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Successful Strategies for Practice-Based Recruitment of Racial and Ethnic Minority Pregnant Women in a Randomized Controlled Trial: the IDEAS for a Healthy Baby Study

Sarah L. Goff^{1,2}, Yara Youssef^{3,4}, Penelope S. Pekow^{2,3}, Katharine O. White⁵, Haley Guhn-Knight^{1,2}, Tara Lagu^{1,2}, Kathleen M. Mazor^{6,7}, and Peter K. Lindenauer^{1,2}

Sarah L. Goff: sarah.goffmd@baystatehealth.org; Penelope S. Pekow: penny.pekow@baystatehealth.org

¹Department of Medicine, Tufts University/Baystate Medical Center, 759 Chestnut St, Springfield, MA 01199, USA

²Center for Quality of Care Research, Baystate Medical Center, 759 Chestnut St, Springfield, MA 01199, USA

³School of Public Health and Health Sciences, University of Massachusetts, Amherst, MA, USA

⁴Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114, USA

⁵Department of Obstetrics and Gynecology, Boston University Medical Center, 72 East Concord St., Boston, MA 02118, USA

⁶Meyers Primary Care Institute, 630 Plantation St., Worcester, MA, USA

⁷Department of Internal Medicine, University of Massachusetts Medical School, 55 Lake Ave N., Worcester, MA, USA

Abstract

Background—Racial/ethnic minority patients are often underrepresented in clinical trials. Efforts to address barriers to participation may improve representation, thus enhancing our understanding of how research findings apply to more diverse populations.

Methods—The IDEAS (Information, Description, Education, Assistance, and Support) for a Healthy Baby study was a randomized controlled trial (RCT) of an intervention to reduce barriers to using publicly reported quality data for low-income, racial/ethnic minority women. We used strategies grounded in a health equity framework to address barriers to recruitment and retention in

Correspondence to: Sarah L. Goff, sarah.goffmd@baystatehealth.org.

Dr. White and Ms. Youssef were employed by Baystate Medical Center while the study was conducted.

Conflict of interest Sarah Goff declares that she has no conflict of interest. Yara Youssef declares that she has no conflict of interest. Kathleen Mazor declares that she has no conflict of interest. Penelope Pekow declares that she has no conflict of interest. Katharine White consults for Actavis. Peter Lindenauer declares that he has no conflict of interest.

The authors have no conflicts to disclose. The study involved human subjects. Approval was obtained from the Baystate Medical Center Institutional Review Board and participants completed informed written consent.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

three domains: preparation, process, and patient-centeredness. “Preparation” included teaching study staff about health inequities, role-playing skills to develop rapport and trust, and partnering with clinic staff. “Processes” included use of electronic registration systems to pre-screen potential candidates and determine when eligible participants were in clinic and an electronic database to track patients through the study. Use of a flexible protocol, stipends, and consideration of literacy levels promoted “patient-centeredness.”

Results—We anticipated needing to recruit 800 women over 18 months to achieve a completion goal of 650. Using the recruitment and retention strategies outlined above, we recruited 746 women in 15 months, achieving higher recruitment (87.1 %) and retention rates (97.3 %) than we had anticipated.

Discussion—These successful recruitment and retention strategies used for a large RCT promoted inclusivity and accessibility. Researchers seeking to recruit racial and ethnic minority pregnant women in similar settings may find the preparation, process, and patient-centered strategies used in this study applicable for their own studies.

Trial Registration—ClinicalTrials.gov NCT01784575, 1R21HS021864-01

Keywords

Recruitment; Retention; Randomized controlled trial; Pregnant women; Low socioeconomic status; Racial and ethnic minority

Introduction

Racial and ethnic minority and lower-income women have the highest birth rates in the USA [1, 2] and the highest rates of sub-optimal pregnancy outcomes, such as low birth-weight [3–7]. Despite the large and growing numbers of children at risk for experiencing both health and health care disparities, little progress has been made in addressing these inequities [8].

Since 1994, the National Institutes of Health has required that clinical trials either include women and minority (for simplification, the term “minority” will be used to refer to “racial/ethnic minority” throughout the manuscript) participants in clinical trials or explain why they were excluded [9]. Despite this policy, researchers have continued to face challenges to recruitment and retention of these vulnerable populations [10–20]. Some of the challenges may relate primarily to minority status [10, 17, 21], while some may be more closely related to economics [22], culture, or language [23]. While much of the existing literature focuses on overcoming challenges related to recruiting participants from minority populations, fewer studies examine the broader scope of barriers to recruitment and retention based on both minority and lower socioeconomic status (SES) [12, 18, 24, 25].

The IDEAS (Information, Description, Education, Assistance, and Support) for a Healthy Baby study is a randomized controlled trial (RCT) that tested an intervention designed to address known disparities in use of ambulatory pediatric quality performance data [26, 27]. The acronym IDEAS stands for the primary goals of the intervention, which are to provide pregnant women with the following: information about the purpose of quality measures, descriptions of quality measures for pediatric care, education about public sources of quality

performance data, assistance using publicly available data, and support for informed decision-making when choosing a pediatrician. The intervention consisted of two in-person sessions with a patient navigator. During the intervention sessions, women learned about health care quality and performance measures used to assess quality, visited a publicly available website that reports performance scores for local pediatric practices [28] with the navigator, and completed a worksheet documenting the scores of practices they viewed. The purpose of the current study was to describe the successful recruitment and retention techniques used in this RCT.

Methods/Design

Setting, Participants, and Recruitment Process

Recruitment, enrollment, baseline data collection, and intervention procedures took place in the Wesson Women's Clinic (WWC), an ambulatory OB-GYN teaching practice with approximately 1100 deliveries annually. The WWC serves a low-income, racially, and ethnically diverse population. Approximately 85 % of women attending the clinic have public health insurance; nearly 57 % are Hispanic, 17 % African American, and 23 % White or "other" race [29]. Study staff included a primary navigator who recruited, enrolled, and carried out study procedures and a study coordinator. The study coordinator was trained as a secondary navigator, recruiting patients when the primary navigator was not available. The Baystate Medical Center Institutional Review Board approved the study.

Recruitment Strategies and Navigator Training

Recruitment strategies were grounded in a health equity framework, and staff-training activities emphasized development of an appreciation for and understanding of social determinants of health. Recruitment strategies comprised three major areas: (1) study team preparation prior to recruitment, (2) ensuring study process-optimized recruitment and retention, and (3) use of patient-centered study procedures (Fig. 1). Specific training and strategies are outlined below.

1. Preparation

a. Engagement of Clinical Staff

One of the study co-investigators (KW) was the division chief of General OB-GYN at BMC and oversaw all outpatient clinic operations. She facilitated meetings with the WWC medical director and practice manager to get input on study processes, to optimize recruitment, and to ensure minimal impact on clinic flow. After these initial meetings, the full research team attended a clinic staff meeting, attended by nurses and medical assistants, to describe the study's goals and objectives and to elicit recommendations for use of available space and minimizing impact on patient flow. A team member then attended monthly meetings during the first 6 months of

enrollment to troubleshoot any issues with the team's presence in the clinic.

b. Navigator Training/Pilot Testing Intervention

In the 6 months prior to beginning enrollment, the team developed study materials, and the PI trained the two study navigators in principles of health equity. This included discussions designed to heighten awareness of the social determinants of health and discussions centered on race, class, language, culture, and health in the USA. Implicit bias was discussed, and navigators were asked to take implicit association tests [30]; discussion of the test and awareness of implicit biases followed test taking. The importance of non-judgment and respect for difference was addressed, and techniques to develop rapport with potential participants in the context of power dynamics related to minority and economic status were also taught and modeled [29, 31, 32]. The navigators role-played techniques for approaching and interacting with participants, with the PI presenting various scenarios the navigator might encounter that would require sensitivity to race, economics, language, and culture. The primary investigator (SG) periodically observed the navigators during recruitment and provided feedback throughout the course of the study. Both of the navigators were female, reducing the potential for participant discomfort with their presence in the clinic exam room or at post-delivery hospital visits. The navigators who recruited participants during the first 12 months of the study were from minority groups.

2. Process

a. Pre-screening

To increase recruitment efficiency, the study coordinator used the study institution's clinical information systems to target recruitment. First, a list of women scheduled for a prenatal visit, spoke English, and were between 16–50 years of age was automatically generated and e-mailed to the study coordinator daily. Only English-speaking women were included because the website used for the intervention had only an English version. The coordinator checked each woman's electronic medical record to assess whether they were in the recruitment window of 20–34 weeks of gestation. Following pre-screening using the electronic health record, the navigator waited in the

prenatal clinic waiting room for women, noted when pre-screened women checked in, and approached them to determine eligibility in person; this included confirmation of age, ascertainment of comfort level with English, and plans as to where they would deliver their newborn. Potentially eligible women were then briefly informed about the study by the navigator while they waited for their prenatal visit to begin. They were then asked whether they would like to hear more about the study, and, if they did, the navigator provided detailed information and obtained written informed consent. Only navigators approached women to inform them of the study and invite them to participate. Each attempt at recruitment was documented in the study database (Microsoft Access): eligibility criteria met or not and whether the woman enrolled in the study, declined to enroll, or asked to be approached at a later date. The navigator checked the registration list frequently while in the clinic so that she would be aware when a targeted patient checked in for her clinic visit.

b. Retention

Women were tracked throughout the study using a Microsoft Access database; we checked the clinic list daily for enrolled women who had missing data or needed to complete intervention procedures. Study procedures were undertaken in the waiting room and in exam rooms to optimize available downtime during the prenatal visit. We ran weekly reports of recruitment statistics, including the number of women with incomplete baseline data collection. If patients were discharged from the hospital prior to completing follow-up data, we contacted them by phone to complete the study. With the exception of vacation periods, a navigator was present in the clinic for 9 of the 11 half-day sessions for which the clinic was open each week, enabling multiple opportunities for contact and completion of study processes. Navigators also covered weekend deliveries so that a study team member was able to gather follow-up data before women were discharged from the hospital.

3. Patient-centered—Protocol

The study protocol was designed to overcome known barriers to participating in research for low SES populations. These strategies included the following: reading each question aloud when collecting baseline and follow-up data to reduce potential challenges related to

literacy, conducting study procedures during regularly scheduled prenatal visits and in the hospital following delivery to reduce the time burden; conducting study procedures over sequential prenatal visits to eliminate the need for women to stay after they completed a prenatal visit, offering age-appropriate toys or drawing materials for siblings to play with if they accompanied their mother to her prenatal visits, using the time patients were waiting time for visits with ancillary staff (e.g., social worker, nutritionist, or glucose tolerance testing) to gain additional opportunities for completing study procedures, and giving \$20 in appreciation of participant time after completion of baseline data and after delivery when study procedures were complete (\$40 total).

Analysis

To calculate recruitment rates, we first determined the number of women potentially eligible for the study based on pre-screening. We then determined the number of potentially eligible women who were approached by the study navigators, and among these, the number determined to be eligible following in-person eligibility screening. This allowed us to calculate the percent of eligible women who enrolled in the study. For retention rates, we calculated the percentage of women enrolled who had completed study procedures following delivery of their infant. We asked women who did not enroll in the study their reason for declining, but we did not collect demographic data from the medical record for these patients in order to maintain patient confidentiality.

Results

Recruitment

Recruitment for the study took place between May, 2013, and August, 2014. We enrolled 746 women in the study over this time frame, exceeding the goal of 650 over 18 months. The study coordinator identified 1161 potential participants during the enrollment window; 265 of these women were not approached. The reasons they were not approached included failure to attend their scheduled prenatal care appointments, attending a clinic session for which there was no navigator coverage, or attending a session where a navigator was present but missed contacting the patient (Table 1). Among the 896 pre-screened patients who were approached, 40 (4.5 %) were ineligible due to either inability to understand English, plans to deliver at another hospital, or already having a child (only applicable after this stratum had reached recruitment goals) (Table 1). Of the 856 eligible participants approached, 110 (11.1 %) declined to participate, deferred their decision to a future visit then became ineligible because they passed the gestational age eligibility period, or were not enrolled for “other” or undocumented reasons. Among the eligible women who declined to participate, the majority (82.5 %) cited having a pediatrician they were happy with as their reason for declining. A total of 746 of the 856 eligible women (87.1 %) who were approached by navigators were enrolled in the study.

Participant characteristics

The median age of women enrolled in the study was 23 years (IQR 20–27); 66.1 % had a high school degree or less; 75.8 % had an income of less than \$20,000 annually or did not know their income level. Approximately half (51.1 %) were married or living with a partner; 59.7 % were Hispanic; and 10.9 % spoke Spanish primarily at home. Health literacy was low with 74.4 % at possible or high likelihood of low health literacy based on Newest Vital Sign screening (Table 2).

Retention

A total of 726 of the 746 enrolled women completed the study. Among those who did not complete the study, nine had withdrawn due to pregnancy loss, infant deaths, or refusal to complete the study; 11 were lost to follow-up. This yielded a retention rate of 97.3%.

Discussion

This randomized controlled trial involving lower-income and minority pregnant women achieved high practice-based recruitment and retention rates. Potential contributors to this success included the following: (1) partnering with clinic staff and the chief of General Obstetrics and Gynecology as valued collaborators; (2) training navigators in patient-centered recruitment and retention techniques grounded in a health equity framework; (3) using health information technology for pre-screening, database tracking a participant's progress through the study once enrolled, and monitoring progress toward recruitment goals; (4) staffing to maximize coverage of the clinic and hospital deliveries; (5) implementing a flexible protocol attuned to the unique needs of an underserved population; and (6) compensating participants for their time.

The success observed may have occurred through several mechanisms. Clinical staff investment in the study likely enhanced research staff access to patients during perinatal visits. Research staff were similar in age to the target study population and were from minority populations, which may have enhanced the capacity to develop trust [13]. Conducting study procedures while women waited for scheduled prenatal visits or were in the hospital following delivery decreased the burden of being in the study. Having the option to complete baseline or follow-up data by phone gave participants enhanced flexibility. Compensation for women's time demonstrated respect and acknowledged the importance of their contributions to the study [25]. Finally, women gained knowledge about pediatric health care quality and information about local pediatric practices' performance on quality measures, which may have enhanced relevance and provided an additional incentive to participate [33].

Challenges to recruiting minority patients to participate in research studies include cultural differences, language barriers, and mistrust of research [10, 12, 13, 15, 16, 19, 20, 22, 29, 31–40]. However, it appears that purposeful efforts to address these barriers may result in higher recruitment rates, as seen in the DC-Healthy Outcomes of Pregnancy Education study, which recruited 85 % of eligible women from minority groups into a randomized trial to promote healthy pregnancy behaviors [31]. Fewer studies have addressed barriers that

may affect lower-income women regardless of their race or ethnicity. These barriers may include lack of transportation, lack of child care, literacy and health literacy, communication, lack of appropriate incentives, and complexity of study protocols [25]. Studies that have attempted to address these potential barriers have found, similar to the current study, that practice-based face-to-face recruitment by research staff that are trained to be flexible and patient-centered in their approach improves recruitment and retention [12, 18, 32]. Engagement of the clinical staff as partners in the study while minimizing work flow disruptions may also promote recruitment and retention by enabling the team to follow patients throughout their visit [31]. Finally, use of existing health data information systems can maximize recruitment efficiency and produce greater yield in a shorter period of time, minimizing waste of study resources [29].

The current study's approach was associated with a substantially higher recruitment rate (87.1 vs. 52.0 %) than that described previously for recruitment in prenatal clinics at the same study site [29]. Retention was also higher than anticipated (97.3 %). The prior study differed from the current study in that it excluded non-Hispanic women. However, bilingual recruiters were used to overcome language barriers in the prior study, and 80 % of the women in that study preferred speaking English, making language differences alone unlikely to explain differences in recruitment rates. Coordination with clinic staff, frequent navigator presence in the clinic, and a broad window for recruitment and baseline data collection may have contributed in part to the differences observed.

The recruitment methods employed in this study also had limitations. First, because the website used to view quality data is only available in English, women in the study had to be comfortable speaking English. This meant that language-based disparities were not addressed in this study. Second, although efforts were made to have a navigator present at most clinic sessions, there were still missed recruitment opportunities due to lack of navigator presence at a clinic session. Third, although the reasons women gave for not participating did not include the need for child care while completing study procedures, it is possible that the distractions offered were not sufficient to overcome this potential barrier for some women. Fourth, because pregnancy is a time when some women are highly motivated to improve their infant's health, it is possible that these recruitment methods would not be as successful in a cohort of non-pregnant women [41]. Fifth, nearly half of participants responded that they did not know their income. Although this may have resulted in misclassification of the sample, this is unlikely given that 90 % of the clinic (communication with clinic director) carry public insurance. Possible reasons for women not knowing their income, as identified in a prior study that recruited in this clinic and pilot testing, include the following: (1) performing episodic work that does not yield a stable, predictable income; (2) minor status or living with extended family and not privy to family finances; and (3) fear of having unreported income detected and risking loss of income-based benefits. Sixth, this analysis uses historical comparators rather than an active control group, which may mean that factors other than the recruitment/retention methods we used contributed to the outcomes. Finally, an experimental design that compares the effectiveness of different recruitment methods would be useful to determine which strategies were associated with recruitment and retention success.

The multi-faceted, recruitment and retention strategies employed in the IDEAS for a Healthy Baby study and grounded in a health equity framework were associated with high recruitment and retention rates. This success suggests that strategies that address the unique barriers to participating in research experienced by women from low SES and minority populations may make research more accessible to these vulnerable populations and may be useful for researchers recruiting a similar population in a similar setting.

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Fig. 1.

Recruitment and retention strategies associated with successful recruitment of lower-income and minority pregnant women into a randomized controlled trial

Table 1

Recruitment rates: IDEAS for a Healthy Baby

	Number
Potential participants	1161
Not approached	263
Patient missed (due to no show, navigator busy, or navigator not in clinic)	201
Reason not approached at first appointment was not recorded	55
Other (incarcerated, with an interpreter, not patronizing the clinic again)	7
Approached	898
Not enrolled	152
Ineligible	54
Unable to understand English	9
Planned to deliver elsewhere	1
Multip (after target reached for stratum)	5
Deferred until no longer eligible (either wanted more time to think about the study or did not have time that day)	39
Reason ineligible not recorded	1
Eligible/declined	98
Enrolled	746

Table 2

Characteristics of study participants

Characteristic	726 (100)
Age, median (IQR) (years)	23 (20–27)
Number of children	
First child	342 (47.1)
Subsequent child	384 (52.9)
Employment	
Employed	264 (36.4)
Homemaker	69 (9.5)
Unemployed	323 (44.5)
Student	67 (9.2)
Don't know/not sure	3 (0.4)
Marital status	
Married/living together	371 (51.1)
Not living together	119 (16.4)
Single/widowed/divorced	236 (32.5)
Education	
Less than high school/Unknown	268 (36.9)
12th grade/GED	212 (29.2)
Some college/post high school training	174 (24.0)
2-year college	41 (5.6)
4-year college/graduate education	31 (4.3)
Race/ethnicity	
White non-Hispanic	163 (22.4)
Black non-Hispanic	107 (14.7)
Hispanic—Puerto Rican	401 (55.2)
Hispanic—Other	33 (4.5)
Other/unknown	22 (3.0)
Income	
\$0 to \$19,999	185 (25.5)
\$20,000 to \$39,999	115 (15.9)
\$40,000	60 (8.3)
Not sure/don't know/refused to answer	365 (50.3)
Newest vital sign (health literacy)	
High likelihood of limited literacy (score 0–1)	223 (30.8)
Possibility of limited literacy (score 2–3)	316 (43.6)
Adequate literacy (score 4–6)	186 (25.7)

IQR interquartile range