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Effectiveness of an Intervention for Adherence to Follow-up Recommendations for Abnormal Pap Tests in Appalachian Kentucky

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Abstract

Objective—In collaboration with rural county health departments (CHDs), we developed a patient navigation intervention to increase adherence to follow-up recommendations for women with abnormal Pap tests.

Methods—Local women were recruited, trained and placed in CHDs. Navigation was tailored to the follow-up care recommended. Effectiveness was evaluated in a quasi-experimental trial that included 13 intervention CHDs and 13 comparison group CHDs. Participants were enrolled from September 2008 through July 2010.

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Human Subjects Approval Statement

This project was reviewed by the Institutional Review Boards of the University of Kentucky and the Kentucky Cabinet for Health and Family Services.

Results—A total of 478 participants were enrolled. The proportion that received recommended follow-up care was greater in the intervention CHDs (91.6%) than in the comparison group CHDs (80.8%) ($p = .01$).

Conclusions—These results suggest that development of policy to promote navigation with rural health care delivery systems has great potential to improve patient outcomes.

Keywords

Appalachia; Pap test; patient navigation; rural health

The National Institutes of Health (NIH), the American Cancer Society (ACS) and other organizations have had a long-standing interest in Patient Navigation (PN) programs.¹ Specifically, in terms of cancer, health policymakers have determined that a major gap exists between cancer research discovery and the delivery of those research findings, resulting in only modest improvement in patient care and outcomes. Unrecognized barriers prevent many Americans from receiving the optimal quality of care, and health disparities arise when the delivery system does not provide access to timely, standard care to everyone in the nation. To meet the National Cancer Institute (NCI)'s goal of eliminating suffering and death due to cancer by 2015,² efforts are needed to reduce the gap between research development and treatment delivery, particularly among medically underserved populations.³ PN interventions have the potential to make a substantial contribution toward reaching this goal. "Patient navigation" in cancer care refers to the assistance offered to healthcare consumers (patients, survivors, families, and caregivers) to help them chart a course through the health care delivery system and overcome barriers to quality care.^{4,5} Thus, Patient Navigators (PNs) help patients move through the complexities of the healthcare system, providing assistance in obtaining information about treatment options, timely treatment, and preventive behaviors.^{6,7}

PN programs are intended to provide patients with culturally competent, knowledgeable education and advocacy to assist them through the health care continuum.⁸ PN programs combine community care with disease management to reduce racial, ethnic, and poverty-based disparities in cancer care and management.⁹ Examples of navigation services may include arranging various forms of financial support; arranging for transportation to and childcare during scheduled diagnosis and treatment appointments, identifying and scheduling appointments with medical specialists who are under contract with the health department; arranging for translation/interpretation services, ensuring that medical records are available at each scheduled appointment, and coordinating referral services.¹⁰

The population of rural, Appalachian Kentucky experiences significant cancer disparities.^{11,12} For example, although cervical cancer mortality has decreased over recent decades,¹³ data from the Surveillance, Epidemiology, and End Results (SEER) program reveals that mortality rates in Kentucky are substantially higher than the national average. Through 2003, when this project began, the US cervical cancer mortality rate was 2.7 per 100,000 (95% confidence interval = 2.6–2.7). During the same period, the rate in Kentucky was 3.2 per 100,000 (2.9–3.6). In the 54 Appalachian counties in the state the rate was even higher, 3.7 per 100,000 (3.5–4.0).¹⁴

To reduce the unequal and unnecessary burden from cervical cancer experienced by rural Appalachian women, we developed a PN intervention program with the goal of increasing adherence with recommendations for follow-up for women with abnormal Pap test results. Previous research had shown that outreach could increase screening for cervical cancer in Appalachia,¹⁵ but there was no known research that tested interventions focused on the second phase of screening; obtaining follow-up care for abnormal Pap tests. The PN program was developed in partnership with county health departments (CHDs) and was designed to be implemented in concert with the Breast and Cervical Cancer Early Detection Program (BCCEDP), a program that provides low-income, uninsured, and underserved women access to timely breast and cervical cancer screening and diagnostic services.¹⁶ (In Kentucky the BCCEDP is known as the Kentucky Women's Cancer Screening Program.) In this paper, we describe the PN intervention program, the characteristics of our study participants, and present results from evaluation of the effectiveness of the intervention in increasing adherence with recommendations for follow-up among women with abnormal Pap test results.

METHODS

Study Design

This project included 2 groups of rural CHDs. Intervention CHDs (N=13) provided navigation services and comparison CHDs (N=13) provided usual care. Eligible study subjects were female patients 18 years and older who had an abnormal Pap test result during the study period, September 2008 through July 2010.

Classification of abnormal Pap test results and management of patients with abnormal Pap tests by the health departments were based on the 2006 Consensus Guidelines for the Management of Women with Abnormal Cervical Cancer Screening.¹⁷ These guidelines are based on the 2001 Bethesda System terminology for cytological classification. The terms used to describe Pap test abnormalities, in order of severity, are atypical squamous cells of undetermined significance (ASC-US), atypical squamous cells cannot rule out high grade intraepithelial lesion (ASC-H), low grade squamous intraepithelial lesion (LSIL), high grade squamous intraepithelial lesion (HSIL), squamous cell carcinoma, adenocarcinoma or adenoma carcinoma in-situ, unsatisfactory, and atypical glandular cells of undetermined significance (AGC).

Recruitment of intervention county health departments and Patient Navigator training—CHDs serving rural populations in Appalachian Kentucky were recruited by the investigators in a 3-step process. The process began with review of state data on Pap test results to document county rates. For counties with rates above the state average, the investigators then contacted the CHD director, described the project and assessed the level of interest in participating in the project. The third step was mapping of the CHDs assessed to be likely to participate and development of a selection process that would avoid enrolling adjacent counties. The final list of CHDs was developed and invitations were sent by email, followed by telephone contact.

The qualifications for the PN position were being female, being knowledgeable of the population served by the CHD, having good communication skills, and being able and willing to interact with CHD patients. PN candidates were identified through advertisements and referrals. The investigators and CHD staff interviewed PN candidates and collaborated in making hiring decisions. The PNs were hired by the CHDs and supervision was shared with the investigators. The PNs were based in a 'home' CHD, but were assigned to work with an area that included a cluster of 2–3 CHDs. The investigators trained the PNs by providing them with information about Pap tests and follow-up care and strategies to help women needing follow-up for abnormal Pap tests navigate the health care delivery systems in their rural communities. A manual developed specifically for this project was used to guide project training. The manual covered the following topics: (1) an overview of the project; (2) patient navigation protocol; (3) human subject's protection; (4) information about cervical cancer risks factors, procedures used to detect and diagnose cervical cancer, and treatment methods; and (5) roles and responsibilities as a PN. Supervision of the PNs was carried out by the investigators in bi-weekly face-to-face meetings. The location of the meetings was rotated among the home CHDs of the PNs.

Recruitment of participants and implementation of Navigation intervention—

CHD staff referred patients age 18 and older with abnormal Pap test results to PNs after patients were notified of their test results. The PNs then sent letters to the patients introducing themselves as PNs and describing the patient navigation program and followed up by telephone, describing the project and inviting patients to participate. Arrangements were made to meet patients at a convenient location at which time the PNs obtained informed consent and administered a baseline interview. Participants were offered a \$25 gift card for their time and travel costs. The interview was administered face-to-face and required an average of 30 minutes to complete. Demographic characteristics, Pap test history, sources of health information, barriers to obtaining health care, and cervical cancer knowledge were included in the interview. Following the interview, the PNs provided navigation services including assistance with making appointments, health education about follow-up procedures, and support in overcoming barriers such as transportation to ensure adherence to follow-up recommendations. The PNs documented all follow-up recommendations, barriers, patient needs, and specific actions taken to ensure adherence to follow-up recommendations. Descriptive data analysis was conducted on all of the intervention subjects, assessing the demographic characteristics of study subjects, the type of Pap test abnormality, and anticipated barriers to obtaining follow-up care.

Collection and analysis of outcome data—Study outcome data were collected from review of CHD medical records. To prevent contamination of medical record reviews and intervention delivery, the reviews began after the intervention was completed. A medical record review form was developed and project staff identified the medical records of subjects and abstracted data on resolution of the abnormal Pap test that generated enrollment in the project. For comparison group CHDs, medical records of all women 18 years of age and older with new abnormal Pap tests occurring during the intervention period were reviewed. We excluded women whose abnormal Pap test result was ASC-US; for most of

these women, their initial follow-up recommendation was a repeat pap in 12 months, and hence, they did not require any immediate navigation services.

Data analyses were conducted to test the hypothesis that women with abnormal Pap test results who received support from the PN intervention would be more likely to adhere to recommended follow-up treatment than women who did not receive the intervention. Recommendations were stratified into 2 levels; follow-up to be obtained outside the CHD (gynecologist referral, colposcopy, and biopsy) or follow-up to be received within the CHD (repeat Pap test). If recommendations included services both outside and within the CHD, the woman was considered to need outside services for analyses. All p-values reported were obtained from models which adjusted for the within CHD correlation as well as any significant differences in the intervention and comparison counties.

RESULTS

Recruitment and Characteristics of Study Participants

A total of 1039 potential study participants were referred to the 6 PNs serving the 13 intervention CHDs over an 18-month enrollment period. Of the 1039 referred, 89 (9%) were under age 18, and therefore, ineligible. The PNs attempted to contact the remaining 950 women by mail and telephone as described previously. Of these 950 women, 656 (69%) were reached and offered enrollment in the project. The remaining 294 could not be reached and were considered lost to follow-up. Among those offered enrollment, 41 (6%) refused; 96 (15%) were considered passive refusals as they initially agreed to participate and then could not be reached again for enrollment; 44 were pregnant so were ineligible and 475 (72%) were enrolled. Among the 137 (21%) women who were offered enrollment but refused, over half were age 18–24. The demographic characteristics of the 478 intervention subjects are shown in Table 1.

Type of Pap Test Abnormality

Almost 90% of the abnormal Pap test findings among study participants were in 2 categories, ASC-US (203, 42%) and LSIL (229, 48%). Only one participant had an abnormal Pap test result of squamous cell carcinoma. The remaining findings included 9 (2%) ASC-H, 33 (7%) HSIL, 1 (<1%) unsatisfactory, and 2 (<1%) ACG.

Anticipated Barriers to Obtaining Follow-up Care

Study participants reported a wide variety of factors that they identified as potential barriers to obtaining follow-up care for an abnormal Pap test. Both micro level and macro level factors were identified as barriers to adherence to recommended follow up care (Table 2). Micro level factors include barriers that originate from individual or personal feelings, attitudes, or limitations, and most barriers would fall into this category. Cost and lack of access to health insurance were reported by 47.5% and 53.6% of women respectively. Frequently, micro level barriers were associated with fear or lack of assuredness related to how to proceed, which included: “I am afraid of what they might find” (35.8%); “I have not had to do this before” (24.1%); and “It will be painful” (25.3%). Macro level factors include barriers at the community or environmental level and were less common when compared to

micro level factors. Only 15.1% of women reported they did not have transportation or a way to get to the appointment and only 6.1% reported the roads made it difficult to get to the appointment.

Effectiveness of the PN Intervention

Data for evaluation of the effectiveness of the intervention were collected from 13 intervention CHDs and 13 comparison group CHDs. We included 774 records in our analyses, representing 230 women who had an abnormal Pap test in the intervention CHDs and were enrolled in the study and medical records from 544 women who had an abnormal Pap test and received usual care from the comparison CHDs during the intervention period. We excluded records from women whose type of abnormality was atypical squamous cells of undetermined significance (ASC-US) because 91% of the participants under age 21 and 59% of those age 21 and older received an initial recommendation to repeat their pap in 12 months and did not need navigation services immediately. The demographic characteristics of the 774 women are shown in Table 3. Women in the intervention and comparison CHDs were similar in terms of race, ethnicity, and type of Pap test abnormality. However, women in the intervention CHDs were older on average, and more likely to have a previous history of an abnormal Pap test than women receiving care in the comparison group CHDs. Among women in the intervention CHDs, 27% were married, only one-third had more than a high school education, 88% reported an income of \$50,000 or less, and 61% reported they did not have health insurance.

Follow-up Recommendations Provided by the Health Departments

Recommendations for follow-up were based on the type of abnormality and the age of the patient. In general, recommendations were either to return to the health department and obtain a repeat Pap test or make an appointment with a community gynecologist under contract with the health department (Table 4). Follow-up recommendations were documented in the medical record for all but 43 women, 40 of whom were in the comparison CHDs and 3 were in the intervention CHDs. The distribution of recommendations differed slightly between the intervention and comparison CHDs. A higher proportion of women (~95%) in comparison CHDs were referred to a community gynecologist than women in intervention CHDs. Although approximately 10% of women in intervention CHDs were recommended to receive a repeat Pap test compared to 5% of women in comparison CHDs, the difference in recommendations was not statistically significant ($p = .49$) when adjusted for patient age and history of abnormal Pap tests.

Type of Follow-up Services Received

Overall, women in the intervention counties were more likely to have received the recommended follow-up (91.6%) than women in the comparison counties (80.8%), $p = .01$, even when adjusting for the differences in patient age and history of abnormal Pap test. The effect of the PN intervention was also analyzed separately for referral to a community gynecologist and referral for a repeat Pap test. Of the women who were referred to a community gynecologist, 83.6% in comparison CHDs and 91.2% in intervention CHDs received the needed service, $p = .03$ (Table 4). Women in the comparison CHDs were about twice as likely as women in the intervention CHDs to be lost to follow-up (ie, no

documentation of having received follow-up was in the CHD records). Of the women who were recommended to have a repeat Pap test, a higher proportion received the repeat Pap test in the intervention CHDs, 95.5%, than in the comparison CHDs, 34.5% ($p < .0001$).

DISCUSSION

The PNs successfully enrolled women for the study, indicating a capacity to interact effectively with this vulnerable population. A noted strength of the study was the 80% enrollment rate of those who were identified as eligible to participate. This suggests that the PN provided program was a needed service in this medically underserved geographic area.

During the baseline interview, the PNs identified potential barriers for women receiving care. These results are consistent with the results of other PN studies suggesting medically underserved populations experience barriers to cancer screening and care, and they are in need of culturally sensitive cancer support services that address barriers they must overcome to obtain diagnostic testing and treatment.^{18,19} Based on information about barriers and the type of follow-up care recommended, the PNs were able to tailor their navigation efforts to meet the specific needs of the patient. The flexibility of the PNs to tailor their efforts to the individual based on personal circumstances is something health department nurses and other providers may not have time to do.

The patient navigation intervention was designed to increase adherence to follow-up recommendations among women with abnormal Pap tests. The researchers assessed effectiveness by comparing the type of follow-up recommendations and adherence to these recommendations among women in CHDs who received patient navigation services to women in comparison counties who received standard of care. The characteristics of women in the intervention and comparison CHDs were similar with the exception that women in the intervention CHDs were older and more likely than women in comparison CHDs to have a history of a previous abnormal Pap test. The reason for this difference is not clear and suggests the need for additional research. Recommendations for follow-up were based on the age of the patient and type of abnormality. Although women in the intervention and comparison CHDs were similar in terms of type of abnormality, we observed slight differences in the type of recommendations made for their follow-up. However, these differences were not statistically significant.

These results suggest that overall, PNs were successful in helping women with abnormal Pap tests navigate the health care delivery system and obtain recommended follow-up care. These results are consistent with previous studies suggesting that PN programs may be effective for addressing cancer disparities in other medically underserved populations.²⁰ For both types of recommendations, the percentage of women who received their recommended follow-up care was higher in intervention CHDs versus comparison CHDs. However, the effect of the patient navigation intervention was strongest among women receiving follow-up care in the health department compared to women referred for follow-up care outside the health department. This finding may be explained by the operational structure of the CHDs. These health departments operate with a set of guidelines that are designed to provide uniform service to women and this structure contributes to the effectiveness of navigation.

The correlations for the matching and clustering of health departments ranged from 0.01 to 0.03 in the models. In working with women in the health department, PNs used existing structures and linkages but in working to get services outside the health department there was less structure and perhaps more barriers. One solution to this problem may be partnering the PNs with social workers, community nurses and other well connected health professionals who may be able to assist with documenting and coordinating resources when services outside of the health departments are needed. More research is needed to determine how best to assist the PNs with coordination of care that may be outside the health department or even outside the geographic area where the patient lives.

The success of PNs in increasing adherence to follow-up care has been noted by others and appears promising as an effort to begin to address the staggering cervical cancer mortality rates present in Appalachian Kentucky counties.^{21,22} The potential for PNs to increase follow-up care with this population also exists, as numerous barriers to follow-up care that could potentially be addressed by the PNs were identified by the patients. Others have suggested that PNs are effective at reducing barriers to cancer care in vulnerable populations.²³ PNs appear to be well situated to help patients overcome identified barriers such as cost, fear and pain, while at the same time freeing up medical staff to concentrate more on screenings and treatment referrals. PNs can also assist patients to seek resources for follow-up which is often an overwhelming challenge for vulnerable populations.

IMPLICATIONS FOR HEALTH BEHAVIOR OR POLICY

These results have the potential to inform policy. Evidence suggests that a coordinated policy change centered on shaping a national policy in support of patient-centered care is needed in the United States, and this effort should focus on policy change that moves beyond relying on technical communication in traditional settings.²⁴ The results presented here support policy change that would integrate patient navigation as a useful component of health care delivery systems – particularly for vulnerable populations. Policy changes at the local, state and even federal level that allocate resources to support patient navigation programs into rural health departments and Federally Funded Health Centers (FQHC) in Appalachia have great potential to increase access to health services. Policy change that reallocates resources and integrates innovative approaches into existing resources is recommended for improving cancer care, particularly in times of limited resources.²⁵ Policy restructuring that increases access to health care has the potential to reduce cancer costs in the long run, and in light of the fact that cancer care costs are projected to increase 39% into the year 2020, any savings achieved could allow for better allocation of public health resources overall.²⁶

For decades, practitioners have been puzzled as to the most effective way to address cancer disparities in Appalachian populations. The success of the current PN project suggests that this approach is promising in terms of making progress towards meeting the goals of addressing cancer disparities in Appalachia, as well as meeting the goals of eliminating death and suffering from cancer by 2015. Whereas additional research is needed to determine how best to develop and administer PN programs, the ongoing success of these projects that is demonstrated by this study and a developing body of literature suggests that

we may be on the right track in addressing cancer disparities that have been challenging to overcome in the past.

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Table 1

Demographic Characteristics of Enrolled Participants, Intervention CHDs, N=478

Characteristic	N (%)
Age	
18–24	225 (47.1%)
25–44	192 (40.2%)
45–64	55 (11.5%)
65+	6 (1.3%)
Race	
White	461 (96.4%)
Black/African-American	5 (1.0%)
Other	12 (2.5%)
Marital Status	
Married	157 (32.9%)
Not Married	318 (66.5%)
Education	
Less than High School	101 (21.1%)
High School	228 (47.7%)
Vocational School	9 (1.9%)
College /Graduate School	140 (29.3%)
Annual Income	
< \$10,000	199 (41.6%)
\$10,000 – \$50,000	224 (46.9%)
\$50,000 +	18 (3.8%)

Table 2

Perceived Barriers to Obtaining Follow-up

	N (%)
Micro Level Factors	
It costs too much	227 (47.5%)
I don't have the time	70 (14.6%)
I didn't realize it was important to get follow-up care	18 (3.8%)
I don't know what to do to take care of my health	23 (4.8%)
I don't have insurance	256 (53.6%)
My physical limitations	19 (4.0%)
I do not trust the health care providers	10 (2.1%)
I cannot understand what the health care providers are saying to me because I do not speak English well enough	13 (2.7%)
I have trouble understanding the written information that I have received because I do not read well	16 (3.4%)
My family/friends don't think I should	5 (1.0%)
I have not had to do this before	115 (24.1%)
I'm afraid of what they might find	171 (35.8%)
I'm concerned about my privacy	48 (10.0%)
It will be painful	121 (25.3%)
I'm too embarrassed	71 (14.9%)
I'm afraid I won't be treated with respect	23 (4.8%)
Macro Level Factors	
There aren't enough doctors in my community	27 (5.7%)
Having a male health care provider	67 (14.0%)
Referral clinic hours	73 (15.3%)
I don't want to go to the clinic recommended	10 (2.1%)
Lack of childcare	63 (13.2%)
The roads make it difficult to get to the appointment	29 (6.1%)
I don't have transportation to get to the appointment	72 (15.1%)

Table 3

Demographic Characteristics of Women in Intervention CHDs versus Women in Comparison CHDs

	Intervention CHDs	Comparison CHDs	p- value
Age (Mean)	29.1	27.7	0.02
Race			
White	227 (98.7%)	527 (96.9%)	0.39
Other	3 (1.3%)	15 (2.8%)	
Ethnicity			
Non-Hispanic	226 (98.3%)	535 (98.3%)	0.62
Hispanic	4 (1.7%)	7 (1.3%)	
History of Abnormal Pap Test			
No	132 (57.4%)	370 (68.0%)	0.004
Yes	98 (42.6%)	169 (31.1%)	
Type of Pap Abnormality			
Low Grade (Low-grade squamous intraepithelial lesion)	185 (80.4%)	415 (76.3%)	0.25
High Grade (Atypical squamous cells-cannot exclude HSIL; High-grade squamous intraepithelial lesion; Atypical glandular cells of undetermined significance)	45 (19.6%)	129 (23.7%)	

Table 4

Recommended and Received Follow-up by Study Group

Gyn^a Consult	Recommended	%	
Intervention	205	90.3	p = .49
Comparison	475	94.2	
Total	680	93.0	
Repeat Pap Test	Recommended	%	
Intervention	22	9.7	
Comparison	29	5.8	
Total	51	7.0	
Gyn^a Consult	Received	%	
Intervention	187	91.2	p = .03
Comparison	397	83.6	
Total	584	85.9	
Repeat Pap Test	Received	%	
Intervention	21	95.5	p < .0001
Comparison	10	34.5	
Total	31	60.8	
Overall	Received	%	
Intervention	208	91.6	p = .01
Comparison	407	80.8	
Total	615	84.1	

Note.

^aGyn Consult = Appointment for follow up with community gynecologist