The Ohio Patient Navigation Research Program: Does the American Cancer Society Patient Navigation Model Improve Time to Resolution in Patients with Abnormal Screening Tests?

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Abstract

Background: Patient navigation (PN) has been suggested as a way to reduce cancer health disparities; however, many models of PN exist and most have not been carefully evaluated. The goal of this study was to test the Ohio American Cancer Society model of PN as it relates to reducing time to diagnostic resolution among persons with abnormal breast, cervical, or colorectal cancer screening tests or symptoms.

Methods: A total of 862 patients from 18 clinics participated in this group-randomized trial. Chart review documented the date of the abnormality and the date of resolution. The primary analysis used shared frailty models to test for the effect of PN on time to resolution. Crude HR were reported as there was no evidence of confounding.

Results: HRs became significant at 6 months; conditional on the random clinic effect, the resolution rate at 15 months was 65% higher in the PN arm ($P = 0.012$ for difference in resolution rate across arms; $P = 0.009$ for an increase in the HR over time).

Conclusions: Participants with abnormal cancer screening tests or symptoms resolved faster if assigned to PN compared with those not assigned to PN. The effect of PN became apparent beginning six months after detection of the abnormality.

Impact: PN may help address health disparities by reducing time to resolution after an abnormal cancer screening test. *Cancer Epidemiol Biomarkers Prev; 21(10); 1620–8. ©2012 AACR.*

Introduction

Despite significant advances in prevention, screening, diagnosis, and treatment of cancer, reductions in mortality have not reached all populations equally (1). For example, the age-adjusted breast cancer mortality rates among blacks increased from 31.8 per 100,000 in 1980 to 35.6 per 100,000 in 2005 ($P < 0.001$), while decreasing among whites from 32.6 per 100,000 to 25.8 per 100,000 ($P < 0.001$) during the same time period (2). Similar trends were seen for colorectal cancer (CRC) mortality rates for those with less than 12 years of education (i.e., no change in mortality rates from 1993 to 2001) compared with those with at least 16 years of education (decreases of 2.4% to 4.8%; 3). Barriers, such as access to cancer care services, attitudes, insurance coverage, and cost, permeate all points of the cancer continuum, ranging from the individual to system and policy levels (4). These barriers, as well as differences in risk factors, screening rates, poor adherence to follow-up tests and treatment, and environmental and biologic factors, all contribute to cancer disparities (5).

Harold P. Freeman introduced patient navigation (PN) as a potential strategy to reduce disparities among African American patients in a Harlem, New York public hospital (6). Among this medically underserved population, PN significantly increased the completion of mammography, and improved early-stage cancer detection, treatment completion, and survival rates for breast cancer (7). Often ambiguously defined in the literature, Dohan and colleagues describe patient navigators as care coordinators who take a flexible problem-solving approach to helping patients overcome barriers to all points of care on the cancer continuum: prevention, screening, diagnosis, treatment, and survivorship (8). Patient navigators attempt to improve timeliness of diagnosis and treatment,

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as well as reduce loss to follow-up, after an abnormal screening finding until cancer-related diagnostic and treatment services have been completed (9).

To date, PN lacks a supportive body of evidence for its effectiveness as well as consistent definitions and training for patient navigators (8). Its success has been measured in increases in cancer screening rates (10), downshifts in stage of diagnosis (11), improvement in follow-up rates for an abnormality (12), and reduced time to diagnosis (12) and treatment (11). However, very few rigorous evaluations of PN interventions (i.e., randomized studies) have been reported among patients with abnormal tests. Moreover, many previous randomized controlled trials examining the effectiveness of PN in follow-up after an abnormal test include small to moderate sample sizes (9, 13).

Partly because of its potential to reduce disparities, the majority of PN studies have been conducted among medically underserved, high-risk, or specific racial/ethnic groups. Moreover, previous studies have mainly focused on breast and cervical cancers only (13–18). These previous studies limit the generalizability of findings to other populations (e.g., males) and patients with other types of cancers. Thus, there is a need for large-scale randomized controlled trials of PN in a broad population, measuring time to diagnostic resolution and treatment as outcomes (8).

The primary goal of the Ohio Patient Navigator Research Program (OPNRP) was to test the Ohio American Cancer Society (ACS) model of PN as it relates to reducing time to diagnostic resolution among persons with abnormal breast, cervical, or CRC screening tests or symptoms in a heterogeneous patient population from primary care clinics and Federally-Qualified Health Centers (FQHC) located in central Ohio. This research program was one of 9 funded grants conducted in 10 sites included in the National Cancer Institute-sponsored Patient Navigation Research Program (PNRP; 19).

Materials and Methods

Study design

The OPNRP used a group-randomized trial (GRT) design, in particular, a nested cohort design (20). In this design, identifiable groups are randomized to study conditions and members of those groups are followed over time to assess the effect of an intervention. In the OPRNP, medical clinics were randomized to conditions (PN or comparison), and individual patients were followed over time to assess the effect of the PN intervention. We used a GRT design instead of an individually randomized design to avoid contamination that would almost certainly occur if patients were randomized to study arms within clinics. Approval to conduct the project was obtained from The Ohio State University Institutional Review Board.

Setting

Clinics. Patients from 12 primary care clinics from the Ohio State University (OSU) Primary Care Research Network (PCRN) and Columbus Neighborhood Health Centers (CNHC) in Columbus, Ohio participated in this study. These clinics provide primary comprehensive health care to a culturally and economically diverse group of patients, including underserved populations (minority, poor, and elderly). At the time the OPNRP was implemented, the OSU PCRN consisted of 15 clinic locations, however, 3 clinics were consolidated into 1 clinic, 1 clinic was closing, 2 clinics specialized in occupational health, 1 clinic was for travel and immunizations, and 1 was an integrative medicine clinic. Thus, only 8 primary care clinics of the PCRN were eligible and participated in the OPNRP. The CNHC is a not-for-profit organization comprised 5 FQHCs located in the city of Columbus, Ohio, with a preponderance of patients from underserved populations. One CNHC served mostly Somalian population that could not participate in the study because of language barriers. Therefore, this clinic was not included. The remaining 4 CNHC clinics participated in the OPNRP. Thus, initially all eligible 8 PCRN and 4 CNHC clinics participated in OPNRP.

Recruitment began in these 12 clinics in 3 groups of 2 pairs. The first group of 4 clinics (2 comparison and 2 intervention) started patient recruitment in November 2006. The second group of 4 clinics began recruitment in February 2007, and the last group began recruitment in April 2007. Because of slow recruitment, 2 Ohio State University Medical Center (OSUMC) gynecology clinics (OBGYN), 2 OSUMC gastroenterology (GI) specialty clinic sites, and 2 smaller OSUMC clinics were added, a general internal medicine (GIM) clinic and a family medicine clinic. Recruitment began in these 6 additional clinics in December 2007. Thus, in total, there were 18 clinics participating with 9 in each study arm. A CONSORT diagram (Fig. 1) outlines the numbers of clinics and patients participating at various stages throughout the study.

Randomization. The initial 12 clinics were matched on clinic type (PCRN vs. CNHC) and proportion of African American patients, then randomized from within pairs to study conditions, providing 6 clinics in each condition. The additional 6 clinics were paired on clinic type (OBGYN vs. GI vs. GIM) and randomized from within pairs to study conditions, providing 3 additional clinics in each condition.

Participants. To be eligible for participation, patients must have been: (i) more than 18 years old; (ii) a regular patient of the primary care practice (i.e., not just coming for a second opinion or consultation); (iii) not cognitively impaired; (iv) able to give informed consent; (v) identified as having either an abnormal screening test, an abnormal diagnostic test, or an abnormal clinical finding leading to diagnostic testing for cervical, breast, or CRC; (vi) without a prior history of cancer, except for nonmelanoma cancer of the skin; (vii) living outside a nursing home or institutional setting; (viii) without prior history of medical navigation; and (ix) able to speak and understand English or Spanish.

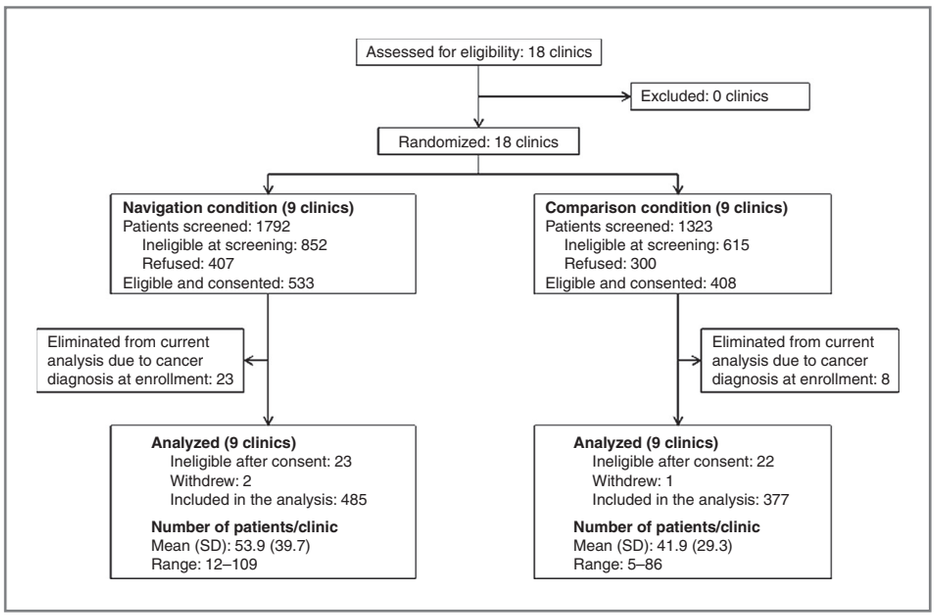

Figure 1. CONSORT diagram, OPNRP.

Several different mechanisms were developed to recruit participants. Some clinics agreed to use "passive consent" as a means of referring patients to the study, whereby research staff screened cytology reports, mammography reports, and charts to identify potential participants, and, if a potential participant was identified through the screening process, the research staff forwarded the name to the physician asking permission to contact the patient. Providers replied only if they did not want the research staff to contact the potential participant. Other clinics required active physician consent. Once consent was obtained from the physician, a letter introducing the study was sent to the patient before any contact by the research staff. Potential participants were then called, the study was explained, and they were asked if they would like to participate in the program. If patients agreed to participate, they had the option of providing verbal consent and completing the baseline questionnaire via telephone or in-person with the study interviewer at either the clinic or a location that was mutually convenient for the patient and study staff.

PN intervention

Behavioral theory. The Chronic Care Model guided the overall development and implementation of the OPNRP intervention (21) by focusing on eliminating problems that exist within the health care system because of breakdowns in communication, decisional support, and coordination of care as patients navigate across different settings and among various providers. The PN intervention was also guided by social support theory (22) and addressed specific constructs of the Health Belief Model (HBM; e.g., perceived severity, perceived barriers, self-efficacy; 23).

Navigators first identified specific barriers to care and then assisted participants by taking actions tailored to the specific needs of the individual. Social support was expressed as concern for the participant's health, and actions taken by the navigators included supportive listening, providing educational materials, and providing referrals for psychologic assistance, if needed. Navigators provided instrumental assistance by helping participants with making appointments, resolving child care problems, and helping with transportation issues, etc. At the participant level, navigators addressed important HBM constructs by counseling them to take important health-related actions. For example, navigators addressed barriers to care or improved patients' confidence (self-efficacy) by providing support or encouragement as they progressed through diagnostic testing and treatment of their abnormality.

Patient navigators. The 3 lay patient navigators for the OPNRP were female, more than 30 years of age, and college graduates. Each had worked within the health care system before starting with the OPNRP. One Hispanic navigator was bilingual and fluent in Spanish, one navigator was African American, and one navigator was non-Hispanic White. If needed, a translation service was also available to assist with questionnaire administration and/or PN issues in Spanish.

Patient navigators were paid employees of OSU and completed onsite training and also attended numerous Ohio (OSU and ACS) and national (PNRP) training sessions (24). Each patient navigator developed their own resource book within a common template to assist participants in addressing barriers to care, and then shared found information with the other navigators. Allowing each navigator to independently develop a resource book provided them the opportunity to become familiar with local, regional, and national resources. The navigators were not embedded in the clinic; rather, they completed

most activities by telephone, following the Ohio ACS model of PN.

Participants from intervention practices were assigned to 1 of the 3 patient navigators. Those who only spoke and understood Spanish were assigned to the navigator who was fluent in Spanish. The assigned patient navigator contacted the participants by phone (or in person, if no phone number was available) within 5 days following the assignment. The navigator then assessed participants' needs, connected participants to community and social support services, facilitated interaction and communication with health care staff and providers, and provided health education to individuals. Patient navigators each had a similar load of participants they were navigating throughout the study.

Comparison condition

Participants from comparison clinics were mailed educational materials focusing on their specific cancer test and/or abnormality within 1 month of completing the baseline questionnaire. Where possible for those who did not speak English, materials in Spanish were made available.

Measures

A trained interviewer administered the baseline and end-of-study questionnaire. Participants completed an end-of-study questionnaire when their abnormality was resolved or at the end of the prespecified follow-up period (censored at 365 days). If a participant was not able to be contacted to complete the end-of-study interviewer-administered questionnaire, the participant completed a mailed survey (14.9%). The end-of-study questionnaire contained items similar to the baseline questionnaire and additional questions for those participants who were enrolled from the PN clinics to assess process measures related to receiving the intervention. Outcome data [e.g., resolution of abnormality (Yes/No) and time to resolution in days] were obtained from the participants as well as from their medical records. The following information was collected on the questionnaires:

Demographic characteristics. Participants provided information about their gender, race, ethnicity, primary language, marital status, educational level, housing status, country of birth, number of dependents, household size, employment status, household income, and health insurance (Table 1).

Psychosocial. Quality of life was measured by the Quality of Life Index (Cronbach alpha = 0.775; 25). Five dimensions of quality of life include activity (occupation involvement), activities of daily living, perceptions of health, support (family and friends), and outlook on life. Each subscale is scored 0 to 2, with a total range of scores from 0 to 10, with lower scores reflecting better performance.

Trust in physicians was assessed with the Trust in Physician Scale (26). This is an 11-item scale (Cronbach alpha = 0.85) scored on a 5-point Likert scale ranging from strongly disagree to strongly agree. Higher scores reflect greater interpersonal trust (dependability, confidence in the physician's knowledge and skills) in patient–physician relationships.

Anxiety was assessed with the Beck Anxiety Inventory (27). This is a 21-item scale (Cronbach alpha = 0.85) that is descriptive of subjective, somatic, or panic-related symptoms of anxiety. Responses are on a 4-point Likert scale (not at all to severely) and higher scores indicate an increasing level of anxiety.

Depressive symptoms were measured using the Center for Epidemiologic Studies Depression (CES-D) Scale (Cronbach alpha = 0.85–0.90; 28). This scale includes 20 items with response categories on a 4-point Likert scale (rarely/none of the time to most/all of the time). Higher scores indicate worse depression symptomatology and a score of 16 or higher is used as the cutoff point for depressive symptoms.

Perceived social support was measured with the Perceived Social Support-Friend Scale (Cronbach alpha = 0.88) and Perceived Social Support-Family Scale (Cronbach alpha = 0.80; 29). Each scale includes 12 statements with responses measured as yes/no/don't know. Higher levels of perceived social support are a result of more statements being answered by "yes."

Process measures were recorded by patient navigators. A form enumerating the number and types of barriers a participant experienced, as well as action steps to be taken by the participant and/or patient navigator, and the time spend was completed for each encounter.

Data analysis

Baseline characteristics of intervention and comparison participants were compared descriptively using means for continuous variables and percentages for categorical variables (Table 1).

A shared frailty model (30, 31) was used for the primary analysis to test for differences in time to resolution (determination of a benign condition or a cancer diagnosis) between the comparison and PN arms. The shared frailty model is an extension of the commonly used Cox proportional hazards model for survival data, which includes a gamma-distributed random effect accounting for correlation among the responses from participants attending the same clinic. Our model contained a fixed effect for study arm (PN/comparison) and a random effect for clinic. Data from all sites (breast, cervical, and CRC) were combined in our primary analysis; differences in the intervention effect by site were explored in a secondary analysis. Secondary analyses extended the model to adjust for participant-level characteristics collected in each PNRP study center (race, medical insurance, country of origin, primary language, marital status, and age) and exclusively in OPNRP (household income, education, household size, number of dependents, housing status, employment status, and number of years in current residence). The proportional hazards assumption of study arm and each covariate was evaluated using Schoenfeld

Table 1. Participant characteristics, OPNRP ($N = 862$)

Variable	Level	Comparison ($n = 377$) N (%)	Intervention ($n = 485$) N (%)	Total ($n = 862$) N (%)
Anatomical site	Breast	199 (52.8%)	282 (58.1%)	481 (55.8%)
	Cervix	144 (38.2%)	176 (36.3%)	320 (37.1%)
	Colorectal	34 (9.0%)	27 (5.6%)	61 (7.1%)
Gender	Female	363 (96.3%)	473 (97.5%)	836 (97.0%)
	Male	14 (3.7%)	12 (2.5%)	26 (3.0%)
Race	White	258 (69.5%)	347 (71.5%)	605 (70.7%)
	Black	88 (23.7%)	98 (20.2%)	186 (21.7%)
	Other	25 (6.7%)	40 (8.2%)	65 (7.6%)
Primary language, English	No	23 (6.1%)	18 (3.7%)	41 (4.8%)
	Yes	351 (93.9%)	467 (96.3%)	818 (95.2%)
Marital status	Single	119 (31.8%)	137 (28.2%)	256 (29.8%)
	Married	165 (44.1%)	241 (49.7%)	406 (47.3%)
	Divorced/widowed	90 (24.1%)	107 (22.1%)	197 (22.9%)
Education level	Less than high school	19 (5.1%)	28 (5.8%)	47 (5.5%)
	High school	38 (10.2%)	79 (16.3%)	117 (13.6%)
	Some college/associate's degree	138 (37.0%)	158 (32.6%)	296 (34.5%)
	College graduate/graduate school	178 (47.7%)	220 (45.4%)	398 (46.4%)
Housing status	Rent	141 (37.7%)	161 (33.3%)	302 (35.2%)
	Own	206 (55.1%)	294 (60.7%)	500 (58.3%)
	Live with family, friends/other	27 (7.2%)	29 (6.0%)	56 (6.5%)
Country of birth U.S.	No	34 (9.1%)	45 (9.3%)	79 (9.2%)
	Yes	340 (90.9%)	440 (90.7%)	780 (90.8%)
Number of dependents	None	210 (56.3%)	262 (54.1%)	472 (55.1%)
	One	79 (21.2%)	102 (21.1%)	181 (21.1%)
	Two	54 (14.5%)	76 (15.7%)	130 (15.2%)
	Three or more	30 (8.0%)	44 (9.1%)	74 (8.6%)
Household size, including self	One	83 (22.2%)	102 (21.0%)	185 (21.5%)
	Two	143 (38.2%)	173 (35.7%)	316 (36.8%)
	Three	62 (16.6%)	104 (21.4%)	166 (19.3%)
	Four	49 (13.1%)	63 (13.0%)	112 (13.0%)
	Five or more	37 (9.9%)	43 (8.9%)	80 (9.3%)
Employment status	Full-time	217 (58.3%)	235 (48.7%)	452 (52.9%)
	Part-time	53 (14.2%)	66 (13.7%)	119 (13.9%)
	Retired	30 (8.1%)	58 (12.0%)	88 (10.3%)
	Disabled	27 (7.3%)	45 (9.3%)	72 (8.4%)
	Unemployed	45 (12.1%)	79 (16.4%)	124 (14.5%)
Annual household income in last year	Less than $10k	49 (13.1%)	50 (10.3%)	99 (11.5%)
	$10K–$29,999	72 (19.2%)	83 (17.1%)	155 (18.0%)
	$30K–$49,999	60 (16.0%)	81 (16.7%)	141 (16.4%)
	$50K+	170 (45.3%)	237 (48.9%)	407 (47.3%)
	Don't know	24 (6.4%)	34 (7.0%)	58 (6.7%)
Insurance	Uninsured	11 (3.0%)	28 (5.9%)	39 (4.7%)
	Private	257 (70.8%)	325 (68.4%)	582 (69.5%)
	Public	95 (26.2%)	122 (25.7%)	217 (25.9%)

	Comparison		Intervention		Total	
	Mean (*SD*)	Range	Mean (*SD*)	Range	Mean (*SD*)	Range
Age at consent	43.4 (15.0)	19–89	45.9 (14.3)	18–86	44.8 (14.7)	18–89
Years in home	7.3 (8.6)	0.1–45	8.0 (9.1)	0.1–60	7.7 (8.9)	0.1–60

NOTE: Missing values have been omitted from the totals.

residuals (32, 33) and a test of an interaction with the natural log of time; if violated, we included the interaction term in the model. Consistent with intention to treat principles, all participants and clinics enrolled in the study were included in the analysis in the study arm to which they were assigned. These analyses were conducted using Stata Intercooled 11 (34).

Results

Participants

A total of 862 patients from 18 clinics enrolled in the study. Participant characteristics are summarized in Table 1. The average participant age was approximately 43 years, and the vast majority (97%) were female. A majority (70.7%) of the participants were white, 21.7% were black, and 7.6% identified as a race other than white or black. Nearly half of the participants were married, with roughly 30% single and 23% divorced/widowed. Almost half (46.4%) of the participants completed college or graduate school, whereas 34.5% had some college experience or an associate's degree. Nearly 60% of the participants lived in a home they owned, and 47.3% reported annual household incomes in excess of $50,000. One quarter (25.9%) of the participants had public insurance, 69.5% had private insurance, and 4.7% of participants were uninsured. There were no apparent differences in any of the demographic characteristics by study arm. A total of 707 patients refused to participate in the study. Their gender distribution was the same as for participants (96.5% female), although on average their age at referral to the study was 2.4 years less.

Primary outcome: Time to resolution

Survival curves for time to resolution by study arm are provided in Fig. 2. The estimated probability that a participant was resolved in the first 6 months was approximately the same across the 2 study arms, after which the estimated probability of resolution was greater among navigated participants. Our shared frailty model confirmed that PN became more effective over time ($P = 0.009$). Table 2 provides HRs comparing those in the PN group to those in the comparison group at 3, 6, 9, 12, and 15 months of follow-up. Conditional on the random clinic effect, the resolution rate at 6 months was 36% higher in the PN arm compared with the comparison arm, and the difference between arms increased with time. Similar results were found after adjusting for participant-level characteristics.

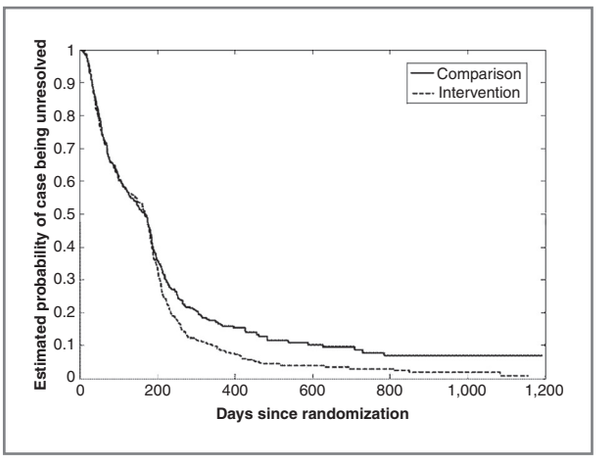

Figure 2. Estimated survival curves for time to resolution. Curves estimated using shared frailty models fit separately to the intervention and comparison data. Curves assume mean frailty value (frailty = 1).

As an exploratory analysis, we tested for effect modifiers of the PN intervention. We found that the effect of PN on the resolution rate did not differ with race (black vs. white; $P = 0.43$), insurance (public vs. private; $P = 0.27$), education (college grad vs. lower; $P = 0.15$), or cancer site (breast vs. cervical; $P = 0.57$), but there was a marginally significant difference in the effect with income ($P = 0.07$). For the first 6 months, the effect of the PN intervention on the resolution rate was greater among participants whose annual household income was less than $50,000; however, as time progressed, the effect became greater among participants whose household income was $50,000 or higher (Table 3).

Secondary outcomes: Navigation process

Fifty-nine participants (out of 485 in the PN arm) did not receive PN, either because they refused PN after consent ($n = 3$), were never successfully contacted by the navigator ($n = 7$), or were not successfully contacted by the navigator before diagnostic resolution or censoring ($n = 49$). More than half ($n = 228$; 53.5%) of the 426 contacted participants reported no barriers. Among those reporting barriers, 99 (50.0%) reported only 1 barrier, 53 (26.8%) reported 2, and 46 (23.2%) reported 3 or more. The 3 most frequently reported barriers among those reporting barriers were misperception/beliefs about a test or treatment (16.4%), communication concerns with health care providers (15.0%), and problems with scheduling (11.5%).

Patient navigators reported 1,152 encounters with the participants in the PN arm. The majority ($n = 1{,}034$; 89.8%) of encounters among patients who accepted navigation lasted less than 15 minutes. The mean number of encounters per navigated participant was 2.7 with a range of 1 to 38.

Discussion

PN has emerged as a possible strategy to eliminate disparities in outcomes experienced by many underserved and minority populations (6). However, little evidence from well-designed studies exists on the effectiveness of PN (18). The goal of this study was to assess the efficacy of a PN intervention—modeled after the Ohio ACS PN program—on improving rates of resolution (i.e., determination of a benign condition or a cancer diagnosis) after an abnormal breast, cervical, or CRC test/finding in a diverse population from academic and FQHC clinics in Columbus, Ohio. The results of this GRT indicate that this model of PN, mainly via telephone from a nonclinic

Table 2. HRs (95% confidence intervals) of case resolution for intervention versus comparison

Month	Crude[a]		Adjusted for variables collected in PNRP (national)[b]		Adjusted for variables collected in PNRP (Ohio)[c]	
3	1.17	(0.90, 1.52)	1.15	(0.95, 1.40)	1.12	(0.93, 1.36)
6	1.36	(1.03, 1.78)	1.35	(1.09, 1.67)	1.32	(1.07, 1.63)
9	1.48	(1.09, 1.99)	1.48	(1.15, 1.89)	1.45	(1.14, 1.85)
12	1.57	(1.13, 2.17)	1.57	(1.19, 2.08)	1.55	(1.18, 2.04)
15	1.65	(1.16, 2.33)	1.66	(1.22, 2.25)	1.64	(1.21, 2.21)

[a] $n = 862$.

[b] $n = 835$; adjusted for race (black, white, other), medical insurance (private, public, none), country of birth (U.S., other), primary language (English, other), marital status (single, married, divorced/widowed), and age (in years).

[c] $n = 851$; adjusted for household income (<$10k; $10k–$29,999; $30k–$49,999; $50k+; don't know/refused), education (<high school, high school, some college, college grad/grad degree), household size (1, 2, 3, 4, 5+), number of dependents (none, 1, 2, 3+), housing status (rent, own, other), employment status (full-time, part-time, retired, disabled, unemployed), and number of years in current residence.

location, improved resolution rates among participants, with equivalent effects among black and white participants, among those with and without a college education, and across cancer sites. Moreover, there was a suggestion that participants from lower incomes benefited earlier from PN.

Previous studies have showed similar results (18). For example, PN reduced time to diagnostic resolution in 2 low-income, minority populations after an abnormal mammogram (14, 16) and increased follow-up in those 2 populations, as well as in another study, which included Asian women (17). In addition, 2 cohort studies and 2 pre-/postanalyses found that PN reduced diagnostic delay and improved follow-up in women after abnormal mammograms in high-risk, urban, safety-net populations (11, 12, 35, 36). Not all previous studies, however, have found a beneficial effect for PN. For example, PN did not improve follow-up when delivered by telephone in a low-income, minority population with breast abnormalities (13) or among Hispanic women with breast or gynecologic cancer (15).

Of interest was our finding that almost half of the participants from the intervention clinics (47.6%) reported no barriers. To our knowledge, no other studies examining PN have reported this result. This suggests that not all patients need PN or that many patients might already be receiving sufficient attention from their health care providers or other support systems. However, this result also points to the fact that almost half of patients did identify barriers and needed assistance to address barriers to complete recommended follow-up.

Table 3. Monthly HRs (95% confidence intervals) of case resolution by annual household income

Months post randomization	Annual household income	
	<50k	50k+
3	1.36 (1.04, 1.76)	1.01 (0.77, 1.32)
6	1.45 (1.08, 1.93)	1.30 (0.96, 1.76)
9	1.50 (1.07, 2.11)	1.51 (1.06, 2.15)
12	1.54 (1.05, 2.27)	1.68 (1.13, 2.50)
15	1.58 (1.03, 2.41)	1.82 (1.18, 2.83)

The fact that PN was effective in the first 6 months among individuals with lower incomes suggests that those individuals had immediate needs the navigator could effectively address, whereas after 6 months those with higher incomes who had not resolved had barriers that at that time were more easily resolved with assistance from a patient navigator. Participants who experienced barriers reported primarily patient-focused barriers, such as misperception/beliefs about the test or treatment, or system-level barriers, such as communication concerns and scheduling problems. These results provide clues as to where the health care system is breaking down for many patients and exactly how PN can help. Findings also indicate that a tailored PN program, i.e., one that focuses on the individual barriers each patient has, may be beneficial.

This study possesses several strengths, including a GRT design, a large and diverse population of participants (both demographically and by cancer site), and a mix of clinic types. Moreover, an easy-to-replicate PN intervention was tested which used well-trained lay navigators representing the communities from which the participants were drawn. There were several limitations to note. First, our sample included only a small number of participants who progressed to a cancer diagnosis, thus limiting our ability to generalize results to that population. Approximately 40% of potential participants did not participate in the study, also limiting generalizability, however, nonparticipants were not very different from those who participated, at least in terms of age and gender.

In addition, more participants with breast and cervical abnormalities than CRC abnormalities were recruited, limiting our findings to women with these 2 cancer types.

In summary, the Ohio ACS model of PN appears to be effective in improving resolution rates among participants with abnormal breast, cervical, and CRC tests. These findings have important implications for hospitals and clinics wishing to establish PN programs to help reduce disparities among underserved populations and reduce disease burden. More research, however, is needed to determine why some individuals use PN although others do not and if this PN model is effective in all populations, including cancer patients and men.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

Authors' Contributions

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