

Factors Influencing Physician Referrals of Patients to Clinical Trials

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Purpose: Initial trials in the NIH Parkinson's disease (PD) network (NET-PD) included 91% Caucasian non-Latino patients, although PD is thought to be as common among African Americans and Latinos. Our purpose was to assess physician attitudes and beliefs about patient recruitment, particularly minorities, into clinical trials.

Methods: We surveyed 200 physicians from areas near the NET-PD clinics with >40% African Americans or Latinos. Physicians were asked about attitudes toward research, likelihood of referring patients to PD trials and past research participation and administered the Trust in Medical Researchers Scale (TIMRS). Using logistic regression, we identified physician characteristics associated with patient referral to clinical trials.

Results: The TIMRS was lower among African American physicians and physicians with high proportions of minority patients. Likelihood of trial referral was associated with previous referral to trials (OR=1.24; 95% CI: 1.09-1.42) and higher TIMRS (OR=1.06; 95% CI: 1.001-1.12). TIMRS results were similar among physicians not previously referring to trial.

Conclusions: Study results emphasize the importance of developing a trusting relationship with local physicians. If investigators expect these physicians to refer their patients to clinical trials, the trust-related barriers to minority-serving physicians, regardless of their own race/ethnicity, seem to mirror the trust-related issues for their minority patients.

Key words: patient-physician relationship ■ clinical investigation

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Including minorities and particularly, elderly minorities, in medical research is particularly important in light of evidence of potential racial and ethnic differences in response to treatment.¹ Yet a common barrier to the development of new knowledge for medical problems affecting racially and ethnically diverse populations is the ability to enroll diverse patients in research studies. In 2 recent studies conducted by the NIH Exploratory Trial in Parkinson's Disease Network (NET-PD), 91% of participants were Caucasian, non-Latino, even though incidence and prevalence data on Parkinson's disease (PD) suggest PD occurs as frequently in African Americans and Latinos.^{2,3}

While many trials have used community approaches to recruitment, these approaches have not been successful for PD. This lack of success may be attributable to the general low prevalence of PD. In the United States, 600,000 to 1 million individuals have PD, while approximately 13 million individuals have coronary heart disease (CHD), a condition where community recruitment is effective.^{6,7} Another potential reason may be that physicians play a significant gatekeeper role in referring patients with PD to clinical trials.

NET-PD is conducting a large phase-III trial, and investigators hypothesized that it would be more efficient to encourage local physicians to refer patients with PD to the trial than to continue their community recruitment efforts. Thus, the National Institute of Neurologic Disorders and Stroke, the agency funding the trial, was willing to fund an ancillary study to randomize sites within the NET-PD trial sites participating in the new NET-PD trial, to a recruitment intervention or control. Since there was no well-tested recruitment approach to encourage physicians of patients with PD to refer to the trial, we conducted a survey of physicians regarding issues related to referral of patients to clinical trials. The purpose of this study was to investigate factors related to physician referral of patients, particularly minorities, to clinical trials for PD.

METHODS

Participants

Participants were community family physicians, internal medicine physicians and neurologists. A ran-

dom sample of 1,250 was drawn from the American Medical Association/American Osteopathic Association Master List of physicians in the cities of: 1) Augusta, GA, 2) Baltimore, MD, 3) Brooklyn, NY, 4) Chicago, IL, 5) Los Angeles, CA, 6) Miami, FL, and 7) Raleigh/Durham, NC, all near NET-PD sites. The samples were restricted to physicians in the 3 medical specialties who did not work in an academic setting to avoid physicians already associated with NET-PD and whose practice was located in ZIP codes with <60% Caucasian, non-Latinos according to the 2000 U.S. Census. No quotas by physician type were specified. The study was approved by the institutional review board of the Medical University of South Carolina.

Design and Procedure

The survey contained both standardized scales as well as items written for this particular study. Prior to implementation, the questionnaire was evaluated through a set of pretests of the specific items and of the internet system of data collection. Modifications based on information gained in the pretests were implemented in the final version of the survey.

Because the NET-PD trial was about to begin and the recruitment intervention had to be quickly implemented, we contracted with a marketing research firm to conduct the physician interviews. Interviewing continued until 200 interviews were conducted. All physicians in the initial sample of 1,250 were sent a letter signed by the investigators on letterhead from the Medical University of South Carolina explaining the survey and instructions about how to complete the survey using the internet. Each physician was issued a unique password to access the survey. After about 2 weeks, all physicians who had not completed the web survey were then telephoned. The physician was asked to do the survey over the telephone at that time. The telephone follow-up served several purposes: it allowed physicians the opportunity to complete the survey over the telephone; it reminded the physicians about the survey causing some to complete it using the web; and it allowed a determination of physicians in the sample no longer eligible (retired, no longer at address, etc.). The survey was conducted between October 4 and November 8, 2006. All participating physicians were offered a \$50 Amazon.com gift certificate for completing the survey either over the internet or telephone.

Variables

Trust in Medical Researchers scale. This 12-item measure has demonstrated validity and internal consistency.⁸ The items are measured on a scale of agreement from 1 (strongly disagree) to 5 (strongly agree), with some items reverse coded so that high scores indicate greater trust in medical researchers, as following the initial creation of the scale. The Trust in Medical Research-

ers Scale (TIMRS) can be used to provide a summary score or as a score on 2 6-item subscales (Participant Deception, Researcher Honesty). Higher scores on the scale have been shown to be associated with a higher reported likelihood of future participation in research. The scores on the TIMRS were recoded from 0–4 giving the total score (sum of scores on the 12 items) a range from 0–48. The TIMRS had not been used to assess physicians and had not been used previously to assess likelihood of physician referral.

Attitudes toward participation in research. Three items regarding potential barriers or drawbacks to research participation were assessed on a scale of agreement from 1 (strongly disagree) to 5 (strongly agree). The items were "Participation in research is too costly in terms of time and resources for my practice," "The requirements of research protocols are intimidating for my staff," and "I am reluctant to present research projects to patients in my practice because I often cannot answer their questions about the details of the study." Agreement with statements regarding attitudes towards research participation were categorized as agree ("strongly agree" or "agree") versus disagree ("neutral," "disagree" or "strongly disagree").

Respondent characteristics. Several characteristics of the physician respondent were assessed, including their gender, age, proportion of their active patient population that was minority, whether the physician had any PD patients in their active patient population and the physician's specialty. Participants were also asked to identify their own race. As an additional estimate of Latino heritage, we also assessed the surnames of the physicians regarding Spanish origin. The information from these 2 race/ethnicity variables was merged together into a new variable.

Respondent participation in research. We assessed research-related experience, including whether the physicians considered themselves to be medical researchers, whether they were part of a practice-based research network and whether they had ever referred patients for participation in a medical research study.

Likelihood of referral of patient to Parkinson's disease clinical trial. Physicians were asked in 4 separate questions how likely (1 = very unlikely, 5 = very likely) they would be to refer patients to a PD clinical trial. They were asked about referral if the patient was: a) <65 years old, b) ≥65 years old, c) Caucasian, and d) minority. For analysis, the likelihood of referral of patients was categorized as likely ("very likely" or "somewhat likely") versus not likely ("neutral," "unlikely" or "very unlikely"). We created a new composite variable for the overall likelihood of referring patients. Physicians who said that they were somewhat or very likely to refer a patient age <65, or were somewhat or very likely to refer a patient age ≥65 were considered likely to refer. Otherwise they were considered not likely to refer.

Table 1. Respondent demographics, attitudes and research experiences, and their relation to the mean total score on the Trust in Medical Researchers scale

	Sample	TIMRS	P
	Number (%)	Mean (SD)	
Overall	197	33.3 (6.8)	
Age			0.881
≤45	93 (47%)	33.4 (6.50)	
>45	104 (53%)	33.2 (7.12)	
Gender			0.324
Male	140 (71%)	33.0 (6.99)	
Female	57 (29%)	34.1 (6.35)	
Race/Ethnicity			0.002
Non-Latino white	89 (45%)	35.2 (6.5)	
Non-Latino black	26 (13%)	30.7 (6.8)	
Latino	11 (6%)	33.5 (2.9)	
Other/not reported	71 (36%)	31.8 (7.0)	
Percent Minority Patients			0.005
>75%	72 (37%)	31.2 (6.98)	
51-75%	61 (31%)	34.5 (6.46)	
25-50%	44 (23%)	35.3 (6.49)	
<25%	18 (9%)	33.1 (6.51)	
Specialty			0.009
Family practice	65 (33%)	32.1 (6.33)	
Internal medicine	120 (61%)	33.4 (6.93)	
Neurologist	12 (6%)	38.6 (5.92)	
Have PD Patients?			0.017
Yes	153 (78%)	33.9 (6.4)	
No	44 (22%)	31.1 (7.7)	
Will Refer a PD Patient Age <65			0.031
Not Likely	58 (30%)	31.7 (7.6)	
Likely	138 (70%)	34.0 (6.4)	
Will Refer a PD Patient Age ≥65			0.036
Not Likely	72 (37%)	32.0 (7.2)	
Likely	125 (63%)	34.1 (6.5)	
Will Refer a PD Patient regardless of age			0.042
Not Likely	48 (24%)	31.6 (7.5)	
Likely	149 (76%)	33.9 (6.5)	
Will Refer a White PD Patient			0.139
Not Likely	65 (34%)	32.3 (7.29)	
Likely	125 (66%)	33.9 (6.55)	
Will Refer a Minority PD Patient			0.208
Not Likely	66 (34%)	32.5 (7.39)	
Likely	127 (66%)	33.8 (6.52)	
Likely to Refer Both a Patient Age ≥65 and Minority			0.155
No	85 (43%)	32.5 (7.20)	
Yes	112 (57%)	33.9 (6.47)	
Do You Consider Yourself a Medical Researcher?			0.638
Yes	44 (22%)	33.8 (7.48)	
No	152 (78%)	33.3 (6.55)	
Are You Part of a Practice-Based Research Network?			0.866
Yes	27 (14%)	33.6 (7.35)	
No	168 (86%)	33.3 (6.76)	
Have You Ever Referred Patients for Participation in a Medical Research Study?			0.053
Yes	131 (67%)	33.9 (6.74)	
No	64 (33%)	31.9 (6.87)	
Research Too Costly			0.018
Disagree	120 (62%)	34.32 (6.76)	
Agree	74 (38%)	31.95 (6.59)	
Protocols Too Intimidating			0.017
Disagree	114 (58%)	34.37 (6.72)	
Agree	81 (42%)	32.04 (6.62)	
Cannot Answer Research Questions for Patients			0.159
Disagree	146 (75%)	33.84 (6.75)	
Agree	49 (25%)	32.29 (6.39)	

Analysis

Mean scores on the TIMRS were calculated for each of the demographic, attitude and research experience questions. Means were compared using standard *t* test or ANOVA statistics.

To identify factors associated with the likelihood of referral of patients, we conducted several stepwise logistic regressions. The first model included physician race/ethnicity, gender, age, specialty, score on the TIMRS, whether self-identified as a medical researcher, whether self-identified as a member of a research network, whether had previously referred patients to a research study and whether currently had PD patients. Subsequent models followed the same procedure but focused on the likelihood of referral to trials based on whether or not the patient was Caucasian, non-Latino. Finally, we computed a model assessing likelihood of referral of patients who would be older and from a minority population. This variable was created based on indicating a positive likelihood of referral to patients aged ≥ 65 and a positive likelihood of referring a minority patient. This model followed the same procedure as the previous regressions.

RESULTS

Of the 1,250 respondents initially sent letters, 184 could not be contacted and were given a code of "bad number" or out of frame. An additional 122 physicians were contacted but were no longer practicing and were also excluded from eligible respondents. Interviewing stopped when 200 interviews were completed, which accounted for 21% of the available sample. At the completion of interviews, 71 forms had been completed over the telephone, 129 had been completed on the web. A total of 66 interviews were completed with family practice physicians, 120 interviews with physicians in general internal medicine and 14 with neurologists.

Three of the 200 surveys had incomplete answers to the 12 TIMRS items and were excluded from the analysis. The demographic characteristics of the respondents are given in Table 1. The mean physician age was 46.8 years (10.6 SD). About 70% of the physicians stated that they would be likely to refer patients to a clinical trial regardless of the age or race of the patient, and 67% have actually done so. Twenty-two percent of these community practitioners consider themselves to be researchers. In terms of their attitudes towards barriers to conducting research, <50% agreed with each of the items.

The total TIMRS scores ranged from 14–48 with a mean of 33.3 (6.8 SD). There are significant differences for the mean TIMRS score for several characteristics. African-American physicians and those with the highest proportion of minority patients in their practices had the lowest levels of trust. Neurologists had the highest level of trust in medical researchers. Physicians with PD patients in their practices scored higher on the TIMRS. Physicians who report that they are likely to

refer a patient to a clinical trial have significantly greater TIMRS scores than physicians who are not likely to refer patients. However, when the patient's race/ethnicity is in question, there is no difference in TIMRS score between those physicians who are likely and those who are not likely to refer the patient. Physicians who consider themselves to be medical researchers or who participate in a practice-based research network do not have significantly greater TIMRS scores. Physicians who have previously referred patients to a research study have significantly greater TIMRS scores than physicians who have not previously referred patients. Physicians who believe that research is too costly, the protocols are too intimidating, or fear an inability to answer patients' questions have lower TIMRS scores.

We used 4 logistic regression equations to examine the relationship of different respondent characteristics, experiences and scores on the TIMRS to the respondent's reported likelihood of referring patients to a PD clinical trial. In the general model of referral, only previous experience referring patients to trials (OR=4.24, 95% CI: 2.09–8.62) and the TIMRS (OR=1.06, 95% CI: 1.001–1.12) were independently related to likelihood of referral. When examining likelihood of referral of white patients to trials, only previous experience referring patients was significant (OR=3.67, 95% CI: 1.90–7.10). Similarly, only previous experience referring patients was significant when referring minority patients to trials (OR=3.94, 95% CI: 2.05–7.57). Fifty-eight percent of the respondents were likely to refer both patients aged ≥ 65 and minority patients. In examining the likelihood of referring both patients aged ≥ 65 and minority patients, the only significant predictor was prior experience referring patients to clinical trials (OR=3.51, 95% CI: 1.86–6.62).

Because prior referral of patients to a research study was the primary predictive factor in likelihood of future referral, we sought to explore which factors are important among physicians with no history of referrals as a way to identify ways to involve more physicians in research. In the general model of referral, TIMRS score (OR=1.139, 95% CI: 1.03–1.26) and being an internal medicine specialist (OR=4.59, 95% CI: 1.41–14.93) were the only significant predictors. The likelihood of referring Caucasian, non-Latino patients was predicted only by TIMRS score (OR=1.10, 95% CI: 1.003–1.20), as was the likelihood of referring minority patients (OR=1.11, 95% CI: 1.01–1.21). No factors were significant predictors of referring both patients aged ≥ 65 and minority patients.

DISCUSSION

The results of this study suggest that past experience with research is associated with the likelihood of future participation and referral of patients into clinical trials. Further, study results indicate that the TIMRS,

which has previously been used with patients, also indicates the importance of trust in medical researchers to referring physicians. Although the level of trust in medical researchers is higher than that previously found in studies of patients, a potential ethnic community difference may exist.^{8,9} African-American physicians and physicians with higher proportions of minority patients reported lower levels of trust in medical researchers. However, when asked about referring patients to clinical trials, neither racial/ethnic status of the physician nor patient population characteristics were independently associated with likelihood of referral. Only trust in medical researchers and past experience of referring patients to trials were associated with the likelihood of future referrals. There were no differences in trust with respect to the likelihood of referring either a white or a minority patient.

These results complement previous research on patient trust in medical researchers. In several studies of participation or refusal to participate in clinical trials of cancer therapy, one of the most common reasons for participating is the advice/trust in the doctor.^{10,11} Focus group data exemplify the critical role of trust in their doctor as well as other entities in the healthcare system when examining participation of African-American adults in medical research. African-American patients describe distrust in the medical community as a prominent barrier to participation in clinical research.¹²

Some recent data exemplify the critical role of trust in their doctor as well as other entities in the healthcare system when examining participation of African-American adults in medical research. Although a recent study has suggested that African Americans and non-Latino whites in the United States are equally willing to participate in medical research, African-American patients describe distrust in the medical community as a prominent barrier to participation in clinical research.¹²⁻¹⁵

Research suggests that physician referral is one of the most effective means of recruiting minority patients into clinical trials; however, there are other data that suggest that community physicians may be reluctant to refer patients to studies because of issues of trust in medical researchers.¹⁶⁻¹⁸ In a recent study, physicians practicing in hospitals serving large numbers of minority patients cited a barrier to patient recruitment in clinical trials as the patient perceptions of being treated like a "guinea pig."¹⁹ Further, 70% of National Medical Association members cited their distrust of the institutions conducting the trials.¹⁶ Thus, our study and the work of others suggest that efforts to increase minority participation in clinical trials should be focused both on modifying patients' and physicians' level of trust in medical researchers. Both may serve as barriers to referral or participation of minority patients in medical research.

Given the association we detected with previous experience in referring patients to research studies, efforts

to expose physicians to medical research, and thereby increase their familiarity and comfort with research, should begin early in their careers, perhaps in medical school or residency training. Additionally, future research should focus on the utility of increasing trust in medical researchers on recruitment and referral of minority patients in PD (and perhaps other) disease trials.

There are several limitations to this study. First, although the sampling frame utilized a probability-based design, the study was conducted with physicians in 7 cities who practiced in highly minority-populated areas. Physicians whose practice is in another area may have different levels of trust in medical researchers and different likelihoods of referring patients to PD clinical trials. However, because of the importance of getting greater participation of minorities into trials, this sampling frame seemed to have significant practical benefits in terms of potential knowledge. Second, the survey design did not allow us to compute a true response rate because of the cessation of data collection once we reached 200 interviews, forcing us to underestimate the rate at 21%. As noted, the decision to stop at 200 was based on time and budgetary constraints. Consequently, the respondents may not be representative of the entire sampling frame. Third, the outcome of interest was the self-reported likelihood of referring patients to a PD clinical trial and not actual counts of referred patients. Although this design may be affected by the difference between self-report and actual behavior, this type of design using a behavioral intention has significant predictive validity for future behavior. Fourth, the participating individuals may be overrepresented by individuals positively oriented toward medical research. A Harris Poll Survey conducted for the Michael J. Fox Foundation (personal communication) regarding awareness of clinical trials in PD shows awareness is relatively low among physicians, and experience with referring patients to PD trials is not common. On the whole, most doctors in both the primary care physician/gerontologists sample (PCPs) and the neurologist sample have never referred a PD patient to a clinical trial. Only 17% of PCPs and 47% of neurologists have referred a patient to a trial. Fully two-thirds of PCPs (68%) and more than a third of neurologists (36%) declare themselves "not at all aware" of clinical trials in their area. A fifth limitation is the use of a Spanish surname to classify individuals as Latino. This strategy can potentially misclassify Latino individuals who do not have a Spanish surname. However, this strategy is not uncommon and has been shown to be a relatively efficient way of identifying Latinos.^{20,21}

Despite these limitations, the findings from this study illustrate important points relevant to recruitment of patients in medical research. Trust matters. Both patient and physician trust in medical researchers are related to the likelihood of participation in (or referral to) research studies. Several research studies in the minority com-

munity have suggested that trust is a potential barrier to participation in research. Our data suggest that it may be worthwhile to introduce efforts to educate and modify attitudes related to medical research among both minority patients and their physicians in order to increase participation of minorities in clinical research. We are currently testing this hypothesis in a randomized trial of NET-PD clinical sites. Site is the unit of randomization for the ancillary study, and percent minorities enrolled is the outcome measure.


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