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Process Evaluation of Recruitment for a Cancer Screening Trial in Primary Care

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Abstract

Many cancer screening studies are conducted in primary care settings yet few systematically analyze recruitment challenges found at these sites. During a randomized trial promoting colorectal cancer screening, we implemented a process evaluation of recruitment. Recruiters maintained logs that registered the numbers of patients entering the clinic, approached by recruiters, declining to participate; and reasons for non-approach and non-participation. One-half of age-eligible patients were approached (n=1489), and half of those who met basic eligibility requirements agreed to engage further (n=527). A small proportion of patients (n=98) completed the 15-minute assessment before their appointment. Major reasons for non-approach included previous approach, patients called to the exam room, and appearing ill. The major reason for non-participation was “not interested”; a few patients did not want to share contact information. Some participants exited the assessment mid-way due to further ineligibility or time limitations. Best practice recommendations for recruitment in primary care are discussed.

Keywords

process evaluation; cancer screening; colorectal cancer; primary care research; recruitment

Primary care clinics can be valuable venues for cancer prevention research. These settings represent an opportunity to reach patients who are linked into the healthcare system but still in need of health promotion interventions. Even among patients receiving regular healthcare,

utilization of cancer screening and other preventive services may be low (Young, McGloin, Zittleman, West, & Westfall, 2007). One benefit of conducting research in primary care settings is that physicians, nurses, and other clinic staff provide a known and often trusted contact for patients and can assist the researchers in promoting clinical trials (O'Malley, Sheppard, Schwartz, & Mandelblatt, 2004). If a trial involves provision of care, follow-up, or preventive care that must be done in conjunction with a medical professional (e.g., screening), the primary care office is a highly practical collaborator. In these cases, patients can receive their care at the same place as the recruitment site (Leathem et al., 2009), which could reduce delays in diagnosis and treatment.

At the same time, recruiting patients for prevention studies through primary care presents unique challenges (Boles, Getchell, Feldman, McBride, & Hart, 2000; Goodyear-Smith et al., 2009). Clinic staff work under time demands and work flow burdens that make finding time for research difficult. Research protocols may be viewed by providers and staff with the same hesitation as quality improvement interventions (Berwick & Kilo, 1999); many improvement processes have been difficult to implement and sustain in the care delivery environment (Farmer, Bastani, Kwan, Belman, & Ganz, 2008). For providers, research that is not perceived as directly clinically important may receive less attention (McKinstry, Hammersley, Daly, & Sullivan, 2007). Patients face time and attention demands in-clinic that may distract them from study participation. Just as preventive care is sometimes overshadowed by acute needs, prevention trials may face more recruitment difficulties than treatment trials (Bell-Syer & Moffett, 2000).

Background

While several studies have described recruitment in primary care based trials (Charlson & Horwitz, 1984; Fairhurst & Dowrick, 1996; Foy et al., 2003; Tognoni et al., 1991), only a few studies extensively examine recruitment (Lai et al., 2006; Maslin-Prothero, 2006; Ruffin & Baron, 2000; Tangrea, 1997). A report of the PLCO (Prostate, Lung, Colorectal, and Ovarian) Cancer Screening Trial found that a small proportion of invitees enrolled, and that enrollment was higher among those who were female, white, older, and living in higher-income census blocks (Lamerato, Marcus, Jacobsen, & Johnson, 2008). These data are consistent with other reports about enrollment in cancer screening trials (Steffen et al., 2008).

Researchers have suggested potential recruitment strategies and advocated for further study. For example, having an experienced trial coordinator, visiting participants at home, high publicity, high perceived clinical benefit by clinicians, and practice incentives contributed to recruitment success in one study (McKinstry et al. 2007). It seems that use of multiple strategies, culturally sensitive approaches, incentives, repeated invitations, and low burden on participant can enhance study enrollment (Grunfeld, Zitzelsberger, Cristine, & Aspelund, 2002; Rubin et al., 2002; Steffen et al., 2008).

Low accrual and inadequate sample sizes are problematic because they can lead to underpowered studies that may not detect significant effects (positive or negative) and that cannot answer the study questions. Poor recruitment can lead to an inefficient use of project resources, and projects with insufficient recruitment risk early cessation (or non-completion). Low accrual has been noted as a reason for the failure of multiple primary-care-based trials [Foy, 2003]. Thus, there are multiple reasons why maximizing recruitment is essential for conducting successful quality research.

Understanding who gets approached and who gets enrolled in a trial is an important piece of evaluating generalizability and enhancing recruitment success. We conducted a process evaluation to examine recruitment reach, rates for approach and non-participation, and

overall accrual and completion of baseline assessment in a primary-care based cancer prevention trial. In our cancer prevention trial, patients were recruited from a widely dispersed group of clinics, including two larger academic medical center clinics and 50 rural practices that were part of a practice-based research network. To provide detailed and controlled recruitment data, we conducted an in-depth process evaluation of recruitment at the two academic practices during an 8-month period. Outcomes of interest included the proportion of patients entering the clinic who were approached by a recruiter (*reach*); proportion of patients reached who agreed to participate (*effectiveness*); and reasons for non-approach or non-participation. Our goal is to identify best practices to improve efficiency and effectiveness of recruitment for health promotion studies.

Methods

Study Design and Description

Colorectal cancer (CRC) is a leading cause of cancer death; CRC screening is recommended for average-risk adults starting at age 50. Only half of age-eligible adults are considered up-to-date for CRC screening (have had it in the recommended time frame), even in primary-care based samples (Hawley, Vernon, Levin, & Vallejo, 2004; Liang, Phillips, Nagamine, Ladabaum, & Haas, 2006; M. T. Ruffin, Gorenflo, & Woodman, 2000; Zack, DiBaise, Quigley, & Roy, 2001). The *Tailored Messaging to Promote Colon Cancer Screening* randomized controlled trial used computer tablets to deliver a tailored or comparison intervention to promote CRC screening utilization. The Healthy Living Kansas tablet computer baseline program verified eligibility and then guided eligible participants through a CRC assessment. Those who completed the assessment were individually randomized into either a tailored intervention arm or a general education comparison arm. In the comparison arm, participants received a summary screen about physical activity and nutrition at the end of the baseline program and received, in the mail, a printout with general CRC education messages and screening reminder. Participants in the tailored arm received a tailored summary message plus a mailed tailored printout reinforcing the CRC screening recommendation. A 90-day telephone follow-up assessed screening utilization, participant discussion with their physician regarding CRC screening, and patient satisfaction. The study was approved by the University's Institutional Review Board. All recruitment and process evaluation discussed in this manuscript relate to this parent trial.

Recruitment Site Description

Clinics were recruited through our practice based research network and were visited in person by the investigators when possible. Of the over 50 sites, process evaluation activities were implemented only at the two academic sites. At the remaining outlying sites such intensive monitoring was not practical, as medical students conducted the recruitment and small patient populations affected our ability to calculate rates. Because most outlying sites were several hours away from the university, those recruiters met through weekly conference calls and emails with the research team.

The academic sites were two primary care clinics in a large urban academic medical center. One clinic was the Family Medicine (FM) Department faculty and residency program (15 faculty; 26 residents) while the other housed the General Internal Medicine (GM) Division of the Department of Internal Medicine (6 faculty; 36 residents). Both were within the medical center complex but the GM office was linked to a large multispecialty medicine office supporting medicine specialty divisions. Total clinic volume, continuity of office hours, and patient return visits across residents and faculty were higher in FM than in GM. The GM office maintained a more resident teaching focus and a higher percentage of government-insured patients (i.e. Medicare, Medicaid) while FM maintained more open-

access appointments and visits tended to be shorter in duration. The FM office also had a physically larger waiting area for recruitment and a laboratory blood drawing station within the clinic rather than in an external hospital location, as was the case in GM.

Recruitment procedures

Recruiter training—Recruiter training for the project included a half-day in-person training session that covered background information on the project and project rationale, role and expectations of the recruiter, recruitment strategies, reporting procedures, and role play. However, recruiters who entered the project mid-way may not have had the formal training session, but instead received one-on-one instruction, a copy of the recruitment handbook (which included all of the information from the training), and shadowed a recruiter before working independently. All recruiters had at least a bachelor's degree and some public health or medicine training.

Procedures—In our academic sites, a total of 5 trained recruiters staffed the clinic waiting rooms most days of the week (times and days were rotated to ensure maximum coverage). The recruiter would attempt to verify incoming patients' age by asking reception staff and checking daily office visit schedules. In some cases, reception staff directed patients to recruiters. It was more common, however, for recruiters to approach patients independent of reception staff. Recruiters wore a badge identifying them as part of the Healthy Living Kansas project in addition to their university ID badge. If patients were age 50 or over, the recruiters were instructed to approach participants, briefly describe the study, and ask if the patient was interested in participating.

Process Monitoring

Log sheets—During each recruitment period, recruiters kept a standardized log of project activities. Per each half-hour block that recruiters were present, they tracked the number of patients who entered the clinic, number approached for the study, reasons for non-approach, participants deemed ineligible post-approach, and number of participants who declined. Reasons for non-approach, ineligibility, and refusal were tracked using an open-text comment field on the log. Log sheets were turned in at the end of each day. Data were compiled in SPSS.

Tablet utilization—Participants who agreed to enroll in the study completed informed consent and the baseline assessment on the tablet (as described in the study summary). The tablet program automatically saved utilization information (e.g., number of questions completed; amount of time spent in program; and if participants exited the program before completion it tracked where they exited and delivery of the intervention messages on-screen). All data were automatically fed into an ACCESS database.

Ongoing Process Mechanisms—In addition to the log data, we conducted two quality improvement meetings with recruiters. These discussions were led by two of the co-investigators (CMD, ASJ) who did not have supervisory roles in recruitment. In order to instill an atmosphere of honesty and comfort, these sessions were not audio-taped and the principal investigator was not present. At the second meeting, the project manager was present to take notes. At the Quality Improvement meetings, recruiters were first reassured that the meeting was not designed to evaluate each person's performance but rather to discuss and improve the project activities. Recruiters were first asked to free list their thoughts on recruitment and challenges in project recruitment. Questions posed to the recruiters during the discussion focused on "how things were going", challenges faced by recruiters (at the patient- and clinic-level), suggestions for improving the process, and recruiter perspectives on how patients felt about the program. These activities were

conducted as quality improvement and data collection management; they themselves were not treated as data collection activities. The research team also informally visited the participating academic sites to assess implementation and talk with the clinic staff.

Analysis

Log data were spot-checked for completeness; range checks were performed on both the log and utilization data. Approach rate (with and without ineligibles) and refusal rate were calculated from log data. Reasons for non-approach and refusal were sorted, collapsed into categories (e.g., “infirm”, “very ill”, and “too sick” were collapsed into “sick”). We also calculated an “hourly rate” based on the number of hours in the clinic (per recruiting session) and the number of people who engaged with the computer. To the extent that such data were available, we looked for systematic factors that affected accrual. However, we did not test rates for significant differences and were not powered to do so.

Results

Approach Rate

Figure 1 describes the flow of recruitment. About a quarter of patients who checked in at reception (n=5143) were approached for study participation. Half of those checking in (n=2518) were deemed not age-eligible (< under age 50) prior to approach by visual check and/or confirmation by the receptionist. Recruiters documented non-approach reasons for 833 of the remaining patients (*see* Figure 1, Table 1). The most common reasons for non-approach were previous approach (n=421) and patients going to the exam room before the recruiter reached them (n=120). Patients who were visibly upset or ill were not approached (n=97).

Thus, of age-eligible patents checking in who had not been previously approached, 68% (n=1489) were approached by a recruiter. Of these, another 378 were deemed ineligible before starting the tablet computer program (e.g., under age, up-to-date, not a patient, etc.), resulting in a sample of 1111 patients who were approached, met preliminary eligibility requirements, and were noted in the log sheets.

Refusal Rate

Of those who were approached and met preliminary eligibility (n=1111), 47.4% agreed to participate. Recruiters documented 466 refusal occasions, most commonly, “not interested” or “don’t want to” (n=280). Other reasons included concerns about giving out personal information or not wanting to be re-contacted for follow-up (n=20), patients who “didn’t do” surveys/studies (n=9), and those who felt they had already done too much in-clinic paperwork that day (n=5). Recruiters were not trained to probe participants further on their reasons for non-participation and no additional data were collected on non-participants.

Recruiter effectiveness

Based on over 200 recruiting sessions and nearly 600 hours of recruiting (recruiters typically took a 3–4 hr block), on average 0.86 participants engaged with the program per recruiting hour. Recruiting was slightly more effective in FM (average 0.948 per hour) than GM (0.770/hour); effectiveness also varied by recruiter within clinic (range = 0.55 – 1.61 and 0.0 to 1.21). Rates varied month to month, but there was no discernible pattern either overall or by clinic. Rates varied by day of the week, recruiting was most effective on Wednesdays (rate = 1.38 and 1.07, respectively). Afternoons seemed to be more effective as well (clinic 1 morning vs. afternoon: 0.90 vs. 1.02; clinic 2: 0.73 vs. 0.84).

Survey completion rate

Survey completion data were obtained from the data automatically recorded on the computer, so the “encounters” numbers may not reflect the exact log numbers. In these two clinics during the log observation period, 988 people engaged with the tablets. Of those who engaged, 471 were then ineligible due to reporting risk factors or previous screening. In total, 98 people completed the program (19.6% of those who engaged and were eligible); 55 (56%) completed the 90-day follow-up. Reasons for non-contact at follow-up included wrong/disconnected telephone numbers and no response to multiple telephone messages.

Quality Improvement Steps

Recruiter meetings were helpful in assessing challenges and suggesting improvements. There was some confusion in the first recruiter meeting about who to approach in the clinic (due to people who entered the clinic but did not have an appointment); and (especially as flu season approached) recruiters were hesitant to approach persons who looked “sick.” Recruiters indicated that having reception staff refer patients to them was helpful, but that some staff did not feel that they had time or permission to refer. Similar reports emerged when informally talking with clinic staff. Although recruiters were not asked to provide any specific educational information to participants, they requested written information about CRC. Having CRC information increased their confidence in talking to participants, as they wanted to be able to answer basic questions. Modifications to the program based on research team meetings and recruiter observations included programming changes in the presentation of demographic questions and consent screens to move this material to the end of the computerized assessment. Recruiters also went through a booster training session. Recruiting for the last stage, after these changes were implemented, resulted in slightly lower approach rates (30.2% of all check-ins were approached pre-modification, 25.7% were approached post-modification,) but also slightly higher participation rate (34.3% of those approached agreed pre-modification, compared to 42% post-modification). Overall, the average hourly accrual rate (recruiter effectiveness) did not change after modification. The extent to which such changes in approach and refusal were a result of improved recruitment procedures or to other variations remains unclear.

Discussion

In this CRC prevention study, we recruited participants from primary care offices by approaching patients in waiting areas. A careful process evaluation of recruitment procedures showed that about one-half of the age-eligible patients who checked in with receptionists were approached for the study; and nearly half of age-eligible patients agreed to participate. These numbers are similar to other evaluations of recruitment in primary care (Joseph, Kaplan, & Pasick, 2007; Keyzer et al., 2005; Pressler et al., 2008). Some of the non-approach was related to repeat patient visits, an issue that will increase in patient populations that are older or managing chronic conditions. Another large group not approached were noted as visibly ill, in distress, or pre-occupied with clinic forms or other activities. Clinic paperwork contributed to both non-approach and disinterest in participation. However, a sizeable number of patients were called back to the exam room while the sole recruiter was with another participant and represent missed opportunities for recruitment. This is a recruitment challenge that could be avoidable if patient flow were anticipated and extra recruitment help was available when needed. These factors need to be considered when planning recruitment for research trials in primary care settings.

Most study refusals were attributed to not being interested in participating. However, we encountered some people who said they did not want to be in a research study, did not want to give out contact information, or did not want to be re-contacted. Unfortunately, we do not

have demographic data on non-participants. It would be helpful to be able to further explore which aspects of the study or the recruitment context contributed to patient decisions; or to evaluate whether recruitment was representative. It could be that people were not comfortable with being approached in waiting areas or by someone other than their healthcare provider. We do not have any objective or anecdotal evidence to suggest that the topic, CRC, contributed to unwillingness to participate.

Recruitment is often a costly part of any trial, thus rates of recruitment over time are a helpful cost-effectiveness assessment. We found that '*recruitment effectiveness*' (number of participants accrued per hour of recruiter time) varied by recruiter and by clinic. This is not unexpected, as there are likely contextual and recruiter approach differences that affected recruitment. There were few changes in recruitment effectiveness by day of week or month, in either clinic, except that Wednesdays and afternoons seemed more productive. We did not test for significance on these differences. Because individual recruiters generally had a set schedule and stayed in one clinic, it was difficult to discern how much of the recruitment differential is related to recruiter versus clinic, or whether there were unmeasured systematic factors that affected both.

While our in-depth monitoring is a strength of this study, our analysis and interpretation has several limitations. Most importantly, our data depend on recruiter reporting and observations of patient reactions and responses. It is possible that patients might have reported different reasons if they were not asked face-to-face or if they were probed more intensely. Second, without demographic or other quantitative data on both participants and non participants, it is difficult to characterize either the representativeness of our sample or compile a profile of those more or less likely to enroll.

Conclusions

While project-specific and clinic-specific factors certainly play a role, our findings may be helpful for researchers who want to estimate recruitment rates in primary care as related to scheduled appointments. Certainly, clinics will vary and we do not feel there is an "ideal" clinic type for this type of research. While some clinics may have more experience with research studies and are better equipped to help recruiters, these clinics may not be representative of the typical patient population. Some level of clinic buy-in will support recruitment efforts and careful relationship building before the outset of a study can cultivate a receptive environment. Thus, we have identified six best practice guidelines that will be helpful to others recruiting in diverse primary care settings:

1. **Anticipate repeat patients and have a plan to address repeaters.** As chronic disease rates rise, we will encounter more 'repeat' patients in offices. While some patients may accept participation on a second approach, it is unlikely that attempts beyond that will be effective or well-received. Approaching the same patient too many times is an inefficient use of project time and resources. Having astute recruiters who pay enough attention to recognize repeats, and having a specific protocol on when and how to re-attempt recruitment is vital.
2. **Have a protocol for "sick" patients and respect recruiters' judgments of the situation.** About 50% of primary care visits tend to be for acute problems or specific complaints (Hing, Cherry, & Woodwell, 2006) and some of these patients are not going to feel well enough to consider informed consent, answer survey questions or (if they do participate) carefully process intervention messages. We found that 12% of recorded reasons for non-approach mentioned patients appearing sick. Not only are these patients unlikely to want to participate in a survey at that time, recruiters felt uncomfortable approaching them. With training and protocols,

recruiters can be consistent with who they do or do not approach. Standardized protocols are helpful, but cannot anticipate every situation in which a recruiter must decide whether to approach a participant for the study. Respecting recruiter judgments not only enhances recruiter confidence and morale, it recognizes that there are situational cues that an astute recruiter will recognize as indicators of whether to approach.

3. **Anticipate and appreciate differences between recruiters and clinics. Encourage collaboration between the recruiter/clinic staff.** It is helpful to consider different aspects of recruitment context: patient availability, number approached, refusal rates, and recruitment effectiveness. Recruiters who approach many patients but have a high refusal rate may recruit just as many participants as those who approach fewer but with low refusal. Some clinics may have more senior or more repeat patients than others or may be more willing (or able) to “refer” patients to the project (thus cross-clinic comparisons are not always informative). Working with clinic staff to understand the unique characteristics of their patients and involving clinic staff might enhance uptake and representativeness of the eventual study sample.
4. **Realize that projects may need multiple recruiters at peak times or different strategies if they intend to reach every patient.** Staffing represents a careful balance in the use of resources. The majority of the time, a single recruiter in-clinic was sufficient for accrual. However, there were times when the multiple tablets were in use, or the recruiter was occupied. Some overlap may be desirable if recruitment needs to occur in a short period of time, even though it may lead to some downtime among recruiters. Our clinics were quite different in their physical set-up, necessitating different procedures and recruiter placement. For example, in FM there was space at the reception desk for our recruiters to sit and in GM this was not possible. Reception staff felt more comfortable referring patients to the recruiters if they were sitting alongside them. In the GM clinic, reception staff seemed more reticent to refer. Recruiters and recruitment procedures need to be flexible enough to accommodate different settings, and projects may need to employ multiple strategies. We had multiple protocols, giving our recruiters direction for different situations they would encounter.
5. **Carefully train recruiters, offer resources, maintain frequent open communication, and offer booster training.** Our recruiters asked for more information about the project and the topic. Open communication venues gave recruiters a chance to discuss the situations they encountered (with the investigators and with each other), share helpful insights (or frustrations), and support and recognize their contribution to the project. Similarly, maintaining open communication with clinic personnel can improve relationships and aid in recruitment attempts. This also keeps investigators informed about how things are going “on the ground”, anticipate and avoid recruitment difficulties, or problem-solve if necessary. Booster sessions were helpful in maintaining recruiter morale and reinforcing protocol fidelity.
6. **Set in place systems to monitor recruitment and assess reasons for referral whenever possible.** Our ongoing assessment allowed us to identify and implement improvements in recruitment and allowed for early recognition of lapses in recruitment and has been noted as an important factor in other studies (Neaton, Grimm, & Cutler). Although we tracked reasons for non participation, a more detailed approach might have uncovered more information about non participation that could result in improvements in recruitment procedures.

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Figure 1.
Flow chart of participant recruitment

Table 1**Documented Reasons for Not Approaching Potential Participants**

	N	%
Did not meet age-eligibility criteria	2518	49.0%
Other documented Reasons (n=833):		
Previously approached	421	50.5%
Called to exam room before contact	120	14.4%
Visibly ill or upset	97	11.6%
Limited English skills	39	<1.0%
Apparent physical or cognitive limitations limiting participation	37	<1.0%
Busy with other clinic paperwork	30	<1.0%
Asleep	18	<1.0%
Other	71	8.5%

Table 2

Documented Reasons for Study Refusal

	N	%
"Not interested"	254	54.5%
Concerns about giving out contact information or do not want to be re-contacted	20	4.3%
"Do not want to"	13	2.8%
"Do not do surveys or studies"	9	2%
"No"	8	1.7%
"Do not feel like it"	5	1.1%
"Already filled out too much paperwork"	5	1.1%
Other	152	32.6%