

ABOUT PRACTICE-BASED RESEARCH NETWORKS

Recruiting Practice-based Research Network (PBRN) Physicians to Be Research Participants: Lessons Learned From the North Texas (NorTex) Needs Assessment Study

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Introduction: The purpose of this study was to examine strategies for recruiting physician subjects in a practice-based research network continuing education research study, using different recruitment methods at four systems, or health plan arrangements.

Methods: The North Texas Primary Care Practice-based Research Network Needs Assessment Study consisted of a survey and five self-directed medical record abstractions. Physicians were recruited to be research subjects from four systems, using different recruitment strategies. χ^2 was used to determine differences in physicians consenting and completing the study between systems. Kruskal-Wallis was used to determine differences in time from first contact to consent and number of contacts required before consent between systems.

Results: One hundred five of 211 physicians (49.8%) consented to participate, of which 90 (85.7%) completed the survey. There was a significant difference by system in the number of physicians who consented ($P = .04$) and number of contacts required pre-consent ($P < .001$) but not in the number of physicians completing the study or time from first contact to consent.

Discussion/Conclusions: Success of recruiting physicians to be research subjects varied between systems using different recruitment methods. Lessons learned include using clinician champions to make initial contact, establishing a relationship with clinic personnel, distinguishing the research team from a pharmaceutical representative, establishing a preferred contact method, and collecting study materials on a set timeline. (J Am Board Fam Med 2011;24:610–615.)

Keywords: Practice-based Research, Research Methods

Practice-based research networks (PBRNs) are positioned to improve patient care through the conduct of translational research emphasizing the con-

tinuum of care through the primary care physician's office.¹ PBRNs provide a venue to conduct research in a clinic setting rather than in an academic institution or hospital and are able to determine if an intervention or a protocol is feasible in the everyday processes and flow of outpatient clinics.² Successfully implementing and conducting research in a PBRN, however, includes overcoming several ob-

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stacles such as lack of physician time, insufficient resources, disruption of clinic duties, and inadequate training in research.^{3,4}

Physician involvement in PBRN research varies, depending on the specific study. For example, a physician may serve as the principal investigator, function as a co-investigator, recruit patients for studies, or participate as an actual study subject. Each of these roles requires a different commitment of time and resources from the physician. Recommended methods to recruit physicians to participate in PBRN research as investigators or to provide access to sites for patient recruitment have been explored and are presented in the literature.³⁻⁶ Little information, however, is available on how to best recruit primary care physicians to serve as research subjects in practice-based research studies.

The purpose of this study was to examine strategies for recruiting physicians to be subjects in a PBRN continuing education research study, using different recruitment methods at four systems, or health plan arrangements. Specifically, we hypothesized that variations in recruitment methods would result in differences in the number of physicians who consent to participate in and complete the study, the time from first contact to obtaining consent, and the number of contacts required to obtain consent. A secondary aim was to determine if system variation was associated with time required to obtain approval for the study. Experiences from the North Texas Primary Care Practice-based Research Network (NorTex) Needs Assessment Study are described.

Methods

The North Texas Primary Care Practice-based Research Network

The North Texas Primary Care Practice-based Research Network (NorTex) is located in North Central Texas and comprises more than 300 physicians at 135 clinics. It is housed within the Primary Care Research Center (PCRC) of the Texas Prevention Institute at the University of North Texas Health Science Center (UNTHSC) in Fort Worth, Texas. NorTex includes outpatient clinics affiliated with an academic institution, two county hospital systems, a pediatrics hospital system, and more than 40 private practices. Multiple types of studies have been conducted using NorTex clinics, including continuing education-based research projects, for

which the primary care physician serves as the research subject.

The NorTex Needs Assessment Study

The NorTex Needs Assessment Study examined the knowledge and practices of local primary care physicians with respect to cardiovascular care, immunizations, cancer screening, and pediatric care. The NorTex Needs Assessment Study created a unique relationship between NorTex and the Professional and Continuing Education (PACE) office at UNTHSC to address the needs of the community. The study consisted of two parts: a one-time survey that could be completed on-line or on paper and five self-directed random chart extractions. Primary care physicians (family medicine, pediatrics, internal medicine, and geriatrics) were invited to participate. The five medical record abstractions consisted of one patient 18 years of age or younger, one patient between 19 and 49 years of age, two patients between 50 and 64 years of age, and one patient at least 65 years of age. Pediatricians were asked to abstract five medical records on patients 18 years of age and younger, and physicians whose practice only included adult patients were asked to review two charts for patients between 18 and 49 years of age. A total of 211 physicians were approached to join the study. The study was designed to last 1 year.

Physicians who participated in the NorTex Needs Assessment Study were recruited from four different “systems,” or health plan arrangements. Each of these systems had a champion, or lead contact, that was a co-investigator on the project. These champions were responsible for working with the primary research coordinator (RC) to select the best methods of recruiting physicians from their system to be subjects in the study. As such, a different method of recruitment was used for each system. The following provides a general description of each physician system and the method utilized for recruitment.

Physician Systems

System A comprised both physicians associated with an academic institution and physicians in private practice. The RC contacted each physician directly for recruitment. The RC referred to the system champion by name when recruiting but worked directly with the potential physician participants. The RC was responsible for all contacts, consenting, and ensuring study completion.

System B included outpatient primary care clinics associated with a large county hospital. The champion at this system helped the RC make first contact with individual physicians. This generally included going with the RC to visit the clinics and giving a short presentation of the study objectives and methods. After initial contact, the RC followed up with the physicians directly. The RC was again responsible for recontacting, consenting, and ensuring study completion.

System C included community-based clinics associated with a different large county hospital system. The champion for system C introduced the RC to a site administrator or lead physician at each clinic. This person then helped the RC make initial contact with potential physician participants at each clinic and helped follow up with obtaining consent and/or study components.

System D included outpatient clinics associated with a pediatrics hospital system. In System D, the champion did all the recruitment personally and had their in-house research coordinator conduct all follow-up. The RC was not permitted to contact and follow-up with physician participants directly for any study component.

All physicians practiced in an outpatient setting. Multiple methods were used to contact each physician including telephone, fax, e-mail, and in person. Additionally, a face-to-face meeting was held with the PI and all system champions on three occasions to ensure study recruitment was progressing and to address any study-related concerns. The NorTex Needs Assessment Study was funded by the Pfizer Medical Education Group through the UNTHSC Office of Professional and Continuing Education. Study procedures were approved at the UNTHSC Institutional Review Board (IRB) as well as three additional IRBs affiliated with the other systems.

Variables

The percentage of physicians consenting to be in the study and the percentage completing the study were calculated. The length of time in days from initial submission to final IRB approval was calculated. Additionally, the mean time in days from first contact to obtaining consent and the mean number of contacts made with physicians before obtaining consent were calculated for each system. The mean time from first contact to consent and the mean number of contacts were not available for System D because all physician recruitment was done within

their organization by their own coordinator. Lessons learned were also developed on the basis of study data presented in the article and the consensus of study investigators. These are presented below.

Statistical Analysis

Descriptive statistics were computed overall and for the four systems. The number of physicians who consented and completed per system were compared using χ^2 . The time from first contact to consent and the mean number of contacts for the three available systems were compared using a Kruskal-Wallis test due to the non-normal distribution of the data. If a significant difference between groups was observed with the Kruskal-Wallis test, a Mann-Whitney test was performed between each pair.

Results

Overall, 105 of the 211 physicians approached (49.8%) consented to join the study. Of those consented, 90 (85.7%) completed the survey. Of respondents, 21 (23.3%) completed the adult survey, 33 (36.7%) completed the pediatric survey, and 36 (40.0%) completed both adult and pediatric survey parts. Seventy-five of the 90 survey respondents (83.3%) opted to take the survey using the paper format instead of the on-line version. A total of 432 chart extraction forms were completed, with 201 (46.5%) on pediatric patients and 231 (53.5%) on adult patients.

Of the physicians who responded to the survey, 33 (37%) were pediatricians, 16 (19%) were internists, 34 (39%) were family physicians, and 5 (4%) were geriatricians. The average age was 46 years (SD = 10) and ranged from 31 to 73. Forty-six (51.7%) of the physicians were male and 13 (14.8%) were Hispanic. Race was assessed separately from ethnicity, and 53.3% were Caucasian, 27.7% Asian, 7.8% African American, and 10.0% other. Most (94.3%) were board-certified, and the average number of years in practice was 14.5, ranging from 1 to 38 years.

A majority (71.3%) of the physicians were employees of a hospital, clinic, or university practice; whereas 12.6% were full- or part-time owners of a physician practice. The average number of patients seen per week in their practice setting varied: 19% reported 75 patients or fewer; 34.8% reported 76 to 100 patients; 27.0% reported 101 to 125 patients;

and 16.9% reported 126 or more patients. Overall, survey responses were obtained from a wide spectrum of physicians.

The total number of physicians asked to be a research subject in the study, the number of physicians who consented, and the number of physicians who completed both the survey and the chart reviews are presented in Table 1. Though 105 subjects consented and 90 subjects completed the survey, 84 of the 105 (80%) completed both the survey and chart reviews. A significant difference in the number of physicians consenting to be in the study ($P = .04$) but not in the number of physicians completing the study was observed between systems. System D had the highest percent of physicians consenting to be in the study (76%) and the highest completion rate (56%). The lowest rates were observed for System B.

The mean time in days from first contact to obtaining consent and the mean number of contacts made with physicians for the three available systems are presented in Table 1. A significant difference was not observed for the number of days from first contact to obtaining consent but was observed for the number of contacts made before obtaining consent ($P < .001$). System C had the highest number of pre-consent contacts (mean = 2.97), followed by System A (mean = 1.72) and System B (mean = 1.71). Significant differences were observed between all systems.

Table 2 provides the dates for initial submission to the IRB for each system, the date of the first approval, date of the final approval, and total number of days from initial submission to final approval. Modifications were made to the protocol after initial approval had been granted to ensure the study procedures were optimal for each physician system. The difference from the shortest to longest time for approval between systems was 123 days. This difference demonstrates the variation in time required for protocol amendments and administrative approval between systems. System D had the shortest time to IRB approval, with 34 days, and System C had the longest, with 157 days.

Discussion

There are several “lessons learned” from the Nor-Tex Needs Assessment Study that will benefit future research and/or CME-related activities targeted to PBRN physicians. This information will be valuable to ensure optimal recruitment of primary care physicians to be research study participants. This study involved multiple physician systems that required varying degrees of administrative involvement and methods of recruitment. Perhaps not surprisingly, these differences resulted in variations in the time to acquire IRB approval, the number of physicians who consented to participate, and in the number of contacts required before consent was obtained.

Table 1. Consent Rates, Completion Rates, and Efforts to Consent Physicians

	Physician Affiliation				P Value
	System A n (%)	System B n (%)	System C n (%)	System D n (%)	
Approached	73	55	58	25	
Consented	33 (45.2)	24 (43.6)	29 (50.0)	19 (76.0)	.040
Completed	27 (37.0)	20 (36.4)	23 (39.7)	14 (56.0)	.355
	Mean (SD)	Mean (SD)	Mean (SD)		P Value
Time from first contact to consent, days	31.24 (44.58)	49.75 (89.75)	32.24 (29.60)		.667
Number of contacts before consent	2.45 (1.72)	1.71 (1.04)	2.97 (0.73)		<.001*

SD, standard deviation.

System A: The Research Coordinator (RC) was responsible for contacting and consenting physicians as well as ensuring completion of study materials. System B: A system physician champion helped the RC make first contact with physician subjects. The RC was then responsible for contacting and consenting physicians and ensuring completion of study materials. System C: The system physician champion selected a lead physician at each clinic. This person worked with the RC for contacting and consenting physicians as well as ensuring completion of study materials. System D: The system physician champion was responsible for all contact with the physician participants. The RC was not permitted to contact physician participants directly. Data for time from first contact to consent and number of contacts before consent were not available for System D.

*Significant differences were observed between all three groups for number of contacts before consent.

Table 2. Time for Institutional Review Board Approval

	Physician Affiliation			
	System A	System B	System C	System D
Date of initial IRB submission	04/24/08	07/09/08	06/09/08	06/09/08
Date of initial IRB approval	05/23/08	09/10/08	10/28/08	06/27/08
Date of final IRB approval*	08/13/08	09/16/08	11/13/08	07/13/08
Total time for final approval, days	111	69	157	34

IRB, institutional review board.

System A: The Research Coordinator (RC) was responsible for contacting and consenting physicians as well as ensuring completion of study materials. System B: A system physician champion helped the RC make first contact with physician subjects. The RC was then responsible for contacting and consenting physicians and ensuring completion of study materials. System C: The system physician champion selected a lead physician at each clinic. This person worked with the RC for contacting and consenting physicians as well as ensuring completion of study materials. System D: The system physician champion was responsible for all contact with the physician participants. The RC was not permitted to contact physician participants directly. Data for time from first contact to consent and number of contacts before consent were not available for System D.

*Difference between date of initial and final IRB approval reflects the need for amendment(s).

Lessons Learned

Based on the study results and consensus of the study investigators, several “lessons learned” are listed below and are summarized in Table 3.

Before Study Initiation

Preparing for study initiation took more time than expected. In the NorTex Needs Assessment Study, physicians were recruited from four “systems” or health plan arrangements; therefore, approval from four IRBs was required. Two of the four IRBs required separate site-specific informed consent documents. This was time-consuming and influenced the start date of the project at all sites.

Recruitment

In large health networks, a physician who specifically works within that health system has historically provided an effective way to establish the first

connection. Using a champion, or physician recruiter, for studies conducted with and without a PBRN has been acknowledged as an effective method of recruiting physicians.⁷⁻⁹ In the NorTex Needs Assessment Study, System D used only the physician recruiter and an in-house coordinator. Although the physician recruiter was only able to contact about half of all eligible physicians, the consent rate and completion rate were higher than the other systems. Recruitment, however, was much more difficult because of time constraints and physician recruiter time.

Office personnel were both the biggest asset to the coordinator and the biggest hurdle to making contact with the physician. In the NorTex Needs Assessment, building a relationship with the clinic staff was essential. Once the relationship was established, collecting study related information from the physician was easier.

Table 3. Lessons Learned for PBRN Research

- Ensure adequate time for IRB approval.
- Take advantage of the established organizational structure within each site.
- Make friends with the office personnel. They control access to the physicians.
- Distinguish the research team from pharmaceutical representatives.
- Establish a preferred method of contact with each physician.
- Set deadlines for study completion.
- Provide information and materials in multiple technological formats to account for individual preferences.

PBRN, practice-based research network; IRB, institutional review board.

Recognition of NorTex

For clinical practices that were part of a larger system of clinics or a large practice plan, reminding physician members of their PBRN affiliation was necessary. Physicians in private practice seemed more knowledgeable about NorTex’s mission than physicians who were members of a larger health network.

The NorTex Needs Assessment Study was funded as a continuing medical education project by a pharmaceutical company. Some physicians were wary of funding from a pharmaceutical company, even after it was explained that they would

not be participating in a clinical trial and the study would not be influenced by the company. A handful of potential participants declined to consent because of the study sponsorship.

Maintaining Contact/Ensuring Completion of Study Materials

Establishing a specific time line and preferred method for contacting each physician allowed for easier physician follow-up. For the NorTex Needs Assessment Study, physician contacts were conducted 2 weeks after consent was obtained and weekly thereafter.

Setting a deadline for physician-participants to complete their surveys and chart reviews was crucial to ensuring the timely receipt of study materials. This was more effective than asking them to return the items on completion (without a specified deadline).

Technological preferences varied widely among physicians. This affected recruitment, follow-up, and administration of study materials. Most physicians (80%) still preferred to complete and return study materials on paper. Other PBRN research has demonstrated the importance of offering a paper-based option.¹⁰

Strengths and Limitations

The NorTex Needs Assessment Study had both strengths and limitations. The large number and diversity of physician participants included provided insightful information about recruiting various types of physicians to be research subjects. Additionally, using different methods of contacting and recruiting physicians at each system allowed future researchers to develop a recruitment plan tailored to their specific study procedures and expected physician participants. Having a champion for each system provided credibility to using a physician recruiter in practice-based research studies for recruiting physicians as study subjects. One of the limitations associated with the study was having different start dates at each system. The different start dates were in response to varying levels of administrative load associated with IRB approval. Despite different start dates, however, each system had to meet the same completion date, leaving less time for recruitment at two systems.

Conclusions

During the course of the NorTex Needs Assessment Study, the investigators discovered several

barriers and enabling factors associated with conducting research in a PBRN. The greatest barrier to enrolling physicians as research subjects was making first contact with the physicians, and in-person meetings were the most effective method of recruitment. Setting a deadline for participants to complete their study-related materials was crucial to ensuring complete participation. Additionally, having a checklist with simple directions was helpful so that the physicians could refer back to all the information in one place. The experiences of these investigators will serve to inform future researchers about the best practices of PBRN research. Results of this project will allow for more effective recruitment of physicians to participate in PBRN-related research projects and better implementation of research projects within NorTex.

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