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# A Comparison of Different Intensities of Patient Navigation after Abnormal Mammography

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## Abstract

**Background—**Patient navigation is a practice strategy to address barriers to timely diagnosis and treatment of cancer. The aim of this study was to examine the effectiveness of varying intensities of patient navigation and timely diagnostic resolution after abnormal mammography.

**Methods—**This is a secondary analysis of a subset of women with an abnormal screening or diagnostic mammogram who participated in the “Patient Navigation in Medically Underserved Areas” 5-year randomized trial. We compared timely diagnostic resolution in women assigned to different intensities of patient navigation including, full navigation intervention, no contact with navigators, or limited contact with navigators.

**Results—**The sample included 1 725 women with abnormal mammogram results. Women who interacted with patient navigators had significantly fewer days to diagnostic resolution after abnormal mammography compared with women who did not interact with patient navigators.

**Discussion—**Results from our study suggest that even limited contact with navigators encourages women to seek more timely diagnostic resolution after an abnormal mammogram, which may offer a low-cost practice strategy to improve timely diagnosis for disadvantaged and underserved women.

### Keywords

patient education; breast cancer<cancer prevention and control; health disparities

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Advances in early detection and treatment have resulted in an overall decline in breast cancer mortality rates in the United States (U.S.) (Berry et al., 2005; American Cancer Society [ACS], 2013; Surveillance, 2015). Despite these advances, significant socioeconomic and racial breast cancer mortality disparities persist. Survival rates are the lowest for African American women among all racial or ethnic groups in the U.S. (Surveillance, 2015). Regardless of race, poverty has been associated with poorer breast cancer outcomes for all women (Bigby & Holmes, 2005; National Cancer Institute [NCI], 2015). At every stage of diagnosis, women living in resource-poor areas have lower five-year survival rates compared with women in higher-income areas (NCI, 2015). Women who are poor and racial and ethnic minorities experience an undue burden of cancer (NCI, 2015). African American women are more frequently diagnosed at a later stage of breast cancer, and as a result, face higher mortality rates relative to their White counterparts (DeSantis, Ma, Bryan, & Jemal, 2014; DeSantis, Siegel, Bandi, & Jemal, 2011; DeSantis, Siegel, & Jemal, 2013).

## Background

Surviving breast cancer is strongly associated with the stage of the disease and tumor size when it is first diagnosed (Surveillance, 2015). Women who are diagnosed at later stages have markedly poorer prognosis for survival because treatment is far less successful for the advanced stage disease (ACS, 2013). In part, late stage diagnosis in socioeconomically disadvantaged and African American women has been attributed to delay in diagnostic follow-up after abnormal mammography (Burack, Simon, Stano, George, & Coombs, 2000; Smith-Bindman et al., 2006; Wujcik & Fair, 2008; Yabroff, Washington, Leader, Neilson, & Mandelblatt, 2003). Timely diagnostic follow-up after an abnormal mammogram is vital to early detection of breast cancer. In order to reduce the breast cancer mortality disparity, it is important to identify practice strategies to improve timely diagnostic follow-up for socioeconomically disadvantaged and African American women living in resource-poor areas (Kim et al., 2015).

Patient navigation is a health care service delivery model that supports patients in attaining timely diagnosis and treatment along the cancer continuum of care (Freeman, 2004; Freeman & Chu, 2005). Patient navigators offer support and assistance to disadvantaged patients by addressing barriers (e.g., financial, communication, health care system) that impede timely access to care, which ultimately is a practice strategy to address disparate cancer outcomes. Since the initial implementation in the 1990s in Harlem, New York, a significant amount of private and public funding has been allocated to patient navigation, and programs have proliferated across the country (Bensink et al., 2014; Markossian & Calhoun, 2011; Paskett, Harrop, & Wells, 2011). However, navigation is a costly intervention, and studies have found only modest improvement in timely diagnostic resolution after abnormal mammography for women participating in patient navigation (Bensink et al., 2014; Markossian & Calhoun, 2011; Paskett et al., 2011). In view of this, it is important to consider low-cost navigation strategies that improve timely diagnosis for disadvantaged and underserved women.

We analyzed data from a patient navigation randomized controlled trial to examine the efficacy of different types of patient navigator contact in improving timely diagnostic resolution in women with an abnormal result after a screening or diagnostic mammogram in medically underserved areas. Our hypothesis was that women who had contact, even minimal contact (i.e., phone call), with a patient navigator were more likely to have timelier diagnostic resolution after an abnormal mammogram compared with women without patient navigator contact. Uniquely, our study examines diagnostic follow-up of women who received a full patient navigation intervention, limited intervention, or standard of care.

## Methods

### Study Sample

Data for this study were from the Patient Navigation in Medically Underserved Areas (PNMUA) randomized, controlled trial conducted in three hospitals in Chicago, Illinois (Molina et al., 2017). The data were collected from June 2011 through June 2014. Located in medically underserved areas (MUAs), the three hospitals ("A," "B," "C") reside in communities with high levels of racial segregation and poverty on the South Side of Chicago (City of Chicago, 2016). The PNMUA study was designed to examine the effectiveness of patient navigation in improving breast cancer screening, time to diagnostic resolution after an abnormal mammogram, and adherence to treatment recommendations for women diagnosed with breast cancer. The PNMUA study eligibility criteria included: 1) being female, 2) being age 18 years or older, 3) not being pregnant, and 4) having been referred by a primary care provider for a screening or diagnostic mammogram at one of the participating hospitals. The Institutional Review Boards of all participating institutions approved the PNMUA study. The full study design of the PNMUA is described elsewhere (Molina et al., 2017). This study examines a subset of women from the PNMUA study (n = 9 506) with an abnormal screening or diagnostic mammogram BI-RADS result of 0, 4, or 5, which requires immediate diagnostic follow-up (n=1 725) (Sickles et al., 2013).

### Intervention

The PNMUA study was designed using a conceptual framework endorsed by the eight National Institutes for Health-funded Centers for Population Health and Health Disparities (CPHHD) (Warnecke et al., 2008). Guided by this conceptual framework, patient navigators were expected to address proximal determinants of health (e.g., demographic, intrapersonal, interpersonal), which in turn, was expected to improve breast cancer screening and diagnostic outcomes (Gunn, Clark, Battaglia, Freund, & Parker, 2014; Molina et al., 2017; Valaitis et al., 2017). During the PNMUA study, a total of eight lay community workers were hired as hospital employees, trained as patient navigators through a 3-day training that covered 10 modules concerning adult learning strategies,(Freund et al., 2008) stationed at one of the three hospitals, and supervised by the Principal Investigator (Calhoun) and a staff member with years of experience in patient navigation. Supervision included qualitative assurance regarding navigation services and data entry, wherein navigators' performance was monitored and feedback was provided via weekly/monthly meetings with the PI and staff member (Molina et al., 2017; Valaitis et al., 2017). Patient navigator racial/ethnic demographics were matched to hospital patient populations, Hospital A and B patients were

matched with African American patient navigators and Hospital C patients were matched with Latina patient navigators.

A post-randomization consent design was used, whereby women were assigned to study arms before informed consent was obtained. The study design and randomization are discussed in detail elsewhere (Molina et al., 2017). Daily, navigators identified eligible women from a list of scheduled screening and diagnostic mammography appointments. Navigators used randomization software that assigned women to either the navigation arm (full intervention; n=3 754) or usual care arm (control; n=5 177). A subset of women randomized into the control arm were non-randomly selected based on appointment date and type of mammography appointment to complete study surveys to complete baseline questionnaires with patient navigators and were reminded about their upcoming mammography appointment (limited navigation; n = 575). Study staff tried to contact this subset up to 10 times to survey questionnaires. Contact was first attempted to obtain consent and administer surveys prior to the initial appointment. Among those who did not interact with study staff prior to attending appointments, surveys were administered during the same day or shortly after attending the initial appointment. Follow-up surveys were also administered to women in the subset who obtained abnormal results and were referred for follow-up diagnostic care and treatment subsequent to a definitive cancer diagnosis. Women in the navigation arm and the subset of women in the control arm received a $10 gift card for study participation. Control and intervention participants were equally assigned to navigators, such that navigators who provided the intervention also were the navigators for control participants with limited navigation. All other women in the control arm received usual care and did not interact with study staff. In sum, women were assigned to one of three groups with a different intensity of interaction including: 1) navigation (patient navigators provided full intervention), 2) control (no contact with patient navigators), or 3) subset (limited contact with patient navigators to complete questionnaires and receive phone appointment reminders).

**Group 1 navigation—**Navigators attempted to contact women in the navigation group by phone up to 10 times prior to their scheduled mammogram appointment. Women contacted by phone were reminded of their upcoming mammogram appointment, the study was explained, and oral informed consent was obtained from women interested in participating in the study. Navigators met women unavailable by phone at their scheduled mammography appointments at which time the study was explained and informed consent was obtained. Then, women completed intake and baseline questionnaires. Navigators also provided women with their contact information and encouraged them to call if they had any questions or needed assistance with any barriers that may prohibit attendance at their scheduled mammogram appointment. While women who completed consent during the initial appointment did not receive full navigation services for that appointment, they did receive the comprehensive services post-abnormal result.

Full navigation services were provided to all women randomized to the intervention group and who provided study informed consent. Navigators called women two days prior to the appointment and used a “teach back” method to ensure the patient understood the instructions for the mammography preparation and answered any questions. Navigators also

helped women identify any potential barriers to the appointment (e.g., fear, transportation, childcare) and problem solved with the women to eliminate any potential barriers. On the day preceding the appointment, navigators called again to remind women about their appointment and re-assessed any potential barriers to attending the appointment. Navigators then met women at their appointments to answer any questions, provide any additional needed information, and discuss how the results of the exam would be communicated. Navigators worked with the hospital staff to ensure results were delivered to women and that women understood the results along with the recommended follow-up (annual rescreening, additional diagnostic testing, or treatment initiation). For women who missed their scheduled mammogram appointment up to another 10 contacts were made to assist in rescheduling the appointment and address barriers to attendance.

For women with an abnormal result (BI-RADS 0, 3, 4, or 5), navigators attempted to contact them immediately to provide support until diagnostic resolution was achieved. A BI-RADS value of 0 indicates an incomplete or unclear mammogram result, a value of 4 indicates a suspicious abnormality, and a value of 5 is highly suggestive of malignancy (Sickles et al., 2013). All three results (i.e., BI-RADS 0, 4, and 5) require immediate diagnostic follow-up (Sickles et al., 2013). A BI-RADS value of 3 indicates that the finding is probably benign, and the recommendation is follow-up with repeat imaging in 6 months (Sickles et al., 2013). For women who received a definitive breast cancer diagnosis, navigators provided support and addressed barriers to care throughout the entirety of their treatment.

**Group 2 control—**Women randomized to the control group received care as usual at each hospital. Navigators did not interact with women in the Group 2 control women and these women were not consented to participate in the PNMUA study.

**Group 3 subset—**Women who were non-randomly selected to the control subset group received care as usual at each hospital. Also, navigators attempted to contact the women in the subset by phone up to 10 times to complete questionnaires prior to their scheduled mammogram appointment. Women contacted by phone were reminded of their upcoming mammogram appointment, the study was explained, and oral informed consent was obtained from women interested in participating in the study. Navigators met women unavailable by phone at their scheduled mammography appointments at which time the study was explained and informed consent was obtained. Then, women completed intake and baseline questionnaires which included items such as mammography history, barriers to mammography, and family history of breast cancer.

## Measures

The outcome variable, time to diagnostic resolution, was the number of days between an abnormal screening mammogram or diagnostic mammogram and confirmation of a definitive diagnosis, either benign or malignant, in the electronic medical record. Analyses included individuals who did not achieve diagnostic resolution, in that their data were right-censored at 365 days. The definitive diagnosis in the electronic medical record was based on diagnostic procedures (e.g., biopsy). We adjusted for variables including, age, race, insurance status, and hospital. Age was measured as a continuous variable. Given that the

majority of the sample was African American, race/ethnicity was dichotomized African American or Not African American. Insurance status was categorized as private, Medicare, or Medicaid/uninsured. Given that the majority of women accessed care at hospital A, the hospital where women received care was categorized as A or B/C. Data were abstracted from women's electronic medical record from each hospital and from the American Community Survey Data 2007–2011.

### Analysis

First, we calculated the frequency of BI-RADS value (i.e., 0, 4, 5). Second, we compared the characteristics of women in the full navigation, control, and subset and found significant differences between the groups including, the average number of days to diagnostic resolution, age, race, insurance status, and hospital where women received breast care. The subset was significantly different from the full navigation and control groups; however, the subset was non-randomly selected from the control group. Models were adjusted to include the variables that were significantly different between the groups. Third, we conducted Cox proportional hazards regression analyses to compare women in navigation (navigators provided full intervention), control (navigators had no contact), and subset (navigators provided limited contact). Next, we conducted Cox proportional hazards regression analyses to compare women with any patient navigator contact (combined the full navigation and subset groups) and women without patient navigator contact (control). No data were missing from the outcome variable, time to diagnostic resolution. We used pairwise deletion for missing covariate measures. Alpha of .05 was used to determine statistical significance for all analyses. We conducted sensitivity analyses to determine the extreme parameters of the Cox proportional hazard models in order to estimate violations of the independence assumptions.

## Results

Ninety-four percent of the women received a BI-RADS value of 0 while the remaining received a value of 4 or 5. Table 1 compares the outcome variable, demographics, and healthcare information by group (navigation, control, and subset). The full navigation and control group where not significantly different ($p < .01$), which indicates the randomization was effective. As shown, women in the full navigation had significantly fewer days to diagnostic resolution after abnormal mammography compared with women in the control and the subset. The average age of women in the navigation and the control was similar at 59 years, whereas the average age of women in the subset was significantly younger at 54 years. The majority of the sample identified as African American. The subset had significantly fewer African American women compared with women in the navigation and the control. Most patients received mammography at hospital A. Women in the subset had significantly fewer women with private health insurance compared with women in patient navigation and control.

Table 2 provides the results of the crude and adjusted Cox survival analyses comparing women in navigation (full intervention), subset (limited navigator contract), and control (no navigator contact). Adjusted models included demographic (age, race) and healthcare

information (insurance status, hospital). Both the crude and adjusted Cox proportional hazards regression analyses were statistically significant. Women in the navigation group who received the full intervention and women in the subset who received limited contact with navigators had greater odds of shorter time to diagnostic resolution than women in the control group with no patient navigator contact.

Table 3 provides the findings from the Cox proportional hazards regression analyses comparing women with navigator contact (combined navigation and subset groups) and without navigator contact (control group). Adjusted models included demographic (age, race) and healthcare information (insurance status, hospital). Both the crude and adjusted Cox proportional hazards regression analyses were statistically significant. Women who had contact with patient navigators had greater odds of shorter time to diagnostic resolution than women without patient navigator contact. Table 4 provides the results of the sensitivity analyses conducted to determine the extreme parameters of the Cox proportional hazard models in order to estimate violations of the independence assumptions. Women were censored at 365 days. The results from the analysis indicated no difference when restricting the analysis to 365 days. Both the crude and adjusted Cox proportional hazards regression analyses were statistically significant and women who had contact with patient navigators had greater odds of shorter time to diagnostic resolution than women without patient navigator contact.

## Discussion

Patient navigation is a practice strategy to address racial, ethnic, and socioeconomic disparities in cancer mortality by eliminating barriers to timely diagnosis and treatment of cancer (Freeman, 2004; Paskett et al., 2011). Our study contributes to the growing body of evidence documenting the effectiveness of patient navigation as a strategy to improve the early detection of breast cancer (Paskett et al., 2011). Previous patient navigation studies have assigned women to one of two study arms, either the intervention or control (Battaglia et al., 2012; Freund et al., 2014; Krok et al., 2014; Markossian & Calhoun, 2011). The PNMUA randomization scheme assigned women to receive either the patient navigation intervention in its entirety or usual care with no navigator contact. Unique to our study, a non-randomly selected subset from the controls received limited patient navigation that included navigator verbal appointment reminders and completion of questionnaires. This allowed us to compare time to diagnostic resolution among women with different intensities of patient navigation intervention. Women who interacted with patient navigators had greater odds of timelier diagnostic follow-up compared with women who did not interact with patient navigators. This is an especially important finding because many of these women had minimal navigator interaction (i.e., reminder phone call, completion of questionnaires), which suggests the possibility that even limited contact with navigators encourages women to seek more timely diagnostic resolution after an abnormal mammogram.

The results of our study also elucidate the potential positive impact of different intensity levels of navigation for women residing in urban areas that have particularly disparate breast cancer outcomes (Force, 2014; Surveillance, 2015). Despite significant efforts and investment to alleviate breast cancer disparities, research persistently documents disparities

at each level of the breast cancer continuum (Surveillance, 2015). Timely identification of breast cancer is vital to reducing mortality disparities for women accessing care in MUAs where cancer disparities are particularly stark (DeSantis et al., 2014; DeSantis et al., 2011; DeSantis et al., 2013; Smith-Bindman et al., 2006). Our sample was comprised of primarily African American women accessing diagnostic care in MUAs on the South Side of Chicago. These women represent risk of poor cancer outcomes that include increased breast cancer morbidity and mortality. Studies continue to document the delay in timely diagnostic resolution in African American women compared with other racial and ethnic groups, moreover studies are emerging that demonstrate patient navigation directly reduces the disparity in diagnostic delay specifically for African American women (Ko et al., 2016). For example, one study found that patient navigation reduced the median days to diagnostic resolution for three racial and ethnic groups (African American, non-Hispanic Whites, Whites), however the African American group receiving patient navigation had the greatest reduction in the median days to diagnostic resolution from 108 to 97 days (Ko et al., 2016). It is important to identify populations that have the greatest need, yet just as important is identifying the population that may benefit the most from patient navigation. Also, while concordance between race/ethnicity of women and navigators existed, it is possible there may have been additional benefits of concordance, given the phone contact may have affected patients' awareness of racial concordance (Newman & Wu, 2011).

There are several limitations to this study. First, during the study period 186 women (11%) in sample with abnormal mammograms never returned for follow-up to the hospital where they received the abnormal mammogram result. Women may have accessed follow-up care from another provider, completed diagnostic follow-up after the conclusion of the study, or decided not to access follow-up care. However, the reason for failure to return for follow-up is unknown. Second, there may be greater variation in patient navigation intensity, as some of the women who had 'full navigation services' may vary in the amount of contact they experienced during the initial visit. Third, women in the subset were not randomly selected to this group. As a result, there is possible selection bias and failure of treatment group allocation. Because the women were not randomly assigned to all three groups, it attenuated the benefits of randomization. In the analyses, we controlled for known differences between the groups, however other unknown and relevant factors may have led to differences between the groups. Future studies are needed that intentionally randomize individuals into arms with differing intensities of navigation in order to confirm our findings. Finally, this study examined data from women accessing care at three hospitals in MUA of Chicago. As such, the results may not be generalizable to other navigation programs or women accessing care in other MUAs.

## Conclusion

Patient navigation is consistent with the intentions of the Patient Protection and Affordable Care Act (2010) that included provisions to improve the quality of care, improve health for vulnerable populations, and transform health care delivery systems. Nonetheless, in a fiscal climate of limited healthcare resources, evidence-based practice strategies for early detection of breast cancer for vulnerable women must be cost effective. Previous studies have examined the cost-effectiveness of patient navigation; however, it remains unclear if the high

cost associated with the intervention is a reasonable cost for the benefits (Bensink et al., 2014; Markossian & Calhoun, 2011; Raich, Whitley, Thorland, Valverde, & Fairclough, 2012). Although conducting a cost benefit analysis is beyond the scope of this study, results suggest further examination of patient navigation programs that offer low-cost interventions (i.e., phone call reminders) is warranted. Likewise, additional research is necessary to determine how to tailor navigation services including, identifying the navigator tasks that are most effective in supporting timely diagnostic resolution (e.g. phone call, mailer, health education), the specific barriers that are most important to address with women (e.g., financial, transportation, communication), and the populations that have the greatest need and derive greatest benefit from navigation. Additional research is necessary to determine if the findings in this study can be replicated in another randomized controlled trial in which all study participants are randomized to each treatment group.

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**Table 1**

Outcome variable, demographics, and healthcare information by group (n = 1,725).

| | Navigation (full intervention) n =809 | Control (no contact) n =829 | Subset (limited contact) n =87 | |
|---|---|---|---|---|
| | **M (SD)** | **M (SD)** | **M (SD)** | **p-value** |
| Days to diagnostic resolution | 10.08 (28.85) | 15.30 (43.08) | 18.64 (57.41) | .008 |
| Age (years) | 58.92 (13.31) | 58.59 (12.66) | 53.60 (12.60) | .002 |
| | n (%) | n (%) | n (%) | |
| African American race | 697 (86) | 710 (86) | 57 (66) | <.0001 |
| Private insurance | 460 (57) | 487 (59) | 36 (44) | <.0001 |
| Hospital A | 709 (88) | 774 (93) | 51 (59) | <.0001 |

**Table 2**

Crude and adjusted Cox survival analyses comparing women in the navigation (full intervention), the subset (limited navigator contact), and the control (no navigator contact).

| | | | Navigation & Subset vs. Control (REF) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Analysis** | **n** | **Crude** | | | | **Adjusted[1]** | | | |
| Number of Days to Diagnostic Resolution | Cox Survival Analysis | 1725 | HR | β (SE) | 95% CI | p | HR | β (SE) | 95% CI | p |
| Navigation | | | 0.68 | −0.39 (.12) | 0.53, 0.86 | <.0001 | 0.70 | −0.36 (.13) | 0.54, 0.90 | <.0001 |
| Control Subset | | | 0.77 | −0.26 (.05) | 0.70, 0.86 | <.010 | 0.72 | −0.32 (.05) | 0.65, 0.80 | <.010 |

[1] All adjusted models include the following covariates: age, distance to facility, African American race, insurance status (Private, Medicare, Medicaid/Other/Uninsured), and hospital (A, B/C).

**Table 3**

Crude and adjusted Cox survival analyses for effectiveness of navigator contact.

| | | | Navigator Contact (Navigation & Subset) vs. No Contact (Control) (REF) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Analysis** | **n** | **Crude** | | | | **Adjusted[1]** | | | |
| | | | **HR** | **β (SE)** | **95% CI** | **p** | **HR** | **β (SE)** | **95% CI** | **p** |
| Number of Days to Diagnostic Resolution | Cox Survival Analysis | 1725 | 0.90 | −0.11 (.03) | 0.85, 0.94 | <.0001 | 0.87 | −0.14 (.03) | 0.83, 0.92 | <.0001 |

[1] All adjusted models include the following covariates: age, distance to facility, African American race, insurance status (Private, Medicare, Medicaid/Other/Uninsured), and hospital (A, B/C).

**Table 4**

Sensitivity analysis for effectiveness of navigator contact.

| | | | Navigator Contact (Navigation & Subset) vs. No Contact (Control) (REF) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Analysis** | **n** | **Crude** | | | | **Adjusted[1]** | | | |
| | | | **HR** | **β (SE)** | **95% CI** | **p** | **HR** | **β (SE)** | **95% CI** | **p** |
| Number of Days to Diagnostic Resolution | Cox Survival Analysis | 1725 | 0.90 | −0.10 (.02) | 0.86, 0.95 | <.0001 | 0.88 | −0.13 (.03) | 0.84, 0.92 | <.0001 |

[1] All adjusted models include the following covariates: age, distance to facility, African American race, insurance status (Private, Medicare, Medicaid/Other/Uninsured), and hospital (A, B/C).