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Timeliness and Completeness of Care as Quality Measures:
The Effect of Nurse Navigation on Breast Cancer Patients
in a Comprehensive Cancer Center

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2008

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Abstract

Timeliness and Completeness of Care as Quality Measures:
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Objective: Patient navigation has been shown to improve timely care in cancer patients. The current quality control study seeks to compare timeliness in the interval from breast cancer diagnosis to initial oncology consultation for a nine-month period prior to and during a nurse navigation intervention at Winship Cancer Institute. The study also seeks to compare completeness of care for patients prior to and during the intervention.

Methods: Navigation services were initiated in July, 2010. All breast cancer patients internally diagnosed with DCIS and Stage I-III disease were identified. Patients in the non-navigated group (diagnosed between October 2009 and June 2010) were compared to patients in the navigation group (diagnosed between October 2010 and June 2011). Time from date of diagnosis to date of initial oncology consultation was measured in days, excluding holidays/weekends. For patients receiving chemotherapy as initial treatment, completeness of care was measured by comparing the proportion of patients prior to and during the intervention who received consultations with three specialists (surgical, medical, and radiation oncologist) before beginning treatment.

Results: Overall, 176 patients met inclusion criteria for analysis of timeliness (100 in the non-navigation group and 76 in the navigation group). After controlling for demographic and clinical factors, navigation was found to significantly improve time to consultation for patients in the older age group (age 61+) ($p=.0002$). For patients 61+, average time to consultation was 13.4 days for non-navigated patients compared to 8.7 days for navigated patients. There was no significant improvement in timeliness for patients in the younger age group (age 31-60). Navigation did not significantly improve completeness of care, but this measure included a small sample ($n=27$).

Discussion: The navigation intervention significantly improved time to consultation for older patients, but not younger patients. Older patients may have greater difficulty navigating the health care system, so navigation had a greater impact on this population. While a reduction of five days in time to consultation may not be clinically significant, empirically measuring timeliness and completeness of care is crucial for identifying delays in cancer care and allows for a more targeted intervention in the future.

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Table of Contents

Background	1
<i>Introduction</i>	1
<i>Barriers to Care</i>	1
<i>Patient Navigation</i>	2
<i>Quantitative Studies</i>	4
<i>Timeliness and Completeness of Care</i>	6
<i>Nurse Navigation Program, Winship Cancer Institute</i>	7
<i>Objectives</i>	8
Methods	9
<i>Patient Population</i>	9
<i>Data Collection</i>	10
<i>Study Variables</i>	10
<i>Data Analysis</i>	11
Results	12
<i>Descriptive Statistics</i>	12
<i>Timeliness of Care</i>	14
<i>Completeness of Care</i>	16
Discussion	16
<i>Timeliness of Care</i>	16
<i>Completeness of Care</i>	18
<i>Limitations</i>	18
<i>Conclusions</i>	20
References	21
List of Tables	
Table 1: Patient Characteristics by Navigation Group	25
Table 2: Patient Time to Consultation by Navigation Group.....	26
Table 3: Simple Linear Regression of Predictors on Time to Consultation	27
Table 4: Multiple Linear Regression of Predictors on Time to Consultation (with all interaction variables).....	28
Table 5: Multiple Linear Regression of Predictors on Time to Consultation, Continuous age	29
Table 6: Multiple Linear Regression of Predictors on Time to Consultation, Categorical age.....	30
Table 7: Multiple Linear Regression of Predictors on Time to Consultation, Age <61.....	31
Table 8: Multiple Linear Regression of Predictors on Time to Consultation, Age 61+	32
Table 9: Logistic Regression of Navigation on Multidisciplinary Care	33

Background

Introduction

Among women in the United States, breast cancer is the most common cancer and the second leading cause of cancer death. The American Cancer Society estimates 229,060 new cases of invasive breast cancer will be diagnosed in 2012 with approximately 39,920 expected deaths from this disease.¹ Fortunately, the 5-year survival rate for women diagnosed with breast cancer is 89 percent,¹ implicating that early interventions targeting breast cancer screening and care have the potential to produce positive outcomes.

As cancer treatment involves complex and often multimodal treatment regimens, navigation of the healthcare system can be challenging and time consuming for patients and families. Patients who are diagnosed often experience emotional distress and disruption of daily life and social processes. In many situations, they are faced with making treatment decisions in a short period of time with multiple options to choose from, each having its own set of side effects and risks. A lack of information, resources, and knowledge in healthcare can also affect adherence to treatment and negatively affect clinical outcomes. Thus, the coordination of care and services, emotional support, and education become significant components of patient-centered care.²

Barriers to Care

Barriers to cancer care vary by location and are based on patient, system and provider level factors. These factors can be broadly grouped into financial (economic) and non-financial (social, cultural and behavioral) barriers to care. Financial barriers include the absence of payment sources, insufficient medical coverage for treatment, lack of affordable transportation to and from the healthcare facility, and lack of access to affordable childcare.² Non-financial barriers can be cultural and include distrust of the

healthcare system, language barriers resulting in poor patient-provider communication, limited education resulting in low healthcare literacy, and conflicting information from multiple providers. Additional system and provider barriers include providers' failure to receive pathology or radiology reports before visits, the unwillingness of specialists' offices to make appointments for uninsured patients, errors in scheduling, provider bias, and poor quality of care.³ Time to resolve barriers often varies based on available resources, even among populations with similar types of barriers.

Patient Navigation

Patient navigation focuses on the identification and resolution of social, economic, cultural, behavioral, and system barriers to help patients receive timely and comprehensive cancer care. Patient navigation is typically a goal-oriented intervention aiming to achieve a particular cancer health care goal, such as improvement in cancer screening rates, treatment adherence, or patient satisfaction with care, by reducing barriers to care.⁴ Harold P. Freeman created the first patient navigation program in Harlem, New York in 1990, which assisted low-income women in screening for breast cancer and seeking appropriate follow-up care.⁵ The program was successful in improving screening rates, increasing the diagnosis of early-stage breast cancers, and reducing the diagnosis of late-stage breast cancers.⁶ Initially, the goal of patient navigation was to assist patients with abnormal findings on screenings – to help them understand the resources available to them to receive appropriate follow-up care, diagnosis, and treatment. Though the role of patient navigator was not initially meant to address psychological, social, and physical support systems, cancer care navigation has become an intervention that seeks to improve quality of life as well.⁷

Patient navigation is a process by which an individual guides a patient from some point in the work-up process, for example after an abnormal screening mammogram,

through diagnosis and treatment, by identifying and removing barriers to care. Patient navigation programs and the backgrounds of those serving as patient navigators vary and are often driven by population needs – different models often fit the needs of different medical systems.⁴ Patient navigators may be lay or community health workers, could consist of a team of nurses, social workers, and lay staff, or may be individual nurses who vary in their background education. Freeman emphasized the need for navigators to be members of the community in which they served in order to personally relate to their patients and have familiarity with the healthcare system.⁷

Most commonly, navigators use an approach based on individual assessment of patient-specific needs. Navigation can include mobilizing financial assistance, coordinating services and appointments, providing education, and offering psychosocial support and advocacy.⁸ Improved outcomes are accomplished by developing relationships with patients and other healthcare providers and providing patients with education related to diagnosis and treatment. Qualitative studies have found that patients seemed to find navigation most effective when patient navigators addressed their emotional and practical concerns, patient family concerns, and access to needs. Effectiveness was also enhanced when the navigator was involved throughout the continuum of care from diagnosis to survivorship.⁴

Breast cancer is ideal for patient navigation because of the known survival benefit of early detection through clinical breast exams, mammography screenings, and early interventions.⁹ However, navigation is important throughout the breast cancer treatment process as well, not just during early detection, because of the complexity of care across the disease, which generally requires a team of multidisciplinary providers. Furthermore, navigation is even more critical in breast cancer care because of the racial disparity across the disease. The 5-year survival rate after first diagnosis of breast cancer is 89 percent for white women but only 78 percent for black women.¹ This disparity may

be due to African-Americans' later stage at presentation of disease, poor adherence to recommended screening tests, non-reporting of clinical symptoms, or tendency to miss appointments compared to white women, all of which are associated with shorter survival.⁷ Thus, navigation may be even more effective for high-risk and underserved populations.

The success of Freeman's program led to the development of additional patient navigation programs for cancer related care throughout the nation, including more than 100 patient navigator programs sponsored by the federal government and private foundations, such as the American Cancer Society, the Avon Foundation for Women, and Susan G. Komen for the Cure.⁹ The federal government has supported three large patient navigation initiatives: the Patient Navigation Research Program in 2005, a 9-site clinical trial designed to provide information on the efficacy and cost-effectiveness of patient navigation¹⁰; six 4-year demonstration programs in 2006 to improve health outcomes for patients with cancer and other chronic diseases;¹¹ and in 2008, six 2-year demonstration programs to support lay patient navigators who provide services that focus on cancer and chronic diseases.¹² These programs provide mechanisms through which navigators assist patients with abnormal cancer screenings or diagnostic tests by identifying and addressing barriers to timely and quality health care.

Because of recent increased interest in patient navigation programs and requests for financial support to fund these, comprehensive evaluation of navigation methods and its outcomes are crucial.⁷ To be most impactful, patient navigation programs should be effective, disseminated, and widely institutionalized with reimbursement mechanisms and training programs in place. These programs should be continually monitored and re-evaluated as necessary.⁴

Quantitative Studies

Patient navigation programs in breast, colorectal, cervical, and prostate cancers have generally been reported to play a significant role in improving clinical outcomes.⁸ Efficacy studies have reported that navigation is associated with increased screening rates,^{13, 14, 15} increased follow-up rates,^{5,16} and improved timeliness in follow-up and diagnosis after screening abnormalities.¹⁷ Patient navigation has also been reported to play a role in promoting adherence to treatment regimens¹⁸ and higher patient satisfaction.¹⁹ Although patients experience positive outcomes while being navigated throughout the cancer care continuum, the current literature on effectiveness shows the strongest outcomes for interventions targeting cancer screening.⁴

Efficacy studies regarding patient navigation interventions specific to breast cancer have reported improved screening mammography rates,²⁰⁻²³ improved rates in follow up and diagnostic resolution after abnormal mammography screening,^{17,24} decreased time between abnormal mammography screening and core biopsy,^{17,25,26} and improved timeliness of cancer treatment initiation.^{17, 27} Other studies found patients to have a lower stage at diagnosis,^{6,28} higher survival rates,⁶ and lower rates of depression and anxiety related to an abnormal mammogram or diagnosis when a navigation system was in place.^{24,29} Patient navigation programs have also helped to improve representation of underserved populations in clinical trials³⁰ and utilization of cancer genetic counseling.³¹ Improved outcomes of patient navigation programs can also be measured by using percentage adherence according to National Comprehensive Cancer Network (NCCN) guidelines³² by evaluating the change in percent of patients receiving radiation after lumpectomy, percent of patients receiving chemotherapy that were diagnosed with stage II or III cancer, and percent of patients who were HR+ that received endocrine therapy after implementation of a patient navigation program.

Psooy et al.²⁶ conducted a retrospective analysis of 536 women who underwent breast core biopsy during two comparable six-month periods, one with a navigator and

one without, to determine the effects of patient navigation. The introduction of a navigator – a health worker and breast cancer survivor – significantly reduced the time from diagnostic imaging to breast core biopsy from 20 days to 14 days.

Another pre-post navigator intervention in an urban, hospital-based setting measured timely follow up in breast cancer patients, defined as diagnostic evaluation within 120 days of an abnormal mammogram.²⁵ Of 314 women in the pre-intervention group, 65 percent had timely follow up compared to 78 percent of 1,018 women in the post-intervention group. Controlling for age, race, insurance status, reason for referral, and source of referral, women in the intervention group had a 39 percent greater odds of having a timely follow-up, suggesting that the patient navigator was effective in reducing delays in breast cancer care for poor and minority patients. Thus, previous studies have found that patient navigation can significantly improve timeliness in the diagnosis of breast abnormalities.

Timeliness and Completeness of Care

Timeliness after the diagnosis of breast abnormalities is a significant indicator that can be used to measure the quality of oncology care. “Timely care” has been included in the definitions of quality care for the American Medical Association and National Consortium of Breast Centers (NCBC).³³ Multiple time intervals have been identified from the diagnosis to treatment, and measurement of these time intervals are included as 7 out of the 31 quality indicators that the NCBC created in its National Quality Measures for Breast Cancers program (NQMBC).³⁴ Timeliness is an important factor in breast cancer care because of the extensive and multidisciplinary process that begins with screening and continues through treatment. Evaluating timeliness of care is important since patients and referring care providers expect rapid access to care, and

there have been documented disparities in access and wait times for diagnosis and treatment.³³

Furthermore, the management of breast cancer entails a multidisciplinary team effort, beginning with identification of symptoms by a primary care provider, an abnormality identified by a radiologist from annual screening mammograms, or a self-palpated mass by the patient and subsequent evaluation by a doctor. Further evaluation of the abnormality is necessary with appropriate imaging, which can include mammography, ultrasound or MRI, and ultimately a biopsy. Once the pathologist conducts an analysis of the biopsy tissue and determines the presence of cancer, the patient must establish or reestablish care with a breast surgical oncologist to discuss surgical management. Depending on tumor and patient characteristics, there may be further referrals to a medical oncologist, radiation oncologist, genetic counselor, plastic surgeon, physical therapist, social worker, gynecologist, or other specialty. Depending on the treatment modality and stage of breast cancer, further diagnostic tests may be necessary. Evaluation by a range of specialists is ideal but can be overwhelming for the patient and prolong time from diagnosis to treatment. Thus, the quality of comprehensive care relies on the timeliness of the multidisciplinary team as well as completeness of care, both areas in which patient navigation can be beneficial.

Nurse Navigation Program, Winship Cancer Institute

In July of 2010, Winship Cancer Institute initiated a breast cancer navigation program by hiring a certified nurse navigator to assist patients with their care. The nurse navigator's involvement begins when the patient is diagnosed and ends when the patient is appointed into the survivorship clinic. Her responsibilities include collaborating with physicians and members of the interdisciplinary teams to triage, coordinate, and manage patient care, educating patients and providing them with a link to research and other

relevant resources, and serving as the primary point of contact for patients and families. The nurse navigator calls recently diagnosed patients within 24 hours of their biopsy, meets patients at the time of one of their visits, helps schedule oncology appointments, and assists patients with obtaining any necessary diagnostic tests. She tracks patients along the system of care to ensure timeliness of appointments, provides coordination of care, is available to patients as a resource during the continuum of care, and refers patients to appropriate education and support group resources. In addition, she ensures timeliness of surgery or radiation oncology care after completion of medical oncology treatment or timeliness of medical and radiation oncology care after initial surgery.

Objectives

While patient navigation studies often examine the time interval from abnormal screening to diagnostic imaging or biopsy, time from biopsy to initial oncology consultation has never to our knowledge been measured for breast cancer. The primary objective of the current study is to evaluate timeliness in the period from initial cancer diagnosis to initial oncology consultation prior to and following the implementation of the nurse navigator. In the current program, this is the first time interval during which the nurse navigator is involved and can make improvements, presumably leading to improved outcomes in overall care. We expect that time from diagnosis to first oncology consultation will be significantly lower for patients who received navigation services compared to those who did not.

The second objective of the nurse navigation program is to ensure that patients receiving chemotherapy as first treatment received consultations with a surgical oncologist, medical oncologist, and radiation oncologist prior to chemotherapy. Thus, completeness of care will also be evaluated by measuring the proportion of patients receiving neoadjuvant chemotherapy who had consultations with these three disciplines

prior to initiating first treatment. Navigated patients receiving neoadjuvant chemotherapy are expected to be significantly more likely to have consultations with all three disciplines prior to first treatment compared to patients receiving neoadjuvant chemotherapy who did not receive navigation.

Methods

As a quality improvement initiative at Winship Cancer Institute, breast patient navigator services were initiated in July of 2010 with the hire of a certified nurse navigator. The current quality control study seeks to compare timeliness with regard to the interval from diagnosis of breast cancer to first oncology consultation for a nine-month period preceding the intervention and a nine-month period following the intervention. In addition, the study seeks to compare completeness of care for patients during these two time periods.

Patient Population

All women with DCIS or Stage I-III breast cancer at initial presentation who received their first diagnosis at the Breast Imaging Center within Winship Cancer Institute of Emory University between October 1, 2009 and June 30, 2010 and between October 1, 2010 and June 30, 2011 were eligible for inclusion in this study. Women who did not follow through to oncology consultation at Winship Cancer Institute (n=7) were excluded from the study as we could not measure time to consultation. Women who did not receive navigation services during the intervention period (October 1, 2010 to June 30, 2011) were excluded. A patient was considered to have received navigation services if she received any assistance from the nurse navigator (e.g. scheduling, in-person meeting, phone call detailing her role in patient's care). The total eligible patient population for this study was 176.

Data Collection

Patients were identified from the Emory Cancer Registry which registers all patients diagnosed and/or treated at Winship. In addition to the data obtained from the cancer registry, information on each patient was retrospectively reviewed by obtaining their medical record. Demographic data, tumor grade and stage, cancer treatment, and appointment information were obtained for all patients who met inclusion criteria.

Because the purpose of the current study was to evaluate the role of the nurse navigator as an outcome measure in patient care, this was considered a quality assessment study for Winship Cancer Institute. Thus, the IRB determined that the study was exempt from IRB approval.

Study Variables

The primary exposure of interest in this study was navigation. Patients were categorized as either non-navigated or navigated depending on the receipt of this service. Other control variables included patient status, race, socioeconomic status (SES), insurance, stage, tumor grade, season of diagnosis, and age at diagnosis. Patient status was categorized dichotomously, referring to patients who were either newly diagnosed at the Breast Imaging Center or patients who were diagnosed while already under the care of a breast oncologist. Race was divided into two categories: Non-White or White. SES was created by geo-coding patient address to develop an area-based poverty score. Patients with poverty scores between 0 and 0.1 were categorized as high SES, those between 0.1 and 0.2 were categorized as medium SES, and those above 0.2 were categorized as low SES. Insurance was also coded dichotomously: one category included self-paid patients or patients with private insurance, and the other category included patients with Medicaid or Medicare.

Stage of cancer at diagnosis was divided into 4 categories: DCIS, Stage I, Stage II, or Stage III. Tumor grade at diagnosis was also divided into 4 categories: Grade I, Grade II, Grade III, or undetermined. The variable indicating season of diagnosis was created to control for time-related factors and was categorized into three different 3-month periods: patients diagnosed between October and December, patients diagnosed between January and March, and patients diagnosed between April and June. The continuous variable age referred to the patient's age at time of cancer diagnosis. A categorical age variable was also created, dividing patients into two age groups: age 31-60 and 61+.

The date of diagnosis was defined as the patient's first biopsy date. The date of initial oncology appointment was defined as the first date the patient had a consultation with either a surgical, medical, or radiation oncologist. A cutoff date of 90 days after date of diagnosis was established; however all patients' initial oncology consultation fell within this time period. In a few cases (e.g. when the patient was traveling from out of state or was on extended vacation), a phone call from the oncologist to discuss pathology results and treatment options was recorded as the consultation date if there was no other consultation before treatment. The time interval from date of diagnosis to date of initial oncology appointment was measured in days, excluding holidays and weekends. The date of initial treatment for cancer was typically the date of a surgical procedure or, if surgery was not the initial therapy, the date chemotherapy or endocrine therapy began.

Time from diagnosis to initial oncology consultation was the primary outcome evaluated in this study. The secondary outcome was the proportion of women receiving neoadjuvant chemotherapy who received multidisciplinary care, which was defined as having consultations with a surgical, medical, and radiation oncologist before initial treatment.

Data Analysis

All statistical analyses were performed using SAS 9.3.³⁵ A two-tailed p-value of ≤ 0.05 was considered significant for all tests. A χ^2 test of independence was used to compare data by navigation group, and an independent t-test was similarly used to compare continuous variables.

Collinearity was screened by assessing variance inflation factors to determine if there was a strong linear relationship between independent variables, or when an interaction variable was introduced into the model. Regression diagnostics were used to check assumptions by assessing scatterplots, partial plots, plots of residuals vs. predicted values, normal probability plots, and histograms of the residuals.

Simple linear regression (SLR) was used to determine the independent relationship between time to consultation and navigation, as well as other study variables (patient status, race, age, SES, insurance, stage of disease, tumor grade, and season of diagnosis). Multiple linear regression was conducted to determine the influence of navigation on time to consultation, controlling for potential confounders (patient status, race, age, SES, insurance, stage of disease, tumor grade, and season of diagnosis). Interaction variables between navigation and all control variables were created to assess interaction. A backward elimination strategy was used to determine the best model including interaction terms. An a priori decision was made to leave all control variables in the model following interaction assessment. Finally, logistic regression was used to determine if navigation had a significant effect upon multidisciplinary care in patients receiving chemotherapy as initial treatment.

Results

Descriptive statistics

Baseline characteristics by study group are shown in Table 1. Bivariate comparisons using χ^2 tests of independence for categorical variables and an independent

t-test for age assessed differences in demographic characteristics between the two groups (pre-navigation and post-navigation); no significant differences between the navigation groups were detected for any of the control variables. Multi-collinearity was examined and the analysis showed no inter-correlation among independent variables. Regression diagnostics showed no gross violations of linearity, homoscedasticity, normality, or independence assumptions.

Of the 176 patients who were included in the study, 100 (57%) were in the pre-navigation group and 76 (43%) were in the post-navigation group. 72 percent of patients were newly diagnosed, and 27 percent were already under the care of a breast oncologist at diagnosis. The racial make-up of patients was predominantly White (64%), with 36 percent of patients in the Non-White category (60 Black and 3 Asian patients). 65 percent of patients were categorized as high SES, 28 percent as medium SES, and 7 percent as low SES. 61 percent had private insurance or self-paid while 39 percent had Medicare or Medicaid. The mean age of all patients was 60.8 (*s.d.*=13.0) and ranged from 31 to 96. Due to an interaction with navigation discovered during the modeling process, age was categorized into two age groups for stratification of the data: age 31-61 (51%) and age 61+ (49%), as 61 was identified as the median retirement age for women in the United States.³⁶

At the time of biopsy, 21 percent of women were diagnosed with DCIS, 36 percent with Stage I cancer, 30 percent with Stage II cancer, and 13 percent with Stage III cancer. At biopsy, 22 percent of patients had a grade 1 tumor, 39 percent had a grade 2 tumor, 31 percent had a grade 3 tumor, and 8 percent of patients had an undetermined tumor grade. 28 percent of patients were diagnosed from October to December, 38 percent from January to March, and 34 percent from April to June. As initial treatment, 70 percent of patients received surgery, 15 percent received chemotherapy, and 6 percent began endocrine therapy. Of 176 patients, 15 (9%) did not receive treatment at Emory.

Timeliness of Care

Table 2 shows time from diagnosis to consultation (in days, excluding holidays/weekends) for demographic and clinical study variables. Overall, patients waited an average of 11.4 days for a consultation, and this time interval ranged from 1 to 32 days. Patients in the non-navigated group waited an average of 12.1 days for a consultation whereas patients in the navigated group waited an average of 10.4 days. For patients older than 61, the average time to consultation was almost 5 days shorter for the navigation group (8.7 days vs. 13.4 days). Conversely, for patients younger than 61, the average time to consultation was an extra day for patients receiving navigation (11.8 days vs. 10.7 days). Simple linear regression revealed that both race ($r^2=.02$, $p=.04$) and stage ($r^2=.02$, $p<.0001$) were significantly and independently associated with time from biopsy to consultation while navigation was not significant in the univariate model (Table 3). On average, time to consultation was longer for non-White patients (12.7 days) than for White patients (10.6 days). Also, a more advanced stage of cancer at presentation predicted a shorter time to consultation: the average wait time for DCIS patients was 15 days compared to 10 days for Stage III patients (Table 2).

Table 4 displays the results of multiple linear regression analyses of navigation as a predictor of time to consultation, in a model adjusting for patient status, race, age at diagnosis, SES, stage and grade of disease, season of diagnosis, and including all interaction variables. The interaction between navigation and age was significant in the full model ($p=.0035$). Other interaction variables were subsequently dropped from the model following a backwards regression modeling strategy, leaving only significant interaction between navigation and age (Table 5). In the presence of interaction, a decision was made to stratify the model by age to present results. Thus, a categorical age variable was created by categorizing women into two age groups: 31-60 and 61+. The cut point of 61 was selected as this was identified as the median retirement age of women in

the United States³⁶ and is close to the median age of patients in the current study (60 years). Interaction between navigation and age was then reassessed using categorical age in the model and was still significant ($p=.0031$) (Table 6). This new adjusted model was significant overall ($p<.0001$) with an adjusted r square of 0.19. In addition to the interaction variable, the navigation ($p=.0316$), race ($p=.0373$), age (categorical) ($p=.0090$), and stage ($p<.0001$) variables were significant as well (Table 6).

From here, stratified models were presented for each of the two categories of age (Table 7, 8). Age was left as a continuous variable in both of these models after again checking for interaction with navigation in each stratified model (interaction was not significant in either group). The stratified analyses revealed that in the 31-61 age group, navigation was not a significant predictor of time to consultation ($p=.6805$). In this adjusted model, the unstandardized Beta coefficient for navigation was 0.6, indicating that navigation increased time to consultation by approximately 0.6 days after adjusting for demographic and clinical factors (Table 7). Stage was the only significant variable in this model ($p=.0097$). The Beta coefficient for stage was -1.7, indicating that each level of advanced stage led to a decreased time to consultation by an average of 1.7 days.

In the 61+ age group, navigation was a significant predictor of time to consultation, adjusting for demographic and clinical factors ($p=.0002$). In this adjusted model, the unstandardized Beta coefficient for navigation was -4.9, indicating that with navigation, time to consultation decreased by almost 5 days (Table 8). Table 8 also shows other significant variables in the model: race ($p=.0329$), age ($p=.0311$), stage ($p=.0002$), and season of diagnosis ($p=.0430$). The Beta coefficient for race was -3.3, indicating that time to consultation was approximately 3 days shorter for White patients than non-White patients after controlling for other factors. For age, Beta was 0.2, indicating that for patients 61 and older, time to consultation increased by 0.2 days on average with each year increase in age. Beta for stage was -2.8, signifying that each level of increase in

stage led to a decrease of 2.8 days on average in time to consultation. Finally, the Beta coefficient for season of diagnosis was -1.6, indicating that time to consultation decreased by 1.6 days on average with the change in season.

Completeness of Care

Only 27 patients in the study (12 in the pre-navigation group and 15 in the post-navigation group) received chemotherapy as initial treatment and were included in analyses to determine if there was a significant change in the number of patients who received multidisciplinary care before and after implementation of the navigation program. Of the 12 patients in the pre-navigation group, 4 patients (25%) had consultations with all three specialists. Of the 15 patients in the post-navigation group, 7 patients (47%) had consultations with all three specialists. Logistic regression analysis revealed that this difference between groups was not significant ($p=.3026$) (Table 9).

Discussion

Timeliness of Care

The primary objective of the current study was to evaluate the impact of nurse navigation on timeliness of care in breast cancer patients, specifically in the time interval from diagnosis to initial oncology consultation. The nurse navigator becomes involved when a patient receives a cancer diagnosis, so this is the first time interval during which her involvement can impact clinical outcomes. Analyses revealed that controlling for demographic and clinical factors, the implementation of the navigation program reduced time to consultation significantly for the older age group (by approximately 5 days), but not for the younger age group. These findings suggest that older patients may generally have more difficulty with navigating the health care system than younger patients. These women may face barriers associated with scheduling appointments in a timely manner

following diagnosis. Such barriers could include a lack of understanding the cancer care process or lack of transportation to the clinic. Thus, navigation would have a greater impact on reducing time to consultation in this population.

Additionally, it is possible that patients in the older age group have less social support than younger women or may be less likely than younger patients to independently seek out information (e.g. from the internet or other social media), which would explain why the older patients benefitted more from the nurse navigator. On the other hand, older, retired patients may be better able to utilize the navigator's services (e.g. by spending more time reviewing educational materials or contacting the navigator when facing difficulties related to their care).

Findings from this study support others which have demonstrated that patient navigation is effective in improving timely follow-up in elderly patients by addressing barriers related to choosing, understanding and using health coverage, providers, and services, making decisions about treatment, and managing conditions and care received by multiple providers.^{25,37} Timeliness and completion of recommended cancer therapy have been associated with improvements in survival, especially in the elderly.^{38,39} Thus, improvements in this time interval may result in improved clinical outcomes for this population.

In addition, race was found to be a significant predictor of time to consultation in older patients, regardless of navigation group. Time from diagnosis to consultation was shorter for white patients than for non-white patients, so certain barriers may exist for minority patients that should be further explored. Patient, provider, cultural, and system level factors have all been identified as barriers to effective and timely cancer diagnostic and treatment services in minority populations, leading to health disparities.^{25,40,41} Patient navigation is one method that can be used to eliminate these disparities. Findings of the current study suggest that it may be beneficial for the navigation

program to focus on identifying and removing the barriers affecting minority patients at the cancer center.

For both age groups, stage at diagnosis was another significant predictor of time to consultation, regardless of navigation. A more advanced stage of cancer at initial diagnosis predicted a shorter time to consultation, demonstrating that Winship moves patients with advanced disease more rapidly through the system than patients presenting with early stages of cancer or DCIS, as these cases require less urgency. Findings regarding race and age should be interpreted with caution, however, as neither race nor age was a primary exposure variable in the current study; interaction was assessed only between navigation and the control variables.

Completeness of Care

The second objective of the navigation program was to improve completeness of care in patients who received chemotherapy as initial treatment by increasing the number of patients who met with three specialists (surgical, medical, and radiation oncologist) prior to treatment. Results indicated that navigation did not significantly improve this metric. However, only a very small proportion of patients received chemotherapy as first treatment (15 %) and were included in this analysis (12 patients pre-navigation vs. 15 patients post-navigation), so results may not be meaningful. The navigator also provided services to external patients, who were excluded from the current study. Thus, the results shown do not reflect her overall impact in ensuring that patients received appropriate multidisciplinary care.

Limitations

While documenting the effect of navigation on patients' clinical outcomes is necessary, this can be difficult because of the wide variation of patient needs and access

to care. The sample size was small in relation to the number of breast cancer patients diagnosed at Winship Cancer Institute each year, as only internally diagnosed patients were included in the study. Externally diagnosed patients received navigation but were excluded from the study as their time from diagnosis to consultation was dependent upon external factors and potential confounders additional to those which exist for internal patients. Such factors (e.g. at which point in time the patient enters the system or the outside clinic sends a patient's documentation) are outside the navigator's control.

Furthermore, the navigator was instrumental in scheduling patients for other necessary appointments (e.g. additional biopsy, PET scan, MRI, genetic counselor, plastic surgeon) – a crucial part of ensuring that a patient receives the appropriate multidisciplinary care. However, the navigator's efforts in this area were unmeasured in the current study. Scheduling appointments between biopsy and initial oncologic consultation is important in ensuring the patient's completeness of care but increases the time to consultation. In these cases, comprehensive evaluation is likely to improve the patient's quality of care and may ultimately be more important than reducing time to consultation alone.¹⁰ Thus, in the future, both aspects of care should be measured as a whole, as improvements in time intervals or multidisciplinary care alone may not be sufficient in improving outcomes.

In addition, the post-navigation data collection period occurred during the first stages of the navigation program. To measure the program more effectively, it may have been beneficial to begin collecting data at least six months after implementation, when the program had become more integrated within the clinic. The navigation program was not being utilized by all specialists during its initial phases, and all eligible patients were not being referred to the navigator. Thus, it may be beneficial to measure the program's impact after the nurse navigator's role was fully developed and the staff had gained familiarity with her role in patient care.

Conclusions

While patient navigation programs often focus on examining the early phases of cancer management (e.g. screening, diagnostic resolution), few studies have evaluated the impact of patient navigation in the phases after diagnosis; the current study is the first to measure time from diagnosis to initial oncologic consultation in breast cancer patients. For the older age group, our findings support studies which have shown that navigation is effective in removing barriers and reducing time intervals in cancer care.^{17,25,27,37} Further examination and understanding of the processes contributing to the navigation program's impact among the older age group may help to identify methods to improve timely care for other patients as well.

Though results were statistically significant, a reduction of five days in the older age group may not be clinically significant and may potentially have little impact on cancer care or clinical outcomes. Also, the time interval from diagnosis to consultation prior to the intervention was already close to the target of ten days that was initially set by the navigation program. Nonetheless, these outcomes can serve as baseline measures for the program to set goals for improvement and continuous monitoring. The National Initiative on Cancer Care Quality (NICCQ) set a clinical target of less than five days for this specific interval³³ – a goal that Winship Cancer Institute can work toward by continuing to utilize the navigation program to identify and address barriers in specific populations. While factors influencing time intervals in breast cancer care are complex, empirically measuring internal processes, such as timeliness and completeness of care, is crucial for identifying delays in access to care and allowing a more targeted intervention in the future.

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Table 1: Patient Characteristics by Navigation Group

	Total n=176	Navigation - n=100 (57%)	Navigation+ n=76 (43%)	Chi-square (p>χ^2)
Patient Status	n (n%)	n (n%)	n (n%)	.1063
Established with surgeon	48 (27%)	32 (32%)	16 (21%)	
New Patient	128 (72%)	68 (68%)	60 (79%)	
Race				.9132
White	113 (64%)	65 (65%)	49 (63%)	
Non-White	63 (36%)	35 (35%)	28 (37%)	
SES				.3371
Low	13 (7%)	5 (5%)	8 (11%)	
Medium	49 (28%)	30 (30%)	19 (25%)	
High	114 (65%)	65 (65%)	49 (64%)	
Insurance				.8042
Private/Self-Pay	107(61%)	60 (60%)	47 (62%)	
Medicare/Medicaid	69(39%)	40 (40%)	29 (38%)	
Stage				.9132
DCIS	38 (21%)	20 (20%)	17 (22%)	
I	63 (36%)	38 (38%)	25 (33%)	
II	52 (30%)	29 (29%)	24 (32%)	
III	23 (13%)	13 (13%)	10 (13%)	
Tumor Grade				.4440
1	38 (22%)	23 (23%)	15 (20%)	
2	68 (39%)	35 (35%)	33 (43%)	
3	55 (31%)	35 (35%)	20 (26%)	
Not Determined	15 (8%)	7 (7%)	8 (11%)	
Season of diagnosis				.6991
October-December	50 (28%)	26 (26%)	24 (32%)	
January-March	67 (38%)	40 (40%)	27 (36%)	
April-June	59 (34%)	34 (34%)	25 (33%)	
Age at diagnosis	<i>(mean, s.d.)</i>	<i>(mean, s.d.)</i>	<i>(mean, s.d.)</i>	(p>t)
<61	60.8 (13.0)	61.0 (12.3)	60.0 (12.7)	.8461
61+	90 (51%)	48 (48%)	42 (55%)	
	86 (49%)	52 (52%)	34 (45%)	

*significant at the .05 level

Table 2: Patient Time to Consultation by Navigation Group (in days excluding holidays/weekends)

	Total	Navigation - (n=100)	Navigation+ (n=76)
All patients	11.4	12.1	10.4
Patient Status			
Established with surgeon	11.7	12.7	10.5
New Patient	10.6	10.9	10.1
Race			
Non-White	12.7	13.0	12.4
White	10.6	12.4	9.3
SES			
Low	13.4	14.6	12.6
Medium	11.3	11.1	11.5
High	11.2	12.4	9.6
Insurance			
Private/Self-Pay	11.3	11.8	10.7
Medicare/Medicaid	11.5	12.6	10.0
Stage			
DCIS	15.1	16.8	13
I	11.3	11.5	11.1
II	9.5	10.4	8.1
III	10.0	10.2	9.7
Tumor Grade			
1	11.7	11.9	11.3
2	11.6	12.4	10.7
3	11.2	11.9	10.1
Not Determined	10.2	12.3	8.4
Season of Diagnosis			
October-December	11.5	14.4	8.5
January-March	11.3	10.0	13.3
April-June	11.3	12.8	9.2
Age at Diagnosis			
<61	11.2	10.7	11.8
61+	11.6	13.4	8.7

Table 3: Simple Linear Regression of Predictors on Time to Consultation

Predictors	r^2	Significance ($p>t$)
Navigation	0.0168	0.0862
Patient Status	0.0051	0.3439
Race*	0.0244	0.0384*
Age at diagnosis	0.0013	0.6351
SES	0.0045	0.3788
Insurance	0.0002	0.8355
Stage*	0.0797	0.0001*
Tumor Grade	0.0003	0.8324
Season of Diagnosis	0.0002	0.8543

*significant at the .05 level

Table 4: Multiple Linear Regression of Predictors on Time to Consultation
(Adjusted Model with all interaction variables)

Predictors	Unstandardized Coefficients		Standardized Coefficients	t value	Significance (p>t)
	B	Standard Error	β		
Navigation	2.6189	8.8922	0.2012	0.29	0.7687
Race	-1.7273	3.1808	-0.1284	-0.54	0.5879
Patient Status	-3.8771	3.2238	-0.2678	-1.20	0.2309
Age (cont.)	0.4448	0.1480	0.8922	3.00	0.0031*
SES	-2.0433	2.4308	-0.1985	-0.84	0.4018
Stage	-3.0437	1.5077	-0.4502	-2.02	0.0452*
Grade	-0.2398	1.5799	-.0346	-0.15	0.8795
Insurance	-5.8463	3.9681	0.4426	-1.47	0.1427
Season of dx	-1.9441	1.8894	-0.2367	-1.03	0.3051
Nav*Race	-0.2175	2.1218	-.0365	-0.10	0.9185
Nav*Status	2.0201	2.2212	0.2636	0.91	0.3645
Nav*Age	-0.2894	0.0976	-1.5946	-2.97	0.0035*
Nav*SES	1.5735	1.5663	0.3041	1.00	0.3166
Nav*Stage	0.6528	0.9801	0.1892	0.67	0.5064
Nav*Grade	0.1171	1.0410	0.0354	0.11	0.9105
Nav*Insurance	3.6274	2.5581	0.5625	1.42	0.1582
Nav*Season	0.8397	1.2318	0.2009	0.68	0.4964

*significant at the .05 level

Table 5: Multiple Linear Regression of Predictors on Time to Consultation
(Adjusted Model with significant interaction variable only and continuous age)

Predictors	Unstandardized Coefficients		Standardized Coefficients	t value	Significance (p>t)
	B	Standard Error	β		
Navigation*	-1.928	0.9275	-0.1481	-2.08	0.0392*
Race	-2.2591	1.0302	-0.1679	-2.19	0.0297*
Patient Status	-1.0005	1.0581	-0.0691	-0.95	0.3458
Age (cont.)	0.3225	0.1128	0.6470	2.86	0.0048*
SES	0.3524	0.7633	0.0342	0.46	0.6449
Stage	-2.0478	0.4814	-0.3029	-4.25	< .0001*
Grade	-0.2414	0.5031	-0.0348	-0.48	0.6320
Insurance	-0.4578	1.2526	0.0347	-0.37	0.7153
Season of Dx	-0.5979	0.5985	-0.0728	-1.00	0.3193
Nav*Age	-0.2053	0.0720	-0.6148	-2.85	0.0049*

*significant at the .05 level

Table 6: Multiple Linear Regression of Predictors on Time to Consultation
(Adjusted Model with significant interaction variable only and categorical age)

Predictors	Unstandardized Coefficients		Standardized Coefficients	t value	Significance (p>t)
	B	Standard Error	β		
Navigation*	6.34674	2.92824	0.48748	2.17	0.0316*
Race	-2.14412	1.02111	-0.15939	-2.10	0.0373*
Patient Status	-0.95387	1.05773	-0.06587	-0.90	0.3685
Age (cat.)	7.75462	2.93245	0.60108	2.64	0.0090*
SES	0.35855	0.76494	0.03482	0.47	0.6399
Stage	-2.14263	0.48274	-0.31694	-4.44	<.0001*
Grade	-0.30491	0.50234	-0.04395	-0.61	0.5447
Insurance	0.33227	1.24039	0.02515	0.27	0.7891
Season of Dx	-0.56548	0.59827	-0.06886	-0.95	0.3459
Nav*Age(cat)	-5.59854	1.86275	-0.88215	-3.01	0.0031*

*significant at the .05 level

Table 7: Multiple Linear Regression of Predictors on Time to Consultation, Age <61 (Adjusted Model)

Predictors	Unstandardized Coefficients		Standardized Coefficients	t value	Significance (p>t)
	B	Standard Error	β		
Navigation	0.56666	1.37102	0.04463	0.41	0.6805
Race	-1.76009	1.44942	-0.13545	-1.21	0.2282
Patient Status	-2.01983	1.54680	-0.14100	-1.31	0.1954
Age (cont.)	-0.06297	0.09794	-0.06616	-0.64	0.5220
SES	1.75647	1.16358	0.16174	1.51	0.1351
Stage	-1.75254	0.66105	-0.27633	-2.65	0.0097*
Tumor Grade	-0.18915	0.72539	-0.02831	-0.26	0.7950
Insurance	2.58856	2.52017	0.10944	1.03	0.3075
Season of Dx	0.72929	0.89368	0.08551	0.82	0.4169

*significant at the .05 level

Table 8: Multiple Linear Regression of Predictors on Time to Consultation, Age 61+ (Adjusted Model)

Predictors	Unstandardized Coefficients		Standardized Coefficients	t value	Significance (p>t)
	B	Standard Error	β		
Navigation	-4.90176	1.25951	-0.36522	-3.89	0.0002*
Race	-3.31841	1.52713	-0.23696	-2.17	0.0329*
Patient Status	-0.60229	1.42896	-0.04117	-0.42	0.6746
Age (cont.)	0.18808	0.08562	0.24685	2.20	0.0311*
SES	-0.70191	1.05562	-0.07063	-0.66	0.5081
Stage	-2.76991	0.71624	-0.38009	-3.87	0.0002*
Tumor Grade	-0.16752	0.75382	-0.02318	-0.22	0.8247
Insurance	-1.78863	1.52195	-0.12226	-1.18	0.2436
Season of Dx	-1.62060	0.78746	-0.20273	-2.06	0.0430*

*significant at the .05 level

Table 9: Logistic Regression of Navigation on Multidisciplinary Care
(in patients who received chemotherapy as initial treatment)

	Total	Navigation -	Navigation +	Odds Ratio	p>χ^2
Multidisciplinary care +	11	4 (25%)	7 (47%)	2.29 (.48, 11.00)	0.3026
Multidisciplinary care -	16	8 (75%)	8 (53%)		
Total	27	12	15		

Multidisciplinary care refers to whether patient had consultation with surgical oncologist, medical oncologist, and radiation oncologist prior to first treatment