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Recruitment of African Americans to National Oncology Clinical Trials through a Clinical Trial Shared Resource

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Summary

In 2000, using National Institutes of Health/National Cancer Institute (NIH/NCI) U54 funds, a clinical trials shared resource was established at Nashville General Hospital at Meharry to attract more African Americans to national cancer clinical trials. This Report from the Field describes the model used to achieve this end.

Keywords

Clinical trials; African American; recruitment

Clinical research is essential for improving cancer care, including the testing of novel agents and incorporating combinations of agents into clinical use as quickly and safely as possible. Approximately 20% of adult cancer patients are medically eligible to participate in a cancer clinical trial, but only 2.5–9% of all adult patients do so[1–4] delaying completion of trials and efficacy assessment of new agents.[5] Accrual is even less for minority and medically underserved populations, and this limits the generalizability of results. A clinical trials shared resource (CTSR) can positively influence accrual to cancer clinical trials.

Disparities in cancer detection, treatment, and mortality have been studied for more than three decades. Two Institute of Medicine reports note that racial and ethnic minority patients often receive lower quality health care than non-minorities, even when insurance and income are controlled.[6–7] In 1993, the National Institutes of Health (NIH) published guidelines for the inclusion of women and minorities in all sponsored research, including cancer treatment trials. Yet minority and low-socioeconomic status (SES) people remain underrepresented in clinical research. This low participation is due to logistical, informational, attitudinal, and sociocultural barriers.[8] Justification for incorporation of minority patients includes the possibility that disparate results might be noted for these patients based on socioeconomic or genetic differences. Furthermore, some cancer diseases, such as basal type (*triple-negative*) breast cancer are more prevalent in minority populations and accurate assessment of clinical research requires their inclusion.[9]

Barriers to clinical trial participation have been identified from the perspective of both patients and providers. Patients and community participants cite fear, suspicion, and mistrust of researchers and medical research.[8,10–12] Patients also report lack of awareness and limited knowledge of health studies, limited community involvement in study design, potential

negative side effects, and use of invasive procedures as barriers to participation.[13,14] Logistical concerns such as lack of transportation, interference with work/family responsibilities, and burdensome procedures limit participation;[14] financial concerns cited include lack of insurance or insurance coverage and out-of-pocket expenses.[15]

An analysis of patient reported barriers to participation from 12 qualitative and 21 quantitative studies grouped issues as protocol-related, patient-related, or physician-related. [16] The most common barriers cited by patients concerned the trial setting, dislike of randomization, general discomfort with the research process, complexity and stringency of the protocol, presence of a placebo or no-treatment group, potential side effects, being unaware of trial opportunities, the idea that trials are not appropriate for serious diseases, the thought that trial involvement will have a negative effect on the patient-physician relationship, and physician attitude towards the trial.[16]

Barriers cited by physicians are more varied. Additional time is required by the physician to find the trial, to establish eligibility, to explain the protocol and side effects to the patient, to obtain informed consent, and to perform the additional work associated with the study.[2,10] The physicians also report that the literacy level of most informed consent documents is too high, adding to the time needed to explain the research.[10] Physicians identify patient cost issues related to lack of insurance, lack of medication coverage, and increased time needed for completing paperwork related to indigent drug programs as barriers.[10] There are often insufficient resources to address these additional requirements[17,18] as well as the extra costs of research personnel,[10,11] while at the same time there is increased pressure for the physician to see more patients.

Physicians also report minority and low-SES patients often do not fit stringent eligibility criteria due to advanced disease at diagnosis and presence of co-morbidities.[10,19–21] Delayed referral and delayed completion of staging testing can also render the patient ineligible due to the lapse of time between diagnosis and start of treatment.[10,19] Community physicians report a lack of awareness of available cancer clinical trials.[14,17] There is also researcher and health care provider bias about the desire and ability of minorities to participate in research[5,6,22] and physician bias regarding the clinical relevance of studies, treatment preference, study duration, and follow-up requirements.[22]

Race and low SES are often cited as barriers to clinical trial participation.[23] Research results differ in the role of race in predicting trust in physicians and research. Some studies found race predicts trust of the medical and scientific community,[3,24–28] while others found that race does not predict trust.[8,29,30] Wood et al. reported no difference between White and non-White participants regarding interest in learning about clinical trials and no difference in rate of previous or current trial enrollment.[31] The literature suggests Whites of lower economic status are less likely than Whites of higher socio-economic status to participate in medical research. [32–34] Studies show minority groups are as willing to participate as Whites, but are less likely to be invited to participate, and those who participate in clinical trials are more likely to be insured and have higher socioeconomic status. Researchers have alluded to the idea that access, not willingness, is where the difficulty lies in recruiting and maintaining minority research participants.[2,10,35,36]

Recommendations to overcome barriers to clinical trial participation include careful planning to address the additional needs of minority and low SES patients,[37] reimbursement for travel to site,[11] and making study site locations accessible or convenient for patients.[11,13] Study staff should be representative of the minorities sought for participation.[11,38] Staff must exhibit sincere commitment, honesty, and patience[11,37] and be prepared to take the time necessary to

explain the research in understandable terms.[37] It is recommended that staff foster personal attributes of flexibility, sensitivity, and adaptability.[38]

Gorelick et al. have described a *recruitment triangle* made up of the patient, key family members and friends, and the patient's primary medical doctor and other medical personnel. [37] The walls of the triangle are held together by social support, education about the nature of the research, and trust in study personnel and the overall program. In order to increase likelihood of successful recruitment and retention of patients in clinical research, the researchers must maintain and support the key components of the triangle.

Additional facilitators for participation identified by patients include financial remuneration, free parking, childcare, flexible times for study visits, health information, and physical exams by physicians.[13] In addition, community participants suggest that providing adequate information about the purpose and benefits of the study and having the request come from a pastor or physician will increase the likelihood of study participation.[13]

Strategies to overcome barriers to minority access are prerequisites to improving minority recruitment to clinical trials. There are few reports describing the infrastructure and resources needed to support minority access to cancer care and clinical trial participation.[22,39,40] Infrastructure includes providing adequate time for clinician-patient discussion of clinical trials as well as adequate research staff for recruitment and maintaining patients on trial. Infrastructure also includes staff with expertise in locating and facilitating additional resources for patients with few financial resources. Information systems to ensure consistent recording of intake demographic information at all points of entry into the organization allows aggregation of information to identify where the system breaks down. In addition, it is critical to reduce organizational barriers, such as accepting insurance of those with Medicaid and facilitating timely completion of documents for disability and indigent status.

Over the past decade, our clinical trials shared resource (CTSR) has developed an extensive program and culled various resources for conducting clinical trials in a public safety-net type hospital. Taking into consideration the many issues of clinical trial accrual, we prospectively identified and studied patient accrual. The objectives of this program were to evaluate the results of our clinical trials program that was designed a) to enhance recruitment and retention of African Americans in national cancer clinical trials and b) to validate our model of clinical trial recruitment designed for maximizing accrual. This report will describe the process of model development, the final model, and the outcomes concerning African American accrual to cancer clinical trials.

Model Development

In 2000, using National Cancer Institute (NCI) U54 funds, a clinical trials shared resource (CTSR) was established at Nashville General Hospital at Meharry (NGHM) to attract more African Americans to national cancer clinical trials. The U54 partnership assisted Meharry Medical College (MMC) to be accepted as a Minority-Based Community Clinical Oncology Program by the NCI in 2003. These resources provided sufficient funding to develop and sustain a complete clinical trials program for accrual to national cancer clinical trials. Prior to the formation of the CTSR, there were no cancer clinical trials being conducted at NGHM.

Meharry Medical College is a minority-serving educational institution with NGHM serving as its clinical facility. Both MMC and NGHM are centrally located in Davidson County, Tennessee, in which, according to the 2000 and 2005 Census information, the overall proportion of the population that is African American was 25.9% and 27.4%, respectively. The NGHM, as the public hospital, provides outpatient and inpatient care predominantly for

patients who are under-insured and uninsured; 55% of the NGHM patients are African American.

The development of the CTSR recruitment model had three phases. Phase one occurred during the first year of operations (2000); data were collected to identify barriers to timely initiation of treatment and clinical trial participation. Questions were proposed by the research team to understand a number of barriers: a) missed appointments (How does the patient enter the system? Who makes the appointments? Who reminds the patient?); b) missed communication (How is the physician notified of the pathology results? How does the patient find out?); c) missed rides (Does the patient have transportation? How reliable is the transportation?); d) lack of insurance (What is the process for patient registration? Who helps the patient apply for assistance? What are additional resources?); and e) lack of understanding (What is the patient's understanding of the diagnosis? Who influences the patient?). As barriers were identified, the research team developed strategies to address and overcome each one.

For the second phase, a model for screening each newly diagnosed patient for clinical trial eligibility was developed and implemented (Figure 1). The model defines procedures and assigns accountability for each step of the procedure. All pathology reports are reviewed by the clinical trials research staff. To address the requirements of the Health Insurance Portability and Accountability Act (HIPAA) implemented in 2003, the NGHM Cancer Committee mandated that all patients with a cancer diagnosis be evaluated for clinical trial eligibility. Upon review of the pathology reports, cancer cases are identified for management by the CTSR staff. The patient information is entered into the program's database and a screening list is generated. Each patient is assigned to a research nurse for follow-up. The research staff uses the list to monitor and report the progress of the patient through the hospital system, arranging appointments and referrals as needed for diagnostic work-up and staging. This model was designed proactively to identify and navigate patients to and through the cancer program with an emphasis on clinical trial participation.

The team, consisting of research staff, physicians, and clinical staff, meets weekly to discuss the status of each patient up to the point of starting treatment. If a clinical trial study is available for the patient's cancer site and stage, the research nurse notifies and assists the physician. When there are issues such as transportation for daily radiation, the research nurse advises the physician of the potential obstacle and the plan to address it. Once the physician has spoken with the patient regarding the diagnosis and treatment options, the physician introduces the research nurse who assists the patient by reviewing the clinical trial. All eligible patients are offered study participation regardless of lack of resources such as transportation, prescription insurance, or caregivers. The research staff members assume responsibility to ensure needs are met.

Upon iterative analysis of data from the first and second phases of the study (2001–2004), the model was refined further. A twice-yearly review of studies open and studies available is conducted to ensure that the studies available match the disease site and stage of the patients being screened (Figure 2). Results of the third phase of the study (2005–2007) indicate continued increases in accrual. In 2009, a Research Nurse Navigator was added to the team to further enhance enrollment. Evaluation of the effectiveness of adding the Nurse Navigator is ongoing.

Measures

To record demographic and screening outcome information, the authors developed a clinical tracking database for each patient screened as advancement to the original collection of data by simple spreadsheet tabulation. Currently, all cancer patients are captured with detailed

records on the program's Access database that was designed to be accessible for data entry and review by the clinical research staff.

Demographic data used for the study include race, ethnicity, insurance status, and diagnosis. Detailed information was recorded from 2001–2004 to understand why patients who had a study available did not participate in the study. These responses were grouped to inform data collection for the third phase of the study. From 2005 to the present, there are two outcome variables, study availability (available, patient eligible; available, patient not eligible; study not applicable; study not available; refused treatment) and study outcome (on study, treated off study, no treatment offered, refused treatment, refused research).

Outcomes

Initial barriers to participation were identified as missed appointments, lack of transportation, inadequate insurance, miscommunication, and lack of patient understanding. From 2001–2004, 569 patients were screened for a clinical trial, 164 (29%) had a study available and 95 (17%) were accrued to a clinical trial and noted as on study (see Table 1). Overall, 95 of 164 (58%) of patients offered a study agreed to participate. Of patients who did not go on study, 66% (n=48) were ineligible due to co-morbidities and only 3% (n=3) were noted as refusing to participate in a research trial (Table 2). A second analysis was done after refinements were made to the model. From 2005–2007, 556 patients were screened, 179 (32%) had a study available, and 138 (25%) agreed to participate (see Table 1). Overall, during this period, 138 of 179 (78%) patients were entered onto a clinical trial. Of patients who did not go on study, 50% did not have a study available, 5% were not eligible, and 4% refused treatment (Table 3).

From 2001–2007, 1,125 patients have been screened, 343 (30%) had a study available and 233 (21%) have enrolled. Overall, 68% of those eligible for a study agreed to participate in a clinical trial. Of those on study from 2005–2007, 61% were African American, 36% White, 2% Hispanic, and 1% Asian Pacific Islander.

Challenges and Lessons Learned

The model of patient recruitment presented in this paper addresses many of the barriers to clinical trial participation cited in the literature. It is clear that the barriers to participation are multi-faceted and no single strategy produces significant improvements in enrollment.

To engage successfully in minority recruitment, the institution must have community trust and an infrastructure that attracts minorities.[8,22,25] Like other local and state-supported institutions, NGHM provides access to health care for medically under-served persons, which includes minorities and uninsured patients. The facility does not discriminate or ration care based on the ability to pay. Both MMC and NGHM have a longstanding relationship with the community. The development of the cancer program at NGHM and establishment of the CTSR allows patient access to state-of-the-art cancer care at a site that is accessible and familiar. The patient does not have to be referred elsewhere in order to participate in a clinical trial. Organizational barriers that are common in public hospitals such as inadequate organization and delivery of health care services, inaccessible locations, limited hours of operation, and lack of awareness of available programs and of available opportunities for financial assistance have been addressed.[22] The cancer facilities at the NGHM include ample clinic and chemotherapy infusion space that provide a suitable professional and supportive environment for the cancer patient.

Three crucial points in the flow of patients from diagnosis to enrollment have been identified.[2,41] The first occurs after the diagnosis is confirmed and staging is underway when the availability of trials is determined. At this point, study availability is determined and the

physician is made aware of possible research protocols. The CTSR staff begins discussion with patients early and proactively in the cancer evaluation and treatment process.[42] The second point is initial eligibility assessment, when there is often disqualification of participants due to co-morbidities, insurance, or logistical issues such as transportation. The third critical point is when the patient is approached. The timing of recruitment plays a role in overall acceptance and participation. Patients approached shortly after learning of their cancer diagnosis report feeling vulnerable[31] and 40% of new diagnosed patients who have a trial available refuse to participate.[21]

In the model presented, the research team identifies the patient at the time of pathologic diagnosis before staging is complete. This allows one to two weeks during which information is collected, needs are assessed, and potential studies are identified. Staff members develop and augment strategies to address obstacles that can be modified such as insurance or transportation so delays are avoided which may make the patient ineligible. Although tests solely for research purposes are not conducted prior to patient consent, the research staff can advise physicians of eligibility requirements during the staging process. By conducting assessment in tandem with the initiation of care, the research staff assists to limit the physician burden with either identifying available trials or dealing with potential obstacles.

This model allows the physician to know what study is available for the patient's disease site and stage and if the patient is eligible according to a preliminary screening at the time when the physician is ready to discuss treatment options with the patient. The physician is thus able to offer the clinical trial in the context of discussing initial treatment and not as an afterthought. All patients receive assistance with transportation, financial resources, and logistics, whether on a clinical trial or not.

Research suggests that physician referral is one of the most effective means of recruiting patients onto cancer clinical trials[2,43,44] as they serve as gatekeepers.[17,18,45,46] In addition, physicians who value minority recruitment are more successful in recruiting minorities.[47] Through consistency of approach, the research staff interacts with all physicians who care for patients with cancer. The primary care physician is contacted once pathology results are known and staff offer to assist in referrals to medical, surgical, and radiation oncologists. Surgeons are notified of the availability of neoadjuvant and adjuvant trials in order to coordinate care and tissue collection. Since the outcome of every patient who had a trial available is discussed at the weekly team meeting and recorded in the database, there is peer accountability to support the program.

Once the physician has introduced the clinical trial option to the patient, the Research Nurse discusses the study details with the patient. Providing adequate time for clinician-patient discussion of clinical trials as well as adequate research staff for recruitment and for obtaining informed consent are critical to the process.[22] The Research Nurse reviews the consent document and study calendar with the patient and family members. To allow time for discussion and acceptance, the preferred method is to allow the patient to take the consent form home, discuss the study with family members, and return at a later time to sign the consent form.

The accrual rates in this study are more than double those reported in the literature. Only one report for specific comparison was found from a similar minority-serving institution.[14] In a one-year period the eligibility rate for clinical trial participation was 8.5%, (20 of 235) and there was 60% enrollment (12 of 20) among those eligible. Co-morbidities caused 17.1% to be ineligible and another 10% were ineligible due to advanced stage and poor performance status. There was no protocol available for 24.2% of the population. Our records, especially after refinements to our process in 2005, indicate a higher percentage of patients eligible for and enrolled in clinical trials.

Limitations

There are limitations to the descriptive report made here. The patients come to NGHM for care and are not recruited specifically to participate in clinical trials. Thus they may not represent the community that does not seek care. Most of the patients do not have other options for health care due to their lack of insurance and may exhibit bias for their care to include participation in clinical research. Although not ever used as an incentive, provision of less costly care by coverage of medications and tests by the clinical trial could also be influential. Despite efforts of the research team to avoid coercion, the patient may feel compelled to accept the research recommendation. Finally, it must be noted that in the second period examined, the trials were therapeutic, cancer control, tissue collection, and registry analysis.

Conclusion

Our records support the view expressed by others that the primary problem with accrual is not the attitudes of patients, but rather a system issue that includes the loss of potential participants as the result of the unavailability of an appropriate clinical trial and the disqualification of large numbers of patients.[8] We attribute our success in recruitment to a proactive approach, adequate resources, additional time and effort allocated for the informed consent process, decreased logistics, and cultural sensitivity of the research staff.

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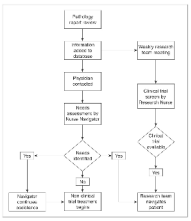

Figure 1.
Clinical trial recruitment process.

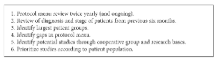

Figure 2.
Steps for regulatory review to match trials available and trials needed.

Table 1

SCREENING RESULTS (2001–2007)

Year	Screened	Study Available	Placed on Study	Total Accrual Rate	Actual Accrual Rate
1	154	32	15	10%	47%
2	108	38	17	16%	45%
3	145	44	27	36%	43%
4	162	50	36	22%	58%
5	138	29	19	14%	66%
6	184	59	53	29%	90%
7	234	91	66	28%	73%
Totals	1125	343	233	21%	68%

Table 2

REASONS PATIENTS DID NOT GO ON STUDY (2001–2004)

Reason	N (%)
Co-morbidity	19 (27)
Eligibility	17 (23)
Performance status	12 (17)
Refused treatment	8 (11)
Prisoner	5 (7)
Refused research	3 (4)
Refused specific trial	3 (4)
Returned to local physician	2 (3)
Insurance denial	1 (1)
Lost to follow up	1 (1)
Transportation	1 (1)

Table 3

OUTCOME OF SCREENED PATIENTS (2005–2007)

outcome	%
Study available, patient eligible	33
On study	30
Refused research	2.5
Treated off study	0.5
Study available, patient not eligible	5
Treat off study	4.5
No treatment offered	0.5
Study not applicable	8
Treat off study	7
No treatment offered	1
Study not available	50
Treat off study	46.5
No treatment offered	3.5
Refused treatment	4