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Understanding practice-based research participation: The differing motivations of engaged vs. non-engaged clinicians in pragmatic clinical trials

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ABSTRACT

Background/Aims: Pragmatic clinical trials (PCTs) represent an increasingly used strategy for "real-world" trials. Successful PCTs typically require participation of community-based practices. However, community clinicians often have limited interest or experience in clinical research. Many barriers to practice-based research have been described, but possible motivations to participate among community practices not active in research have not been well explored. The tendency is for researchers to assume similar motivations and priorities across all candidate practices. This is not necessarily the case. A better understanding of the range of reasons clinicians might see for participating in pragmatic trials could be key to promoting this type of practice-based research.

Methods: Semi-structured interviews were conducted with 30 clinicians and staff members. Half of the interviewees had experience doing practice-based clinical trials and half did not. Individuals in these two groups were also diversified in terms of their practice size and location. Participants were asked about motivations and barriers to doing practice-based research in the context of a planned osteoporosis pragmatic clinical trial. Interviews were transcribed, coded, and analyzed.

Results: Barriers identified for both experienced and not-experienced clinicians and staff members included: a lack of time, increased paperwork, disruption to work flows, and concern over practice finances. Similar findings have been reported in the US, UK, Europe, and Australia. However, regarding positive motivations of practices to participate, we found systematic differences in attitude between research-engaged and research-naïve practices that have not been previously reported. The research-experienced group offered a greater number and variety of reasons to take part than the not-experienced group. While both groups expressed motivations related to patient care, clinicians and staff members experienced in practice-based clinical trials were much more likely to cite intellectual, professional, and societal benefits not envisioned by the other group.

Conclusions: We conclude that clinicians not already participating in practice-based trials may have a narrower range of motivations than those already participating. The lack of a broader view of possible benefits to participation may also translate into more obdurate recruiting challenges. These results point to the need for recruitment, engagement, and messaging approaches differentially tailored to the needs and interests of non-participating practices.

1. Introduction

Traditional randomized controlled trials (RCTs) often lack generalizability to routine care settings and fail to account for heterogeneity in patient characteristics and preferences. [1–4] One

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strategy to enhance trial relevance is to use pragmatic clinical trials (PCTs) [1,5,6]. PCTs are large RCTs designed to admit variations more representative of real-life conditions of care than traditional "explanatory" RCTs in which patient population characteristics, care setting, care administration, and follow-up are tightly controlled [7–9]. To capture variations across broad populations and care settings, PCTs should ideally be conducted across a range of practice settings, including community-based practices not typically involved in RCTs.

PCTs have increasingly gained purchase. Programs such as the NIH Collaboratory (a pilot program to conduct PCTs through a network of health systems) [10] and the Agency for Healthcare Research and Quality's Practice-based Research Networks (PBRNs) [11] have helped to establish the infrastructure and best practices needed for successful community-based trials. Nevertheless, important challenges remain. Broad-based participation by many practices not routinely engaged in research is required for a robust clinical research enterprise capable of exploring less common conditions or adverse events across varied community settings. Yet 85% of physicians who participate in clinical trials do not repeat the experience [2], pointing to a significant disconnect between the expectations of novice clinician-researchers and the current reality of doing trials.

Further, many practicing clinicians have little interest in research. While many barriers to involvement have been described in the literature, the possible motivations to participate among those not currently active in PCTs have not been well explored. The tendency is for researchers to assume similar motivations for prospective practices to participate. This is not necessarily the case. A better understanding of the range of reasons clinicians might see for participating in pragmatic trials could be key to promoting this type of practice-based research.

Below we describe a set of interviews in which we asked physicians and staff members in community practices about barriers to participating in PCTs and reasons to do so. We found notable differences, especially in the motivations to participate in PCTs, between those who already participate and those who do not. These results may provide insight into how PCTs can be better planned, communicated, and implemented for enhanced relevance to, and recruitment of, community-based practices.

2. Methodology

A total of 30 semi-structured interviews were conducted with 24 physicians and 6 staff members. The interview guide was designed to inform the development of an iPad-based informed consent tool in a planned osteoporosis PCT. If successful, the project would address a key barrier to doing community-based PCTs—work flow disruption associated with informed consent—to make practice-based PCTs more practicable. To understand the relative importance of this one barrier to clinicians and staff (both those already participating in practice-based trials and those who are not), the interview guide included questions on the barriers to, and chief reasons to participate in, clinical trials that use their practices as sites for recruiting, implementation, and data collection ("practice-based trials").

Interviewees were recruited through email listservs of the Alabama Practice Based Research Network (APBRN) and the American Academy of Family Physicians (AAFP). Participating physicians received $100 and staff members received $50 as honorarium for the 30- to 60- minute interview. Not-experienced prospective interviewees proved resistant to recruitment. After multiple failed email appeals, we ultimately identified and recruited not-experienced physicians by having network directors specifically reach out to colleagues in the network known to lack practice-based trial experience.

The initial recruitment target was 12 experienced and 12 non-experienced practice members for a total of 24. Among each subgroup of 12, 6 would ideally be rurally located while another 6 would operate in suburban or urban settings. Differing practice sizes were also desired across these subgroups. Since we were soliciting volunteers through a listserv and recruitment was relatively slow, we would not have been able to select specifically for practice size or other characteristics without significantly increasing the size and duration of the investigation. For the purposes of the project, this was deemed unnecessary. However, experienced practice members were initially oversampled in an effort to encounter volunteers who were non-experienced (before network directors were asked to assist with recruitment). This resulted in 30 total interviewees of the composition shown in Table 1. A first set of 9 interviews were accomplished to pilot test the interview guide and assure that all key topics of interest were being covered. Then the remainder of the interviews were completed.

We defined "experienced" clinicians and staff as those who, at a minimum, had participated in patient recruitment and consent procedures for clinical trials (whether of pragmatic or explanatory design). Those having only quality improvement research experience or experience with observational studies were considered to be "not-experienced" for the purposes of this study.

Experience status, practice size, and location were determined through self-identification by key informants. Initial identification of experience status for screening purposes was accomplished through self-identification in an electronic response form. The first 9 (pilot) interviewees were purposively sampled (i.e., specifically selected for interviews [12]) consistent with the criteria used for the larger group, with practice size and location confirmed through online research.

Interviews were recorded, transcribed, and coded for analysis. Development and refinement of codes was accomplished through collaborative team-based coding (using two coders) and facilitated by NVivo software [13].

3. Results

3.1. Challenges to participating in clinical trials

For our interviewees, chief among the concerns regarding practice-based PCTs was a possible strain on practice resources. Half of all interviewees (15, 8 of whom had clinical research experience as defined above) indicated that finding time for clinical

Table 1
Characteristics of Interviewees and their practices.

Characteristic	% of informants (N = 30)
Interviewee Characteristics	
Male	53%
Female	47%
Clinician	70%
Staff Member	30%
Has experience with clinical trials	53%
Has no experience with clinical trials	47%
Practice Characteristics Associated with Each Interviewee	
Practice Location	
Urban	37%
Suburban	33%
Rural	30%
Practice size	
Solo (1 attending physician)	20%
Has 2 to 4 attending physicians	37%
Has 5 to 7 attending physicians	37%
Has more than 7 attending physicians	7%