science and might help the patient, but might also lengthen the patient’s treatment depending on the arm to which she was randomized.

Patients at Social Hospital often asked providers why they would want to participate in a trial when the standard treatment was effective and the experimental treatment offered little if any potential for personal benefit. Providers could not count on trials “selling themselves” to patients
hoping for a miraculous cure or because standard therapies were so poor. Rather, providers had to appeal to patients’ general sense of altruism or their specific feelings of obligation or gratitude to their provider, clinic, or community. Dr. Taylor often suggested to her patients that participation might help women with breast cancer 5 or 10 years down the road, and she told us,

For many women, the appeal of helping other women out is a very strong motivator. I think in part because our patients are getting something for free and feel a sense of debt for that and that this is one way they can pay back other people and help other people when they’re in a bad situation of their own. I rarely have people [say] “what’s in it for me?”

In the US, where health insurance and healthcare are privileges not rights, the idea that marginalized patients feel indebted for their care is not surprising. However, the idea that patients participate in trials because they may feel indebted to their providers deserves further investigation. Some patients found that even being asked to participate in a trial was burdensome. In the hallway of breast clinic, one patient told me that, as she remembered it, the doctor was telling her about recommended treatments and two people whom she had never met came into the exam room to ask her some questions about a trial. She felt that they had interfered with her ability to get the information she needed about possible treatments. Another Social Hospital patient, a 28 year old white woman who had just completed surgery, listened curiously and emotionally as Dr. Taylor explained the standard treatment for her diagnosis, and a clinical trial for which she was eligible. But she seemed dismayed to find that after Dr. Taylor left the exam room, Ana and I were still there. She looked up at us and asked in a tired voice, “What can I do for you?” To my surprise, Ana responded as if the patient could in fact do something for her: “please don’t say you’re not interested. If you sign the consent form today, I won’t do anything with it until you come back next week anyway. And you can always remove your consent.”
Clearly patients respond to the idea of participating in a clinical trial in varied ways. For some, even considering participation is an additional burden at a time when they may feel overwhelmed by all that accompanies a cancer diagnosis. For others, the concept of clinical research may be new; it must be explained with unknown capacity to achieve truly informed consent. The meaning of participation is clearly different when a patient participates to get what he perceives is the best treatment “opportunity” for a terminal condition compared to when a patient participates to pay back a perceived debt for “free” care. In these situations, the exchange of the benefits and burdens of research differ in critically important ways.

Who is giving and who is receiving the benefits and burdens of research may turn on the patient, the trial, the diagnosis, and the clinical context. In part, forms of exchange reflect the structural conditions that enable patients to access care in particular facilities and providers to access and open specific kinds of trials in certain types of institutions. From the point of view of recruitment, investigator-initiated trials in places like Davis Center have numerous advantages, not least the ability to offer patients access to otherwise-unavailable drugs or treatments. One Social Hospital provider stated that she would be more inclined to discuss a Phase I or II trial with patients because “the access to a new type of drug is a big motivator for me for something that's pretty widely known to be metastatic and incurable with a short life expectancy.” While this perspective perhaps involves some degree of “therapeutic misconception” on the part of the provider (and thus likely also the patient), providing a new investigational treatment that was only accessible through a trial not only seemed consistent with the emphasis on clinical care at Social Hospital, but also with the women’s health and AIDS activists who in the 1980s pushed Congress to act and facilitated the development of the inclusion mandate (Epstein 2007). At Davis Center, an oncologist recounted this kind of situation as fairly routine.

In kidney cancer we have two new drugs that were just approved. Going on a trial with any of those drugs was better than the standard of care and we all knew it, everybody
knew it; patients knew it, we all knew it and it was just a matter of getting patients on those drugs and, yet, you have to – until they become FDA approved they're experimental. So you run into this issue of saying, "Well, you have kidney cancer. The standard of care is to go on Interferon but we're doing a clinical trial with this or that drug and I really insist you go on this trial because I know that this drug is better for you." I don't think any of us felt ethically conflicted during that time period and certainly now we have other examples of that.

The goal of access to new experimental drugs is quite different from, and much more narrow than the mandate for inclusion of minorities in clinical research overall which involves many trials of drugs and treatment regimes that are not fundamentally new and that are not addressing an urgent matter of life and death.

While the types of trials and the forms of exchange they entail are not exclusive to particular institutional settings, we see clear patterns. The prevailing recruitment model at Social Hospital was altruism, in which patients were asked to participate for the good of society or the future of medicine and science; and in which some patients may be inclined to “give back” because they feel indebted for the “free” care they receive in the public hospital. The “gift” of participation is essentially a “return gift” made in exchange for the “free” care the patient has received from the State (Mauss 1954; Axler 2008; Rajan 2006). It reproduces the publicly insured patient’s position of being ‘in debt to society’ for ‘free’ care. At the Davis Center, we were more likely to see participation based on a sense of mutually perceived benefit. Patients participate because trials offer something to gain—a desired, and in some cases commodified form of care—while the investigator-clinician is partly motivated by the chance to complete the study. Here, the “gift” is an experimental treatment ‘opportunity’ for the patient, and in return the provider can complete the trial. Both scenarios reinforce structurally unequal positions of the
patients within a neo-liberal economy — with access to particular kinds of institutions that have access to particular clinical trials.

Strikingly, in the NIH Revitalization Act, inclusion is discussed as a third kind of exchange. Rather than an individual patient’s altruism or benefit, inclusion in research is viewed as a way to provide redress at a population level—to right a social wrong in the aggregate. However, in so doing, the Act does not account for the structural and institutional complexities that shape the processes of inclusion or the meaning of trials participation in a given clinic.

Recent proposals by bioethicists at the NIH suggest that research should be re-framed as an obligation or duty because research is a public good (Schaefer et al. 2009). But such proposals fail to adequately address how public goods are differentially distributed across social groups, or the increasing role of public-private partnerships in the “public” research enterprise.

Conclusions

This study of oncology clinical trials recruitment highlights how the practices of inclusion in clinical trials, and the relations of exchange such inclusions involve are conditioned by the “particularities of place” (Rajan 2006) which shape not only the patient populations in particular clinics, but also the research cultures and infrastructures, and the differential access to particular types of trials. While ostensibly supporting increased enrollment of minorities, the Davis Center, Social Hospital and trials’ sponsors (NCI’s Clinical Trials Support Unit) continued to allocate resources for trials recruitment based on a generic model of a well-educated, English speaking, middle class patient in a well-funded clinic. The Davis Center strategy for including more minorities in clinical research by expanding recruitment at Social Hospital absent efforts to address structural and institutional differences raises questions about the ethical and fair distribution of the benefits and burdens of participation in therapeutic oncology trials. Other strategies for increasing trials’ diversity – such as the NCI’s Minority Based Community Clinical
Oncology Program (MB-CCOP) – similarly aim to bring trials to places where there is a large minority patient population while also including additional resources for recruitment (McKaskill Stevens 2005; Kaluzny 1993). According to NCI, MC-CCOPs are successful, as they accounted “for less than 20 percent of the CCOP network but enrolled half of the minority patients in the studies” in 2003 (NCI Cancer Bulletin 2005). This institutional approach appears better positioned to address the goal of the inclusion mandate. It leaves unanswered, however, the broader issues of the nature of exchange relationships in attempts to change the racial/ethnic composition of biomedical research participants.

The practical daily realities of trials recruitment in resource-poor contexts like Social Hospital and in academic medical centers like Davis which have more substantial resources point to the multiple contingencies at stake in inclusion processes. Our data begs the question of whether including socially and economically vulnerable ethnic and racial minority patients is an expansion of “opportunity” or a burden on an already under-resourced system serving disenfranchised patients. The focus on recruitment of the so-called “hard to reach” ethnic and racial minorities rather than a focus on the institutional and social constraints that structure trials enrollment, moves the fundamental inequality in our healthcare system out of frame. Meanwhile it reifies social categories of difference that may undermine the goal of reducing health disparities while ignoring others, such as social class. As one Davis Center research nurse bluntly put it,

There is a part of me, the jaded part, that thinks: ‘how dare we try to improve recruitment’ because we are not doing it for the patients. It’s for the doctors and their careers, especially with underserved people. To pull them into studies for treatments that might kill them—we’ll end up killing more African Americans. If we really want to help underserved people we should have universal healthcare, so they can get the best treatment.
Thus, our findings support those of other ethnographers of clinical trials both within and outside the US, with regard to how inequities in access to care intersect with clinical trials research infrastructures and recruitment practices (e.g. Fisher 2009; Biehl 2007). Simultaneously, we extend the scope of such research by examining clinical trials recruitment in the context of public and academic medicine, rather than private, pharmaceutical industry trials where most ethnographic research on clinical trials has been conducted to date (e.g. Biehl 2007; Dumit n.d.; Fisher 2009; Lakoff 2007; Petryna 2009, Rajan 2006). Furthermore, our ethnographic examination of the practical and ethical implications of implementation of the Revitalization Act’s inclusion mandate extends Epstein’s work on the “inclusion and difference paradigm” (2007; 2010) by demonstrating how the biopolitics of inclusion and difference is playing out on the ground in academic medical center and public hospital cancer clinics. Our ethnographic data shows the equity premise of the Revitalization Act sitting uncomfortably alongside the participatory logics of recruitment for distinct reasons in each of our research sites. The logics accord different benefits and burdens to patients who choose to participate in clinical trials, and also to the providers who are tasked with recruiting them. The meaning of participation for a patient seeking the best treatment “opportunity” for a terminal condition differs in vitally important ways from a patient who participates to pay back a perceived debt for “free” care. Recruitment with the support of a substantial research infrastructure compared with recruitment in a resource poor context with limited commitment to the research enterprise and limited ability to access a full range of trials also makes for distinctive processes of inclusion. The homogeneous concept of ‘inclusion’ implied by the federal mandate, and in some of the ‘recruitmentology’ literature (Epstein 2008) fails to acknowledge how inequities in the health care system may be reproduced in the context of clinical research, and thus may inadvertently reinforce existing inequities. Consequently, it is far from evident how inclusion in clinical trials
might begin to address health disparities, or even fail to reproduce health and healthcare inequities.

Our study has some limitations. Clinical research in academic and public sector clinics and hospitals represent an increasingly small percentage of clinical research conducted in the US and throughout the world as a result of the phenomenal growth in pharmaceutical industry sponsored trials in the past two decades (more than 60% of trials overall) (Petryna 2009). Our findings are limited by the particularities of the two institutional settings where the research was conducted. In contrast to our sites, in some settings, where there is no public/county hospital, the academic hospital is the provider of last resort. Such a setting would likely have different clinical trials recruitment dynamics. Further research, perhaps of a non-ethnographic nature could better determine the extent to which the dynamics of trials recruitment, research infrastructure, and access to types of trials we have described here apply to other academic medical centers and public safety net hospitals across the US. Also, our research did not examine the quality of trials that reach each organization, or consider how quality of clinical trials in different institutional settings might be assessed. Finally, for this study, our focus was on providers’ roles and institutional context for ‘inclusion’ in cancer clinical trials. Therefore, we did not interview patients, and thus we did not have the opportunity to explore in depth patients’ perspectives on the recruitment process.

Despite these limitations, our research at Davis Center and Social Hospital raises critical questions about the relationship between clinical research and disparities reduction. The inclusion of marginalized members of our healthcare system may actually have the unanticipated effect of facilitating an unequal sharing of the risks and burdens of trials participation as well as the potential benefits. While the health benefits of Phase I and II trials are rare, and they typically entail greater risk than Phase III trials, they are sometimes perceived as a patient’s only hope, by both patient and provider. As we have seen, in cancer care, many providers consider trials a
critical component of good care. Furthermore, we consider here benefits and burdens beyond the risks and benefits discussed in a standard informed consent form. The burdens, as perceived by providers at Social Hospital, include not only patient participation in a process they might not fully understand (e.g. randomization), in extra exams that may not be covered by Medicaid and in a trial that likely does not offer access to a new medication, but also burdens on the providers themselves. They must take time to learn and then explain trials to those unfamiliar with research, in a chaotic clinic setting, where trials discussions may eat up the limited time they have to provide the basic care, which is their primary mission. Although the underlying premise of the NIH mandate is that inclusion may help to reduce health disparities and increase equity, our research suggests that multiple meanings of inclusion emerge in the daily practices of recruitment in these clinics, and addressing inequity is not primary among these meanings for many providers and patients involved in the process.
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