

Diversity of Participants in Clinical Trials in an Academic Medical Center

The Role of the 'Good Study Patient?'

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BACKGROUND: Only 2.5% of adults and even fewer minorities participate in cancer therapeutic trials. Researchers have concluded that many barriers to participation stem from how recruitment is performed by clinician investigators. The objective of the current research was to document specifically *how* these barriers impede recruitment in the clinical setting. **METHODS:** The authors conducted a case study of recruitment in an academic medical center using ethnographic research methods (direct observation of provider-patient interactions and in-depth interviews with providers) to collect data. Qualitative data analysis was used to identify themes related to the provider's role in the recruitment processes. **RESULTS:** In the clinics that were studied, the authors observed that providers subjectively assessed which patients seemed to be 'good study patients' to target for recruitment. 'Good study patients' were identified as those who were able to adhere to complex trial protocols, thus helping clinician researchers to complete studies in a timely and efficient manner. These patients were perceived as meticulous, proactive, and compliant; they were considered good communicators; and they were embedded in the kinds of strong social support networks that facilitated their trials participation. **CONCLUSIONS:** The providers that were studied sought 'good study patients' for therapeutic trials because they wanted to perform studies in a timely and efficient manner. Future research should examine whether providers in other settings also target their recruitment efforts for this or other reasons. Further research also should consider whether differentially recruiting 'good patients' can impact the ethnic/racial diversity or other characteristics of trial participants in ways that may bias the outcomes or conclusions of therapeutic trials. *Cancer* 2009;115:608-15. © 2009 American Cancer Society.

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Only approximately 2.5% of adult cancer patients enroll in clinical trials, and an even smaller proportion of trial participants come from minority backgrounds.^{1,2} A substantial body of literature addresses the challenges of recruiting cancer patients to therapeutic trials. Many articles report on research or interventions that address barriers to minority participation in trials. These barriers include lack of knowledge regarding trials, lack of trust of medical research or of the clinical research community, and other factors that affect patients' knowledge of, interest in, or willingness to enroll in a trial.³⁻⁶ It is noteworthy, however, that authors of a

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recent literature review also identified dozens of barriers to recruiting diverse patients to trials that impact investigators rather than patients, leading the authors to conclude that a major role is played by investigators in determining the extent to which trials are accessible.^{2,7} Research and interventions have sought to address patient and community factors that impede the recruitment of diverse study participants; it is also important to address clinic-based and provider factors that impede accrual to clinical trials.

Not all clinicians play an equal role in trials recruitment. National Cancer Institute (NCI)-designated cancer centers are charged with engaging in research to reduce cancer incidence, morbidity, and mortality. In addition, cancer centers are subject to National Institutes of Health mandates requiring clinical research to include and provide outreach to diverse populations.⁸ Thus, clinical investigators working in NCI designated centers play a crucial role in the advancement of clinical science through trials recruitment in general, and they also may be expected to take a leading role in attempts to include diverse populations in research. Nevertheless, cancer centers may find it challenging to recruit patients from 'minority' backgrounds to participate in cancer trials and to recruit a substantial fraction of their adult patients to participate in therapeutic trials.⁹⁻¹² Simply mandating the recruitment of more diverse patients to trials may not be sufficient to address clinic-based barriers to accrual. A better understanding of how cancer center investigators engage in trials recruitment may provide insights into how clinic-based barriers impede the recruitment of diverse populations and patients in general to cancer trials. An improved understanding of these processes also may help inform interventions to improve recruitment.

Currently, the research on how investigators go about recruiting patients within the clinic is relatively limited. Previous studies have used surveys of providers or administrative data, but there has been little direct observation of how trials recruitment occurs in day-to-day life. Our approach in this study was to examine 3 questions: 1) how do investigators within cancer centers seek to recruit patients to trials in everyday life; 2) what are the barriers to recruitment related to the provider's role in the recruitment process; and 3) how are recruitment activities related to clinic-based barriers to recruitment? Our expectation entering the research was that everyday life for clinical

investigators in a cancer center involved multiple, competing demands for attention and resources. We expected that some of these demands fostered or encouraged the recruitment of diverse patients or patients in general to trials but that other demands would distract clinical investigators from those goals. Thus, an important reason for undertaking this study was to discover whether there are ways either to reduce demands on investigators or to align the demands on investigators in a manner that could improve the process of trials recruitment.

MATERIALS AND METHODS

Study Design

The case study described in this article is part of a larger comparative project examining minority recruitment to cancer therapeutic trials in 3 settings: a nonprofit academic medical center (AMC), a public safety net hospital, and a private oncology practice. This article uses data collected during 7 months of ethnographic fieldwork at 2 site-specific cancer clinics at the AMC's NCI-designated comprehensive cancer center. Ethnography is defined as a scientific approach to investigating and discovering cultural and social patterns and meaning within communities, institutions, and other settings.¹³ To maintain the anonymity of study participants, we do not name the clinics where we conducted research, we use pseudonyms for all patients and providers, and we alter certain nonconsequential details of the sites.

Setting

The AMC sees approximately 5000 patients annually; and, in 2005, approximately 9% of patients were enrolled on therapeutic trials (unpublished results). We purposefully selected the site-specific clinics at the AMC to provide contrasting perspectives on recruitment routines. Although clinician investigators in both clinics actively recruited patients for research, 1 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 2 nurse practitioners (NPs). The other program had few core resources, so investigators depended on financial support from individual studies and relied on 2 NPs for research support.

Data Collection

We followed well described data collection procedures, including direct observations and in-depth interviews.¹⁴ Direct observation allows researchers to document, from a relatively objective standpoint, the actual behavior, everyday language, and specific meanings that individuals give to basic concepts such as patient compliance, including behavior that study participants may not be consciously aware of and, thus, may not report.¹⁵ In-depth, semistructured interviews generate data that illuminate the subjective perspective of research participants and, thus, help explain and contextualize the data gained through observation.¹⁶ Observations consisted of shadowing providers as they treated patients, including discussing trials with patients and conducting other tasks, and attending weekly research meetings and tumor board meetings. We observed 85 provider-patient interactions, including 39 discussions of clinical trials in the 2 site-specific AMC clinics. We recorded longhand notes in situ and wrote full field notes using word-processing software soon after leaving the field.

During the observations, we spoke informally with providers to gain insights into aspects of recruitment practices in the clinic. On 3 occasions, these informal conversations turned into extended interviews that we documented in detailed, handwritten notes and later transcribed into computer files using word-processing software, which is standard practice in ethnographic research. While conducting observations, it became clear that some providers had particularly rich understandings of recruitment processes in their particular clinic, and we asked those providers to participate in formal, tape-recorded interviews. We conducted 8 of these formal interviews with providers (2 MDs, 4 CRCs, 2 NP research nurses) using a semistructured, open-ended protocol that allowed participants to introduce substantive topics that we had not considered and to address topics in their own way.¹⁷ Topics included discussion of 'shadowed' observations, patient care responsibilities, activities related to clinical trials and general views of medical research, and personal and professional background. We voice-recorded the formal interviews and later transcribed these into electronic word-processing files. We conducted data analysis simultaneously with data collection so that emerging ideas, issues, and interpretations could inform ongoing fieldwork.¹⁷

The research protocol was approved by the appropriate institutional review board. We obtained verbal informed consent for observations and informal interviews and written consent for formal interviews. All formal interview participants were compensated \$20 for their time.

Data Analysis

To facilitate qualitative data analysis (QDA), we entered the word-processed field notes and interview transcripts into a qualitative database using Atlas-ti QDA software.¹⁸ Atlas-ti facilitated searching and coding all data, including field notes and interview notes and transcripts. We coded data according to substantive content to identify the key themes presented in this report.¹⁹ Coding is a procedure to label raw data according to substantive content to facilitate data retrieval and interpretation. Each research project has a unique coding scheme, and ours reflected our interest in social criteria used for enrollment.²⁰ The first author conducted most data analysis, including writing memos that highlighted interpretations, findings, and examples that emerged during the coding process. The second author independently reviewed data and codes to check analytical reliability, but we did not formally assess intercoder reliability.

RESULTS

Characteristics of the 'Good Study Patient'

A central finding of this study was that providers used a complex, flexible, and subjective process to assess which patients might constitute 'good subjects' for particular trials. While seeking a good outcome for patients and responding to research program leaders' pressure to 'compress the timeline for studies' and publish study results, providers (physicians, nurses, and CRCs) considered the patient's match with the protocol, the trial's need for research participants, and the clinic's ability to provide appropriate support for patients on trials. In considering patient-protocol match, providers evaluated cancer-specific criteria (eg, site, stage, previous treatment), comorbidities that might or might not be specified in the protocol, and social criteria suggested but not specified in the protocol (eg, ability to make 'extra' clinic visits). This

subjective assessment led providers to conclude that it made sense to commit limited research resources, such as trial slots and providers' time, only to certain patients. Providers believed that these 'good study patients' would be better able to adhere to the complex protocols and would enable them to complete their studies in a more efficient, less burdensome manner. In evaluating who was likely to be a good study patient, providers used various types of information, including the patient's employment, behavior during prior treatments (eg, keeping notes), approach toward future treatment (eg, getting second opinions, 'shopping' for trials), and their own subjective assessment of the patient's personal and social characteristics. They generally favored patients who seemed meticulous, proactive, and likely to comply; patients with whom they could communicate easily; and patients who had social support to facilitate participation.

Personal and Social Characteristics of the Good Study Patient

Adherence, generally called 'compliance' by the AMC providers, was a major concern given the numerous appointments and tests required of research participants. A CRC said that, without compliance, 'it's like dominoes, if one gets knocked over, the whole thing just falls apart.' Patients who appeared to be meticulous were seen as more likely to be compliant, as illustrated in 1 physician's characterization of a patient as a 'perfect candidate' for a trial because 'he would follow the rules and really comply. . . . He is a meticulous guy—works at a bank.'

Meticulousness was prized, but physicians appreciated that being detail-oriented could become a double-edged sword. Some patients mastered the details of a trial's protocol, using this mastery to address individual needs. For example, an oncologist expressed frustration with his patient, a man who had been calling in sick and missing every other treatment. According to the oncologist, his patient 'was concerned that the [study drug] was preventing [a shoulder injury] from healing properly.' The patient was a competitive swimmer, so the injury was diminishing his quality of life, and the oncologist was sympathetic, 'it's possible he's right, actually, but it's a side effect that we can't grade and say it is a reason to hold treatment.' The oncologist wanted to 'accommodate' his patient, because the drug seemed to be effective in fighting

his cancer, but it was only available on study. Struggling to address his patient's health needs while maintaining the integrity of the research and the timeline for completing the study, the oncologist concluded that he would have to inform his patient that, 'if this continues to happen. . . then we're going to have to take you off the study.' Meticulous patients may help providers complete studies, as this example illustrates; but they also may learn to 'game' protocols to suit their individual needs and, thus, challenge researchers' ability to gather data effectively.

The AMC also attracts some patients who actively are seeking out or 'shopping' for a clinical trial. Such patients have decided to participate in an experimental treatment before arriving at the AMC, either because standard treatments offer little or no hope (eg, for advanced pancreatic or lung cancer) or because, after several treatments, their disease is progressing. For example, we observed the first appointment of a patient who recently was diagnosed with stage IV cancer and was accompanied by his wife. The physician asked questions concerning work and family, and the patient described his executive position at a high-technology company and his children's attendance at East Coast prep schools and colleges. The physician responded, 'Well you both seem extremely bright;' then, the patient and his wife acknowledged that they both already had talked to 2 other oncologists, read about various trials in the United States and Europe, talked to the physician's research nurse about this trial, and read the trial's consent form. The physician agreed that a clinical trial was the appropriate choice 'for someone like you.' The patient informed the physician that he already was scheduled to start an experimental protocol elsewhere the following week. Thus, the question as the appointment continued was whether the patient would choose this physician's trial or go elsewhere. The patient expressed concern regarding the legal language in the consent form and concerning the level of service or 'handholding' he could expect. The physician reassured the patient about the consent form and promised that telephone calls to his research nurses would be returned within the hour. The patient concluded that participating in the physician's trial was 'close to a no-brainer.' The physician hesitated about the patient's plan to continue working, warning that treatment had to come first, 'particularly if you are doing a study protocol.' The physician wanted to be sure that compliance with the trial protocol

would be the patient's priority. This example illustrates that providers may discover that highly motivated, proactive patients constitute a double-edged sword. These patients could decide quickly and efficiently to join a trial and successfully comply with a complex protocol. At the same time, they may expect providers to be similarly proactive in responding to questions or concerns, and their independence could make them 'difficult' to manage.

Communication and the Good Study Patient

Providers considered whether they would be able to communicate effectively with patients. For example, during the visit of the second patient described above, the oncologist clearly valued the patient's ability to ask 'all the right questions [and to] understand the uncertainty' of being on a trial. In this interaction, the oncologist and patient communicated effectively to come to a mutual understanding regarding the costs and benefits of the trial for the patient. Providers often struggled to achieve this kind of clear and effective exchange with patients who were less well informed regarding clinical research. Providers also preferred that the logistics of communication be unproblematic. One physician, who considered effective communication 'a top priority,' expressed concern about patients who were hard to reach; noting that, if 'they had some labwork done. . . and you have no way of reaching them, something very bad could happen to them because [the trial is] experimental.'

Given concerns regarding communication, providers sometimes considered patients with limited English proficiency (LEP) poor candidates for clinical trials participation. These concerns could be mitigated if the LEP patient had family or others who could speak English well and communicate effectively on the patient's behalf. For example, 1 nurse who provided symptom management care by telephone everyday found the telephone interpreter service difficult and time-consuming; however, using family members for interpreting raised privacy issues. He also could not help wondering whether the family may have been 'sugar coating my messages or the patient's [messages] to me.' Conversely, the AMC had limited interpreter services, so family members often seemed to be the only practicable way to recruit and retain an LEP patient on trial. One physician noted that LEP

patients often had many of the characteristics of 'good candidates' for clinical trials 'because they're motivated by coming here, they tend to have motivated families;' however, the ability of LEP patients to be considered 'good study patients' depended on having 'family members who speak English and so they are able to coordinate the care.'

Social Structural Factors That Facilitate Protocol Adherence

We observed that providers were reluctant to offer trials to patients whose social situation, distance from the AMC or lack of social support, might make them less likely to complete a study protocol successfully. The distance from the treatment site was burdensome, particularly for the nurses who closely monitored patients for adverse events and treatment side effects. One NP admitted that he preferred to enroll individuals who lived in the area, because 'it is easier to provide nursing care to people who are local – easier to call in prescriptions, to arrange for x-rays.' Another nurse mentioned that coordinating with patients' local providers, if they lived far from the AMC, could complicate and thereby increase the nurses' workload. In addition, retention was a concern: 'if someone has to sit in the car for 3 hours to get treatment. . . it is a real burden. . . people may be gung ho at the beginning but once they start driving. . . and they're having symptoms and side effects, it gets a lot harder.' Thus, geographic barriers could make even a motivated and proactive individual a less than ideal study patient. Because the AMC drew approximately 1 of 3 of its patients from outside the local urban area (unpublished results), providers regularly encountered patients for whom geography and transportation might be perceived as barriers.

Similarly, if providers perceived a patient as lacking in social support, then that patient did not meet their 'good study patient' criteria. Some providers hesitated to enroll patients they perceived as lacking support because they believed such patients might be unable to comply with complicated regimens, ask the AMC for support they would get otherwise from their social network, and be a higher risk for a poor outcome when receiving a potentially risky experimental treatment. One physician stated, 'We see people here. . . who obviously aren't good research candidates because they can't comply with complicated regimens [because] they don't have the support network and all.' Providers believed that patients might

need help keeping track of appointments, completing tests and treatments, and communicating effectively about symptoms and side effects. Patients with less social support were perceived as more likely to consume institutional resources, such as physicians' and nurses' time. According to 1 oncologist, patients without such social support 'aren't necessarily included in clinical research. . . we are in the situation where you have limited resources and so we have to focus on the people' who are able to comply with the help of their own support network. Finally, providers worried that patients who did not have a 'stable social situation and home life' might be exposed to 'excess risk' on an experimental treatment. Another physician noted, 'you could kill someone very easily if they decide to not call us back or not get the labs done. . . so people who have marginal social situations I think it's often not safe to put them on clinical trials.'

DISCUSSION

Enrollment in therapeutic clinical trials for cancer is a complex process that is shaped by many factors, both biomedical and social. Although some of the literature on recruitment has addressed the influence of provider attitudes,^{7,12,21-23} the current case study illustrates *how* providers subjectively evaluated social criteria in deciding which patients to recruit for clinical research. In assessing a patient's appropriateness for research, providers sought to balance the patient's clinical needs with their own need to complete trials in a timely fashion by focusing their recruitment efforts on patients who could adhere successfully to complex protocols. Providers believed that patients who were compliant, meticulous, proactive, motivated, and effective communicators constituted 'good patients' for trial enrollment, although they also appreciated that some of these same qualities could make patients more difficult to retain and manage once on trial. Providers also considered barriers such as transportation,^{3,24} social support,²⁵ and language.¹² Researchers have tended to conceptualize these barriers as discouraging patients from seeking trials enrollment.² Here, we suggest that the providers' perception of these 'patient' barriers may impede their willingness to offer enrollment.

Our findings have several limitations. An ethnographic case study design allows us to examine the micro-level interactional dynamics of recruitment in an exploratory manner, but it precludes generalizing.

Although it is plausible that providers in other academic centers also consider who may be a 'good study patient,' additional studies are needed to examine whether this is true empirically. A related limitation is that we cannot determine whether or how the 'good study patient' is understood differentially by physicians, nurses, and CRCs or how provider training may shape these understandings. Larger provider samples might reveal such distinctions and, thus, further our understanding of the trials recruitment process. Another limitation of our study is that the ethnographic research methods we used cannot be replicated precisely. Thus, it would be helpful to operationalize the concept of the 'good study patient' quantitatively. Patient demographic information or provider surveys might be able to test for a 'good study patient' effect and how provider roles and training impact its influence on the recruitment process in different clinical research settings.

While remaining cognizant of this study's limitations, its implications for understanding how trials are conducted and interpreted are worth considering. Anthropologists have demonstrated that the local context in which healthcare is delivered shapes medical practice and what providers consider reasonable care.²⁷⁻²⁸ Local context helps explain why AMC providers saw some patients as 'good' for studies and targeted these patients for recruitment. Providers working in other contexts also may target certain patients for recruitment, but they may use different personal or social criteria to decide which patients are 'good' for studies. Our research in other settings suggests that this may be the case. In the safety-net setting, some providers believed that any patient who expressed an interest in clinical research participation could be a good study patient; in the private setting, the practice earned substantial income by enrolling eligible patients on industry trials so that providers would appear to be focused on biologic eligibility rather than personality or social characteristics. Future research should examine the extent to which practical and logistical elements of local context shape providers' assessments of patients' suitability for clinical research as well as how assessments may vary in different kinds of research settings.

Another implication of this study is whether and how recruiting 'good study patients' may shape the results and conclusions of clinical research. At the AMC, the providers' preference for recruiting 'good study patients'

appeared to undermine the cancer center's goal of enrolling patients from diverse ethnic-racial groups on trials. Interventions that change the clinical context of recruitment, eg, by providing more support for patient transportation or making consent forms easier to understand, may help align providers' rational interest in efficiently conducting trials with society's interest in including a diverse sample of individuals in clinical research.

Finally, our findings may have implications for the validity and generalizability of clinical research. Clinicians may not seek to oversample 'good study patients,' but contextual factors may lead them to do so anyway. If studies are more likely to include patients like those described above who 'shop' for a preferred trial and 'game' their participation, then how should the results be interpreted? In terms of biologic efficacy, we know of no evidence to suggest that patients who are meticulous, proactive, compliant, effective communicators, and well supported socially differ from the general population in terms of their response to cancer therapies. In terms of effectiveness, however, there may be cause for concern. Providers target 'good study patients' precisely because of their ability to understand and adhere to complex therapeutic protocols. Results from these studies may overstate the effectiveness of an intervention in a real-world setting with patients whose personalities and social characteristics may hinder their desire or ability to adhere to treatment. This implication is significant given the interest of policymakers in comparative effectiveness research.²⁹ Our qualitative data cannot address this issue, but other methods, such as a retrospective comparison of outcomes from clinical trials versus clinical practice, should be used to examine this issue.

Conflict of Interest Disclosures

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