Clinic type and patient characteristics affecting time to resolution after an abnormal cancer-screening exam

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Abstract

Background—Research shows that multilevel factors influence healthcare delivery and patient outcomes. The study goal was to examine how clinic type (academic medical center (AMC) or federally-qualified health center (FQHC)) and patient characteristics influence time to resolution (TTR) among individuals with an abnormal cancer screening test enrolled in a patient navigation (PN) intervention.

Methods—Data were obtained from the Ohio Patient Navigation Research Project, a group-randomized trial of 862 patients from 18 clinics in Columbus, Ohio. Patient's TTR after an abnormal breast, cervical, or colorectal screening test and the clinics' patient and provider characteristics were obtained. Descriptive statistics and Cox shared frailty proportional hazards regression models of TTR were used.

Results—The mean patient age was 44.8 years and 71% of patients were white. In models adjusted for study arm, FQHC patients had a 39% lower rate of resolution than AMC patients (*P*=0.004). Patient factors of having a college education, private insurance, higher income, and being older were significantly associated with lower TTR. After adjustment for factors that substantially impacted the effect of clinic type (patient insurance status, education level and age), clinic type was not significantly associated with TTR.

Conclusions—These results suggest that TTR among individuals participating in PN programs is influenced by multiple socioeconomic patient-level factors rather than clinic type. Consequently, PN interventions should be tailored to address SES factors that influence TTR.

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Conflict of Interest Statement: There are no actual, potential, or perceived conflict of interest by any of the authors.

Impact—These results provide clues regarding where to target PN interventions and the importance of recognizing predictors of TTR according to clinic type.

Introduction

Despite advances in the prevention, screening, diagnosis, and treatment of cancer, disparities by race/ethnicity and socioeconomic status (SES) remain (1–6). For example, the 5-year survival rates for blacks are lower than those for whites for all of the major cancer sites (7). Previous studies have shown that low-income, racial and ethnic minority patients are more likely to delay or miss follow-up appointments (8–11). Timely diagnostic care can be impeded by numerous factors ranging from personal (i.e., socioeconomic, cultural) to organizational barriers (i.e., system fragmentation, limited or poor accessibility), as well as a lack of social support to obtain necessary care. These barriers may result in more advanced stage at diagnosis, lower survival rates, and higher death rates for populations who have historically been underserved by the medical system (12).

Medically underserved populations are much more likely to depend on urgent care, emergency rooms, and/or federally qualified health centers (FQHCs) for their routine medical care (6,13). However, FQHCs typically have high patient volumes, limited resources, and preponderance to acute care, all of which contribute to delayed follow-up care (14). The implementation of the Patient Protection and Affordable Care Act (PPACA) will likely increase FQHC patient populations seeking a variety of services, including cancer prevention and diagnosis (14). In order to improve the efficiency of coordinated services, two system changes, patient-centered medical homes and electronic medical records, are being implemented in FQHCs (14,15). A study by Allen and colleagues found that representatives from FQHCs identify patient navigation as a third organizational strategy to improve cancer outcomes in FQHCs (15). Patient navigation has been identified in the PPACA as an important component for improving health care in vulnerable populations, however, payment for these services has not been determined (14).

Patient navigation (PN) is a patient-centered health care service delivery model that assists individuals, particularly the medically underserved, in overcoming obstacles encountered across the cancer care continuum (16). PN has been demonstrated to increase cancer screening rates, improve follow-up rates after an abnormal cancer screening test, reduce time from a cancer diagnosis and treatment initiation and decrease cancer treatment costs (12,17–19). While a growing number of studies have documented the efficacy of PN in obtaining and adhering to cancer care, disparities in time to diagnostic resolution (TTR) remain by SES (20,21).

The extent to which clinic type (e.g., FQHCs or academic medical centers (AMCs)) or patient-level characteristics contribute to the variability in TTR is poorly understood. The few studies that have explored clinic type and TTR have found that patients receiving care in

FQHCs have longer TTR (22–25). Proposed explanations for these delays include system-level factors, such as limited workforce and capacity at nonprofit facilities, as well as patient characteristics such as SES. Further research is needed to determine whether patient-level SES factors impact TTR and whether these factors vary according to clinic type (26–28).

The primary objective of this study was to examine how clinic type (primary care clinic within an AMC or FQHC) and patient characteristics influence TTR following an abnormal cancer screening test among individuals enrolled in a PN intervention. Because other studies have only analyzed data at the patient- or clinic-level, this investigation adds new information by examining data at both levels to attain a more precise measure of differences in TTR among individuals enrolled in a PN program.

Materials and Methods

Study design and population

We used data collected as part of the Ohio Patient Navigation Research Project (OPNRP), a group-randomized trial with a nested cohort design (29). Details regarding the study design and population have been previously published (17). Briefly, the study initially recruited patients from 8 primary care clinics from the Ohio State University (OSU) Primary Care Research Network (PCRN) and 4 Columbus-area FQHCs. Due to slow recruitment, 2 Ohio State University Medical Center (OSUMC) gynecology clinics (OBGYN), 2 OSUMC gastroenterology clinics (GI), a general internal medicine clinic, and a family medicine clinic were added. A total of 18 clinics were randomized to receive either the PN or comparison conditions. The initial 12 clinics were matched according to clinic type and proportion of black patients, with 6 clinics randomized to each condition. The additional 6 clinics were matched according to specialization only (OBGYN vs. GI vs. general medicine clinics). Following randomization, there were 9 clinics in each of the PN and comparison groups.

Several different mechanisms were used to recruit participants. Some clinics agreed to use "passive consent", where research staff screened cytology reports, mammography reports, and charts to identify potential participants. If a potential participant was identified through this screening process, a research staff member forwarded the name to the physician asking permission to contact the patient. 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 were interested in participating in the program (17). Patients who agreed to participate in the study completed the baseline questionnaire with a study interviewer via telephone or in-person interview. Of those patients eligible to participate, 56.1% and 43.8% of patients from AMC and FQHC clinics participated, respectively. Rates were similar by age, with 53.9% of those 50 or younger participating as compared to 56.9% for those over 50. All study participants provided informed consent.

Individual patients were then followed to determine the effect of the PN intervention on TTR after an abnormal breast, cervical, or colorectal test. Eligible patients were at least 18

years old, a regular patient of the primary care clinic, not cognitively impaired, resided outside of a nursing home or institutional setting, spoke and understood English or Spanish, and were able to provide informed consent. In addition, participants must have been identified as having an abnormal screening test, diagnostic test, or clinical finding leading to diagnostic testing for cervical, breast, or colorectal cancer. Participants with a positive history of previous medical navigation or cancer, with the exception of non-melanoma of the skin, were ineligible. The study was approved by The Ohio State University Institutional Review Board.

The PN intervention was developed based on the Chronic Care Model (30), the Social Support Theory (31), and specifically addressed constructs included in the Health Belief Model (32). Each participant was assigned to 1 of 3 lay patient navigators used for the study. These navigators were paid employees of OSU. Each navigator was over the age of 30, female, a college graduate, had previously worked within the health care system, and had completed multiple training sessions. One Hispanic navigator was fluent in both English and Spanish, one navigator was black, and the last navigator was non-Hispanic white. Participants from the intervention practices were randomly assigned to 1 of the 3 patient navigators with the exception of those who were not primary English-speaking participants. Navigators fluent in Spanish were assigned to participants who only spoke and understood Spanish. Among patients of clinics randomized to receive the PN intervention, navigators contacted participants by telephone within 5 days of being assigned a patient to identify specific barriers to care. Navigators then tailored their assistance to the specific needs of patients through supportive listening, educational materials, referrals for psychological care, assistance with making appointments, resolving childcare and transportation problems, etc. Patients from clinics randomized to the comparison condition were mailed educational materials that focused on their specific cancer test and/or abnormality within 1 month of completing the baseline questionnaire.

Trained interviewers administered baseline and end-of-study questionnaires. The end-of-study questionnaires were conducted when each participant's abnormality was resolved or at the end of the study period. In order to ensure the accuracy of the TTR information, trained research staff reviewed paper records and/or electronic records at clinics, as some clinics only had paper medical records and other had some information electronically and on paper. The resolution was confirmed and copies of the procedure records and path reports were obtained as source documentation of the resolution diagnosis. Participants who were unable to be contacted by phone for the end-of-study questionnaire were mailed a survey (14.9%). The baseline and end-of-study questionnaires collected similar demographic and psychosocial information (i.e., age, race, education, income).

Analyses

Baseline characteristics of AMC and FQHC participants were compared descriptively using means for continuous variables and percentages for categorical variables. Fisher's exact test was used to compare categorical variables by clinic type and the two-sample t-test for age. Estimates of median TTR were calculated using the Kaplan-Meier method. A model building process was conducted to determine which factors (if any) meaningfully impacted

the effect for clinic type (AMC vs. FQHC) on the outcome of TTR. TTR was defined as the number of days from the qualifying abnormal test to diagnostic resolution of the abnormality. Patients without a documented resolution were censored at the last date of chart review. Consistent with the trial design and the analysis in the primary outcome paper (17), a Cox proportional hazards regression modeling framework with a shared-frailty parameter was used with clinic as the random effect. A log(time) by treatment interaction was included, as in the primary analysis, due to a violation of the proportional hazards assumption. A fully conditional imputation method (utilizing SAS PROC MI) was used to impute income and/or insurance status when this information was missing. Ten imputation datasets were created ($n = 850$ each). Twelve cases were eliminated that were missing data on one or more of the other potential predictors. SAS PROC MIANALYZE was used to combine the results obtained from the Cox proportional hazards regression model estimates. A forward selection process was used adding one variable at a time to a base model including arm, arm by time interaction, and clinic type and evaluating the change in the coefficient associated with clinic type. Large changes in the coefficient (e.g. > 20%) indicated a potential confounder of the effect and were retained in the multivariable model. All analyses were conducted in SAS (v9.3, SAS Institute, Cary, NC).

Results

Sample characteristics

Baseline characteristics of the 862 participants are shown in Table 1. For those participants receiving care at an AMC, the mean age was 45.4 years, and the majority of participants (97%) were female. AMC participants were predominately white (72.3%), 20.6% were black, and 7.1% identified as a race other than white or black. Most participants receiving care at an AMC reported being married or living as a couple (49.6%), being employed full or part-time (69.2%), having private health insurance (73.3%), having household incomes $50,000/year (54.4%), having at least a high school education (97%), and owning their own home (61.8%). According to MRR, more than half of the participants (59%) had an abnormal breast screening result, 34% of the participants had abnormal cervical screening results, and 7% had abnormal colorectal screening results.

Participants receiving care at FQHCs were predominately female (97%) with a mean age of 37.5 years. The majority of the participants were white (51.5%), 34.8% were black, and 13.6% identified as a race other than white or black. Most participants receiving care at a FQHC reported being single (49.3%), not having full or part-time employment (62.1%), having public health insurance (56.9%), having household incomes < $50,000/year (96.5%), having at least a high school education (65.7%), and not owning their own home (83.6%). According to MRR, more than half of the participants (74.6%) had an abnormal cervical screening test result, 17.9% of the participants had abnormal breast screening results, and 7.5% had abnormal colorectal screening results.

Predictors of TTR

In models adjusted for study arm, the interaction between time and study arm, FQHC patients had a 39% lower rate of resolution than AMC patients (HR = 0.61, $P = 0.004$);

college educated patients had an 87% higher rate of resolution than patients with less than a high school education (HR = 1.87, *P* = 0.0007); privately insured patients had a 79% higher rate of resolution than uninsured patients (HR = 1.79, *P*< 0.0001); patients with annual incomes $50,000 had a 51% higher rate of resolution than patients with annual incomes < $10,000 (HR = 1.51, *P* = 0.02); and there was a 4% increase in the rate of resolution for each five-year increase in patient age (HR = 1.04, *P* = 0.004) (Table 2).

Confounders of the effect of clinic type on TTR

After using multiple imputation to impute income and insurance status where missing, factors that potentially confounded the effect of clinic type on TTR were assessed using forward selection model building process. Patient insurance status, education level, and age were found to significantly impact the clinic type effect. After adjustment for these patient-level factors, clinic type was not significantly associated with TTR (HR = 0.88, *P* = 0.49) (Table 3).

Discussion

The goal of this study was to examine how clinic type (primary care clinic within an AMC or FQHC) and patient characteristics influence TTR among individuals enrolled in a PN intervention. Results of this study indicate that regardless of intervention group (PN or comparison), those patients receiving care at AMCs had a more timely diagnostic resolution compared to patients receiving care at FQHCs. Furthermore, patients who were older, college-educated, privately insured, and had incomes more than $50,000 had a reduced TTR, regardless of PN. These findings indicate that, among individuals participating in our study, TTR is influenced by multiple socioeconomic (SES) patient-level factors, rather than clinic type. Previous research found similar results, identifying measures of SES (i.e., income, insurance status) and other demographic factors (i.e., age, race) as important determinants of timely follow-up after abnormal screening tests (8–12); however, few have examined differences according to clinic type, as we have done in this study. Although past studies have shown that clinic type influences timeliness to follow-up (22–25), they have not examined multiple sites for each clinic type, several cancer types within their sample, and/or the effect of PN. Furthermore, previous studies did not consider patient-level predictors of TTR as it relates to differences in TTR according to clinic type.

The effect of clinic type on TTR may be explained by differences in demographic characteristics between the patient populations at AMCs and FQHCs. This is supported by our observation that after adjustment for patient insurance status, education, and age, the effect of clinic type on TTR was no longer significant. These results are not surprising given that previous literature has consistently reported sociodemographic differences in patient populations at FQHCs and AMCs (6,13). It is interesting to note that race/ethnicity did not influence the effect of clinic type to TTR, suggesting SES is more influential than race on TTR. Future interventions to reduce TTR should consider multiple demographic factors to guide interventions that will hopefully address health disparities.

An alternative explanation for the difference in TTR by clinic type may be the age difference in the type of abnormality for which the patients were receiving follow-up care.

In our sample, older women were receiving follow-up care at AMCs for abnormal mammograms, a screening test recommended to start at 50 years of age (for average-risk women), while those in FQHCs mostly had an abnormal cervical screening test. However, there was no age difference in study participation rates between women younger or older than 50 years.

It is also possible that the effect of clinic type on TTR is reflective of unmeasured differences in the availability and coordination of follow-up care practices between FQHCs and AMCs that could not be accounted for in this study. For example, similar to non-federally funded safety net clinics, FQHCs often lack the specialized staff and refer patients off-site for their follow-up care (5,33). However, this referral process can often be impeded by patient characteristics such as SES (5,34,35).

Coordination and patient tracking systems can be another unmeasured system-level difference between FQHCs and AMCs. Previous research has found patients receiving care at AMCs, which may be more likely to have tracking systems, are more likely to receive timely or complete follow-up (36,37). Other system-level differences, according to National Committee for Quality Assurance, can include data availability on abnormal test results from laboratories, accessibility of data within administrative databases, and variability in follow-up care for abnormal results (38). Further exploration into the presence of systematic issues within FQHCs and AMCs may help explain the delays in TTR. This difference may reflect resource constraints, different barriers to care, and how patient navigators and patients prioritize their healthcare needs.

Strengths and Limitations

This study possesses several strengths, including a unique exploration of clinic effect on TTR, a group-randomized trial design, a large and diverse population of participants, and a mix of clinic types. There were several limitations to note. First, our sample included a small number of participants from FQHC compared to AMC due to the lower number of patients receiving follow-care at the FQHC than patients receiving care at off-site locations (not participating in the study) and difficulty contacting FQHC patients. The low response rate, 56.1% and 43.8% from the AMC and FQHC clinics, respectively, is a limitation. Another limitation is that this study cannot determine if the intervention worked better or worse at specific AMC and FQHC sites. Furthermore, more participants with breast and cervical cancer screening abnormalities versus colorectal cancer were recruited, limiting generalizability.

Conclusion

In conclusion, differences in TTR after an abnormal breast, cervical, or colorectal test between individuals enrolled in a PN program have more to do with the populations served by these clinics than the clinic type itself. After adjustment for three demographic factors (i.e., insurance status, education, and age), the effect of clinic type was no longer significant, which indicates that differences in TTR between FQHC and AMC patients are driven by the contrasting sociodemographic composition of the patient populations. Future studies should strive to identify high-risk individuals (e.g., low SES, younger age) across different clinic

types in order to increase abnormal screening follow-up rates through targeted PN efforts. Additionally, exploration of clinic characteristics such as physician knowledge, clinic resources, and coordination of services may help clarify clinic-specific factors that significantly impact TTR. Further research is needed to determine what strategies are successful in reducing TTR among diverse patient populations receiving care in multiple settings.

Acknowledgments

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Table 1

Participant characteristics by type of clinic, OPNRP (*N* = 862)

Characteristic	Academic Medical Center (*n* = 795) n (%)	Federally Qualified Health Center (*n* = 67) n (%)	Total (*N* = 862) *n* (%)	*P*
Age (Mean (SD))	45.4 (14.6)	37.5 (14.1)	44.8 (14.7)	<.0001
Gender				
Female	771 (97.0)	65 (97.0)	836 (97.0)	1.00
Male	24 (3.0)	2 (3.0)	26 (3.0)	
Race				
White	571 (72.3)	34 (51.5)	605 (70.7)	.0017
Black	163 (20.6)	23 (34.8)	186 (21.7)	
Other	56 (7.1)	9 (13.6)	65 (7.6)	
Marital Status				
Single	223 (28.2)	33 (49.3)	256 (29.8)	<.0001
Married	393 (49.6)	13 (19.4)	406 (47.3)	
Divorced/Widowed	176 (22.2)	21 (31.3)	197 (22.9)	
Education level				
Less than high school	24 (5.1)	23 (34.3)	47 (5.5)	<.0001
High School	99 (12.5)	18 (26.9)	117 (13.6)	
Some College/Associate's degree	274 (34.6)	22 (32.8)	296 (34.5)	
College graduate/Graduate school	394 (49.8)	4 (6.0)	398 (46.4)	
Housing Status				
Rent/Live with family, friends, other	302 (38.2)	56 (83.6)	358 (41.7)	<.0001
Own	489 (61.8)	11 (16.4)	500 (58.3)	
Full time/Part-time Employment Status				
No	243 (30.8)	41 (62.1)	284 (33.2)	<.0001
Yes	546 (69.2)	25 (37.9)	571 (66.8)	
Annual Household Income				
Less than $10K	71 (9.5)	28 (49.1)	99 (12.3)	<.0001
$10K–$29,999	129 (17.3)	26 (45.6)	155 (19.3)	
$30K–$49,999	140 (18.8)	1 (1.8)	141 (17.6)	
$50K+	405 (54.4)	2 (3.5)	407 (50.7)	
Insurance				
Private	577 (73.3)	5 (9.8)	582 (69.5)	<.0001
Public	188 (23.9)	29 (56.9)	217 (25.9)	
Uninsured	22 (2.8)	17 (33.3)	39 (4.7)	
Anatomical site				
Breast	469 (59.0)	12 (17.9)	481 (55.8)	<.0001
Cervical	270 (34.0)	50 (74.6)	320 (37.1)	

Characteristic	Academic Medical Center ($n = 795$) n (%)	Federally Qualified Health Center ($n = 67$) n (%)	Total ($N = 862$) n (%)	P
Colorectal	56 (7.0)	5 (7.5)	61 (7.1)	

Note: Missing values have been omitted from the totals. Frequencies (pct) included for categorical predictors and mean (SD) for continuous.

Table 2

Predictors to Time to Resolution (TR) for both PN and control groups

Predictor	Level	Median TTR, unadjusted (95% CI)	HR (95% CI)	*P*
Clinic type	FQHC	192 (164, 246)	0.61 (0.44, 0.86)	0.0044
	AMC	161 (136, 174)	1.00	
Age	5-yr increase		1.04 (1.01, 1.07)	0.0035
Race	Black	142 (107, 185)	0.82 (0.68, 1.00)	0.1146
	Other	178 (147, 192)	1.04 (0.80, 1.37)	
	White	167 (143, 176)	1.00	
Marital status	Married	162 (128, 175)	1.20 (1.01, 1.43)	0.1049
	Divorced/Widowed	174 (112, 185)	1.06 (0.86, 1.29)	
	Single	167 (125, 183)	1.00	
Education level	High School	143 (96, 182)	1.61 (1.08, 2.40)	0.0007
	Some College/Associate's degree	170 (146, 182)	1.43 (0.98, 2.08)	
	College graduate/Graduate degree	162 (122, 177)	1.87 (1.28, 2.71)	
	< High School	189 (116, 262)	1.00	
Working full or part time?	Yes	154 (122, 174)	1.12 (0.96, 1.32)	0.1468
	No	175 (161, 186)	1.00	
Housing status	Own	168 (147, 178)	1.11 (0.94, 1.30)	0.0112
	Family, friends/other	180 (95, 209)	0.67 (0.48, 0.94)	
	Rent	153 (117, 178)	1.00	
Annual household income	$10K-$29,999	101 (76, 168)	1.38 (1.05, 1.82)	0.0161
	$30K-$49,999	173 (98, 185)	1.31 (0.98, 1.75)	
	$50K+	162 (131, 175)	1.51 (1.17, 1.95)	
	<$10K	193 (176, 222)	1.00	
Insurance	Private	151 (122, 170)	1.79 (1.23, 2.61)	<.0001
	Public	182 (150, 194)	1.28 (0.86, 1.90)	
	Uninsured	193 (100, 251)	1.00	
Anatomical site	Cervix	133 (115, 167)	0.90 (0.76, 1.06)	0.2279
	Colorectal	70 (48, 98)	1.15 (0.82, 1.62)	
	Breast	180 (168, 185)	1.00	

Note: HR estimates and 95% CIs from Cox shared-frailty model adjusting for arm, time by arm interaction and clinic as the random effect. Unadjusted median TTR estimates and 95% CIs were calculated by Kaplan-Meier method.

Table 3

Final multivariable Cox shared-frailty model estimates for TTR (combined across the imputations with adjustment for confounders of the clinic type effect)

Parameter	Parameter Estimate	HR (95% CI)	*P*
Arm (PN vs. control)	−0.828756		0.0368
Log (time) x arm interaction	0.216187		0.0085
FQHC vs. AMC	−0.131797	0.88 (0.60, 1.28)	0.4934
Insurance			
Private	0.436305	1.55 (1.04, 2.30)	0.0049
Public	0.152104	1.16 (0.78, 1.74)	
Uninsured	0.0	1.0	
Education			
High school	0.395038	1.48 (0.98, 2.25)	0.0606
Some college/Associate's degree	0.240543	1.27 (0.86, 1.89)	
College graduate/Graduate degree	0.419448	1.52 (1.02, 2.28)	
< High School	0.0	1.0	
Age (5-year increase)	0.03406	1.03 (1.01, 1.06)	0.0133