





The NCCCP Patient Navigation Project

Using patient navigators to enhance clinical trial education and promote accrual

Patient navigation has been a significant component of the National Cancer Institute Community Cancer Centers Program (NCCCP), which seeks to explore the best methods to enhance access to quality care and research in community hospitals, with a focus on minority and underserved populations.¹ (The NCCCP was established in 2007 as a pilot program with 16 sites, expanded to 30 sites in 2010, and currently has 21 sites.) To address these aims, the program established six major focus areas: Disparities, Clinical Trials, Biospecimens, Information Technology, Survivorship and Palliative Care, and Quality of Care, with an additional requirement to address disparities in each of these areas. Patient navigator roles at the NCCCP sites vary based on local needs, though navigator interventions span the cancer care continuum and could include community outreach, screening, early detection, care coordination, and multidisciplinary conferences and clinics.

Since navigation is a barriers-focused intervention,² NCCCP sites considered how the navigator's role could naturally extend to address barriers to clinical trial enrollment for minority and underserved populations. Through their educational and advocacy activities, navigators are familiar with the communities where their patients live; they have an established, trusting relationship with patients after months of coordinating care, and an intimate understanding of the barriers to cancer care and overall healthcare needs for the underserved populations in their service area. Thus, the navigator is uniquely poised to help with patient- and system-related barriers³ to enrolling minority and underserved populations to clinical trials.

The NCCCP Patient Navigation Project

Starting in 2009, patient navigators from the 30 NCCCP sites met monthly as part of a working group designed to help the network hospitals enhance their patient navigation programs. Collectively, they identified core measures essential to a successful cancer navigation program and created a tool to help the sites

measure progress with their individual navigation programs. The NCCCP Navigation Assessment Tool included 16 core indicators, each with five assessment levels to show increasing competence and program maturity.⁴ One of these indicators—Engagement with Clinical Trials—was a novel area of involvement for navigators at community hospitals and one that this working group felt warranted inclusion based on the NCCCP's programmatic goals.

The hospitals rated their navigation programs in this area from a Level 1, where navigators simply share a basic understanding of cancer clinical trials with patients, to a Level 5, where navigators are engaged with research teams and assist with specific trial referrals for underserved populations. To further assess the effectiveness of engaging patient navigators to increase minority and underserved accrual to clinical trials, the NCCCP developed a demonstration project in 2010—the NCCCP Patient Navigation Project.

Site participation in the NCCCP Patient Navigation Project was voluntary, and 15 sites chose to participate. The non-participating sites chose to opt out due to physicians' desire to be the first to discuss clinical trials, time commitment, data collection challenges, and/or the need to change staff and patient flow and procedures. Of the 15 sites that implemented the project, several did not participate for the entire duration given the challenges associated with the project's data collection requirements.

The core concept of the NCCCP Patient Navigation Project was to determine the feasibility of integrating navigators with research teams at NCCCP sites in an effort to remove barriers to clinical trial enrollment for underserved populations. The sites self-selected clinical trials for cancer types of high incidence in their service area for the targeted minority and underserved population and then trained patient navigators to assist with accrual. This training involved educating navigators to equip them with the tools necessary to discuss clinical trials as a treatment option with patients. The level of discussion depended on

the navigator’s experience and educational background. The navigators’ role in the project included:

Planning

- Identifying, with the research team, a minority and underserved population to target.
- Identifying, with the research team, a barrier to accruing this population to relevant clinical trials and planning strategies that address the barrier.
- Focusing on clinical trials for cancers with high incidence in the chosen target minority/underserved population.

Implementation

- Providing educational materials to patients about clinical trials with the aim to empower patients to ask their providers about clinical trials.
- Linking patients to the clinical trials research team.
- Ensuring that a clinical trial is provided as an option when treatment decisions are discussed.
- Identifying strategies to address barriers.

Navigators at the participating NCCCP sites used a spreadsheet, called the Patient Navigator Data Collection Tool (Figure 1, below), to document key data items, such as the number of patients educated and/or provided educational materials, the number of patients referred to the clinical trials research team, barriers to clinical trial accrual encountered, and strategies to overcome these barriers. Process measures included the number of minority patients screened for clinical trial eligibility and the number of minority and underserved patients informed about or offered clinical trials. The working group hoped that engaging navigators with the clinical research teams would lead to increased patient awareness and education about clinical trials before



Research nurse and nurse navigator review patient cases and trial options after a MDC conference.

meeting with their care providers to discuss treatment options. The group also hoped that early engagement with navigators would allow earlier identification of clinical trial participants and earlier referral to the research team, and ultimately result in enhanced enrollment of minority and underserved populations to clinical trials.

This article describes how, through implementation of the NCCCP Patient Navigation Project, three NCCCP sites successfully integrated navigators and clinical research teams. The description of their experience includes their challenges, successes, and program sustainability.

Sanford USD Medical Center

Sanford USD Medical Center (SMC), Sioux Falls, S.D., is the largest tertiary hospital in South Dakota and a teaching hospital

Figure 1. Image of Patient Navigator Data Collection Tool

NCCCP PATIENT NAVIGATION INFORMATION							
	Patient ID	Race	Ethnicity	Age	Did you discuss clinical trials?		If clinical trials were not discussed, please indicate reason
					YES	NO	
1							
2							
3							
4							
5							
6							
7							

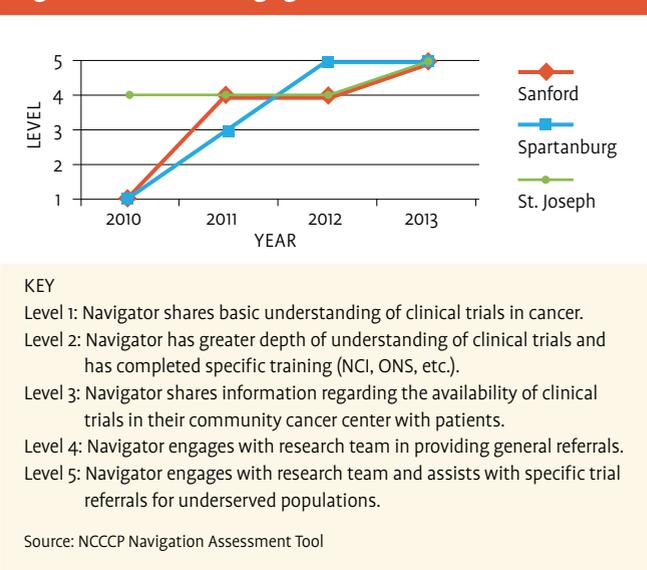
for Sanford School of Medicine at the University of South Dakota. SMC is part of Sanford Health, an integrated healthcare system that is the largest rural not-for-profit healthcare system in the nation. It has a presence in 126 communities in 9 states. SMC serves mainly a rural, Caucasian population within a 250 mile radius. Table 1, page 48, provides a brief overview of Sanford's research program.

Although Sanford already had a few nurse navigators in place, in December 2010, with funding from the NCCCP to support additional navigators and to better meet the program's research and quality of care goals, Sanford established a nurse navigation department. Sanford chose a disease-specific navigation model because the large volume of analytic cases by disease site could support a full-time nurse navigator in each area. A navigator coordinator directs the navigation efforts with leadership from the Vice President of Cancer Services.

Within the department, the six professional nurse navigators are registered nurses (RNs); the breast navigators are certified breast care nurses (CBCNs), and the lung and GI navigators are oncology certified nurses (OCN®). The nurse navigators are located in their disease-site clinics but can meet with patients and caregivers anywhere on campus. The navigators identify barriers to care, refer patients to appropriate resources, and answer patient questions related to cancer and treatment. Overall, these nurse navigators provide another level of support and add to the quality of care patients receive. They are advocates for clinical trials, providing clinical trial education to patients, as well as referring patients to the clinical research team.

In addition, a lay navigator works with the refugee and immigrant population to provide cancer screening and prevention education, coordinate cancer screening appointments, and provide follow-up. Upon diagnosis, a disease-specific nurse navigator takes over navigating the patient. An on-site American Cancer

Figure 2. Level of Engagement with Clinical Trials



Society lay navigator also assists patients with financial, transportation, lodging, and support group resources after diagnosis.

Prior to the NCCCP Patient Navigation Project, nurse navigators had limited involvement in clinical trials advocacy. Sanford's navigation team used the different building blocks of the project's guidelines and the NCCCP Navigation Assessment Tool to enhance its navigation program and increase nurse navigation engagement with clinical trials. This new focus helped Sanford move from a Level 1 in 2010 to a Level 5 in less than three years in terms of "level of engagement with clinical trials" (Figure 2, above).

NCCCP PATIENT NAVIGATION INFORMATION

	Did you provide clinical trial education?		Did you refer the patient to the clinical trials research team?		Barriers and challenges encountered	Strategies to overcome these barriers and challenges	Partnerships and resources used for outreach and clinical trial recruitment
	YES	NO	YES	NO			
1							
2							
3							
4							
5							
6							
7							

To implement the NCCCP Patient Navigation Project, Sanford's nurse navigators had to be educated on clinical trials. Initially, navigators were uncomfortable about discussing clinical trials with patients; however, education and use of a script to guide discussions helped them to become more at ease.

Now, three years later, the clinical research department and nurse navigators work as a team to accrue patients to clinical trials. Clinical research staff and nurse navigators attend tumor board conferences where the patient's course of treatment is discussed, including eligibility for clinical trials. Clinical research coordinators operate under a model consistent with therapeutic area assignments (non-oncology and oncology). At times, however, coordinators must cross-train, depending on the portfolio of available trials. Coordinators are assigned to industry-funded, federally-funded, and investigator-initiated trials within their respective area of non-oncology or oncology.

For the NCCCP Patient Navigation Project, Sanford selected clinical trials for each navigated tumor site and identified the underserved target population, considered barriers to trial enrollment, and developed strategies to overcome these barriers (see Table 2, right, for an example).

Sanford created a script to help navigators introduce general information about clinical trials to patients and answer common questions to minimize patient concerns. Still in use, the script emphasizes that clinical trials may be one of many treatment options—empowering patients to make informed decisions about their treatment. Additionally, the navigators provide materials to assist with educating patients about clinical trials, such as the NCI's *Taking Part in Cancer Treatment Research Studies* brochure. Sanford also created a clinical research brochure that is given to patients, and the cancer resource library includes informative videos, such as the NCI's Understanding Cancer Clinical Trials DVD that are available for patient viewing. (This complimentary DVD can be ordered online at <https://pubs.cancer.gov/ncip/detail.aspx?prodid=Q021>.)

Completing the project's Patient Navigator Data Collection Tool was a time consuming aspect of project implementation. The navigators documented if clinical trials were discussed, if education was provided, and if patients were referred to the clinical research team. During the project time frame, navigators provided a clinical research brochure and general clinical trial information to nearly 75 percent of the patients seen with a highly suspicious finding or positive diagnosis, referring more than half (i.e., 56 percent) of navigated patients to the clinical research team. If navigators refrained from clinical trial discussions, the main reasons were that the patient had already started treatment, the physician preferred to have the conversation, or there was not time during the appointment.

The project was a catalyst to developing a strong partnership

Table 2. Sanford Patient Navigation Project

CLINICAL TRIAL FOCUS EXAMPLE

Trial: Phase II Study of DCA (dichloracetate) vs. placebo in combination with Cisplatin and definitive radiation in Stage 3–4 squamous cell carcinoma of the head and neck (Sanford Health DCA 2010). Trial aim: To evaluate the safety and effectiveness of giving an investigational study medication (DCA) to patients diagnosed with squamous cell head and neck cancer that is either recurrent or newly diagnosed advanced (Stage 3 or Stage 4).

Target Population: Native American and rural populations (patients within specific zip/RUCA codes).

BARRIER	STRATEGY
Some Indian Health Services (IHS) doctors do not support research due to risks of side effects.	Show how research benefits Native Americans and the general population. Follow up with those who enroll and tell them the outcome of the trial. Start with other CTs such as baby formula studies so they get used to research. Place research topic segments on TVs in IHS waiting rooms to prompt patients to ask their doctors about CTs.
Transportation costs.	Provide gas cards and telemedicine services.
Meal costs.	Provide all cost-related details when trial is introduced to minimize cost concerns. Some trials offer a meal stipend.
Lodging logistics and costs.	Inform patients about available lodging programs.
Lack of insurance coverage.	Collaborate with IHS to address coverage of routine patient care costs in clinical trials.

Table 1. Sanford Research Program Overview

Hospital beds	545
New cancer cases annually	1,500
Management (director, manager) FTEs	2
Clinical research nurses (CRNs) FTEs	6
Clinical research associates (CRAs) FTEs	2
Research program support FTEs (e.g., regulatory specialists, trial coordinators, insurance, budget, finance, Quality Assurance, etc.)	4
TOTAL FTEs dedicated to clinical research	14

between nurse navigators and the clinical research team. For the first time, all the nurse navigators became more informed about how research processes are carried out in the clinical setting and they became advocates for research. In addition, a study on navigation in partnership with the American Cancer Society recently opened.

After three years of participating in the project, nurse navigators now routinely refer patients to the oncology clinical research department; the head and neck nurse navigator also assists in screening patients for a clinical trial developed by one of Sanford's head and neck cancer surgeons and researcher.

St. Joseph Hospital

St. Joseph Hospital of Orange is a values-based Catholic health-care provider founded by the Sisters of St. Joseph in 1929 and one of 14 healthcare ministries within the St. Joseph Health System, the tenth largest not-for-profit health system in the U.S. Its comprehensive cancer program, the Center for Cancer Prevention and Treatment (CCPT), serves as a centralized location, catering to the unique needs of cancer patients and their families Table 3, below, provides a brief overview of the St. Joseph research program.

At St. Joseph, patient navigation was initiated in 2004 when a professional nurse navigator was hired to assist cancer patients who come from a diverse population base in Orange County. In 2005 the cancer program added five navigators and began a disease-site specific navigation model to coordinate the care of patients diagnosed with breast, melanoma, lung, urologic, colorectal, and head and neck cancers as they move through the different phases of cancer care from diagnosis, treatment, follow-up, and survivorship. All navigators are highly skilled, disease-site-specific OCN certified nurse navigators.

The navigation program continued to evolve through St. Joseph's active participation in the NCCCP. With NCCCP funding to support the hiring of additional navigators and the NCCCP's



Members of the St. Joseph Hospital navigation program.

Table 4. St. Joseph Patient Navigation Project

CLINICAL TRIAL FOCUS EXAMPLE	
<p>Trial: NSABP P-5: Phase III Statin Polyp Prevention Trial in Patients with Resected Colon Cancer. Trial Aim: To determine if rosuvastatin (Crestor) compared to placebo can help prevent the return of colon cancer and the development of new cancers or polyps for patients with Stage 1 or 2 colon cancer that has been removed by surgery.</p> <p>Target Population: Hispanic.</p>	
BARRIER	STRATEGY
Ineligibility of many patients due to statin use.	Re-educate stakeholders to ensure that patients are screened for statin use upfront.
Limited referrals to clinical trials.	Use research coordinators for physician outreach and education and community events. Collaborate with the colorectal program and surgeons to improve screening efforts. Have colorectal navigator support screenings.
Cultural considerations and language barriers.	Use a community spokesperson to enhance the credibility of the trial and research in question. Use short forms to obtain consent from non-English speaking patients. Use certified interpreters employed by the hospital, phone interpreters, or Nextalk laptop translating system. Have patients self-report race and ethnicity. Research database working effectively and with financial information incorporated.
Lack of educational materials.	Develop trial fact sheets (English and Spanish). Partner with the NSABP and the NCCCP network to provide clinical trials information during community outreach events and health fairs.

Table 3. St. Joseph Research Program Overview

Hospital beds	525
New cancer cases annually	1,655
Management (director, manager) FTEs	1
Clinical research nurses (CRNs) FTEs	4
Clinical research associates (CRAs) FTEs	2
Research program support FTEs (e.g., regulatory specialists, trial coordinators, insurance, budget, finance, Quality Assurance, etc.)	3
TOTAL FTEs dedicated to clinical research	10

overarching quality of care and research goals, St. Joseph restructured processes to encourage use of and collaboration with navigators during patient treatment. The navigators are a blend of registered nurses, allied health professionals, and non-nursing staff that are introduced to patients at various points of their cancer care; however, it has been the goal of the cancer program to influence patient care as early as possible—at the time of diagnosis. This phase is critical, especially for access-challenged patients, yet education and social support are also needed to navigate the complex process of treatment planning and decision making. Navigators help cancer patients overcome barriers to care and open doors by introducing them to a wide variety of available resources—including community programs, local and national agencies, support groups, social workers, genetic counseling services, and research participation opportunities.

When the NCCCP Patient Navigation Project was launched, the St. Joseph navigators increased their focus on building clinical trial awareness to empower patients to ask their physicians whether a clinical trial might be a treatment option for them. The process began by matching clinical research associates and disease-site-specific cancer research nurses with disease-site-specific navigators. St. Joseph selected several breast, colorectal, and urologic trials as specific areas of focus to track patient education by the navigator and referral to research. The metric tools provided by the Patient Navigation Project were integrated into the home-grown navigator and cancer research databases to facilitate data tracking and reporting.

Completing the Patient Navigator Data Collection Tool presented challenges, as gathering the data was time consuming and not always the navigator's priority. Accordingly, St. Joseph found that accurately tracking the total number of patients referred by a navigator to the clinical trials team—along with the number of patients accrued as a result of the referral—was not always possible. Both databases could potentially produce reports showing these data; however, most reports came from the cancer research database, which relied on the information gathered and entered by the cancer research personnel. While attempts to refine data collection are ongoing, the increased interaction between the navigation program and the research team is a direct result of the NCCCP Patient Navigation Project. Table 4, page 49, provides an example of a trial selected for the NCCCP Patient Navigation Project along with the target population, barriers to enrollment, and strategies developed to overcome the identified barriers.

Today, through the shared cancer conference responsibility of the navigators and research coordinators, St. Joseph has increased awareness in clinical trial availability and eligibility, which facilitates the screening and referral process. A clinical trials algorithm, with each study linked to its eligibility requirements and schema, is readily available during the cancer conferences.

When the NCCCP Patient Navigation Project ended, stakeholders continued to track data albeit inconsistently as there was no longer a requirement to do so. In 2012, however, the navigation-research collaboration at the Center for Cancer Prevention and Treatment was re-launched using the tools and guidelines developed during the NCCCP project. St. Joseph focused on

Table 5. Spartanburg Research Program Overview

Hospital beds	341
New cancer cases annually	1,664
Management (director, manager) FTEs	2
Clinical research nurses (CRNs) FTEs	9
Clinical research associates (CRAs) FTEs	5
Research program support FTEs (e.g., regulatory specialists, trial coordinators, insurance, budget, finance, Quality Assurance, etc.)	9
TOTAL FTEs dedicated to clinical research	25

defining the role of the navigator as an advocate for clinical trials to conduct high-level screening and encourage referrals of potentially eligible patients to research for more in-depth screening. The disease-site-specific navigators coordinate with disease-site-specific research coordinators for training and education to assist with specific trial referrals with special attention to underserved populations. Navigators and research staff consider the metrics recommended by the NCCCP Patient Navigation Project; they meet monthly to discuss protocol updates, barriers to screening and research, and patient treatment updates to ensure more effective communication. Through this collaborative method, screening and referral processes have improved, duplication of efforts has decreased, and navigators ensure that cancer patients are informed about clinical trials as a treatment option.

St. Joseph used the NCCCP Navigation Assessment Tool to monitor and enhance its navigation program. Over the course of the project, St. Joseph's rating for the "Engagement with Clinical Trials" evolved from the navigators working with the research team by providing general referrals to assisting with specific trial referrals—with particular interest in serving patients typically under-represented in cancer clinical trials. The endeavor was largely supported by the community outreach nurse navigator with the assistance of the financial coordinator as appropriate. Clinical trials are a top priority at St. Joseph, and clinical trial accrual updates are shared in the Cancer Committee on a quarterly basis.

Spartanburg Regional HealthCare

Spartanburg Regional HealthCare is a three-hospital system in South Carolina; the medical center is located in a rural area of the state's northwest region. In 1999 the hospital built a comprehensive cancer center, housing all cancer services in one building, including inpatient oncology. Table 5, above, provides a brief overview of Spartanburg's research program.

When the cancer center opened, a multidisciplinary model for

breast care was implemented with a multidisciplinary clinic and two nurse navigators to support the program. A lung cancer program started several years later with a lung navigator as the program coordinator. In 2007 Spartanburg Regional became a NCCCP site and worked to enhance the disease-site navigation program; it quickly grew as Spartanburg focused on creating an evidenced-based model for navigation with metrics, including return on investment that could support expansion. The navigation program added a prostate/GI navigator, a head and neck navigator, and hematology/CNS navigators. Today Spartanburg has 8 navigators for 10 disease-site programs.

Spartanburg’s navigation program is linked to disease-site multidisciplinary conferences (MDCs) and uses both nurses and a social worker in a collaborative team-based supportive model. The navigation department is structured under the Cancer Support Division along with all of the other support services that span the cancer care continuum. In addition to traditional navigation services, the program is responsible for MDC coordination, case presentation, and supporting the physician lead in quality and disease-site program goals.

As part of its NCCCP participation, Spartanburg used the NCCCP Navigation Assessment Tool to assess the navigation program and focus on key elements to guide development of a stronger program. When the NCCCP Patient Navigation Project began in 2010, Spartanburg’s navigators did not see research interface as their role and had minimal comfort level in that area. Additionally, the clinical research nurses were not aware of the potential value of navigators’ support in increasing accruals.

As Spartanburg prioritized clinical trial accruals and required every patient to be screened for an available clinical trial at each disease-specific MDC, the value of the navigator’s role increased. Navigators began to educate patients on clinical trials, refer appropriate patients, and track the interventions; the perspective of the research staffs slowly changed. Initially research staff was somewhat resistant to collaborating with the navigation team, viewing the navigators’ clinical trial efforts as duplicative of other referral sources and not valuing the education that the navigators provided to patients.

Spartanburg began to pair each navigator with a disease-site research nurse. The navigators were required to attend the investigator meetings and monthly research and navigator staff meetings. It took nearly a year for the research staff and navigators to embrace the new model and roles. Becoming more informed about clinical trials and the importance of providing clinical trial education to patients helped the navigators become very engaged in the process. Once research staff was partnered with navigators, they were able to identify ways in which the navigators could benefit accrual. The research nurses and navigators now work hand-in-hand to dispel myths and educate patients about clinical trials as a potential treatment option. The navigators are responsible for addressing accrual barriers, such as transportation, access to screening, and trial education. The nurse navigators receive education regarding the cancer type they navigate and the relevant clinical trials. Because of this education, several nurse navigators have become quite comfortable pre-screening patients for eligibility, including looking

at the stage and molecular markers, following evidence-based guidelines, and educating patients about specific trials.

The navigator works closely with the research team to best address issues that impact eligibility. For example, the navigator coordinates referrals to primary care physicians and specialists for management of co-morbid conditions. This capacity for care coordination is one of the primary advantages to Spartanburg’s disease-site model for its navigation program.

For the NCCCP Patient Navigation Project, Spartanburg selected clinical trials for each navigated tumor site and identified the underserved target population, considered barriers to trial enrollment, and developed strategies to overcome these barriers (see Table 6, below, for an example).

NCCCP participation and work over the course of the NCCCP Patient Navigation Project have been catalysts to the evolving role of Spartanburg’s navigators. Navigation responsibilities now include, but are not limited to:

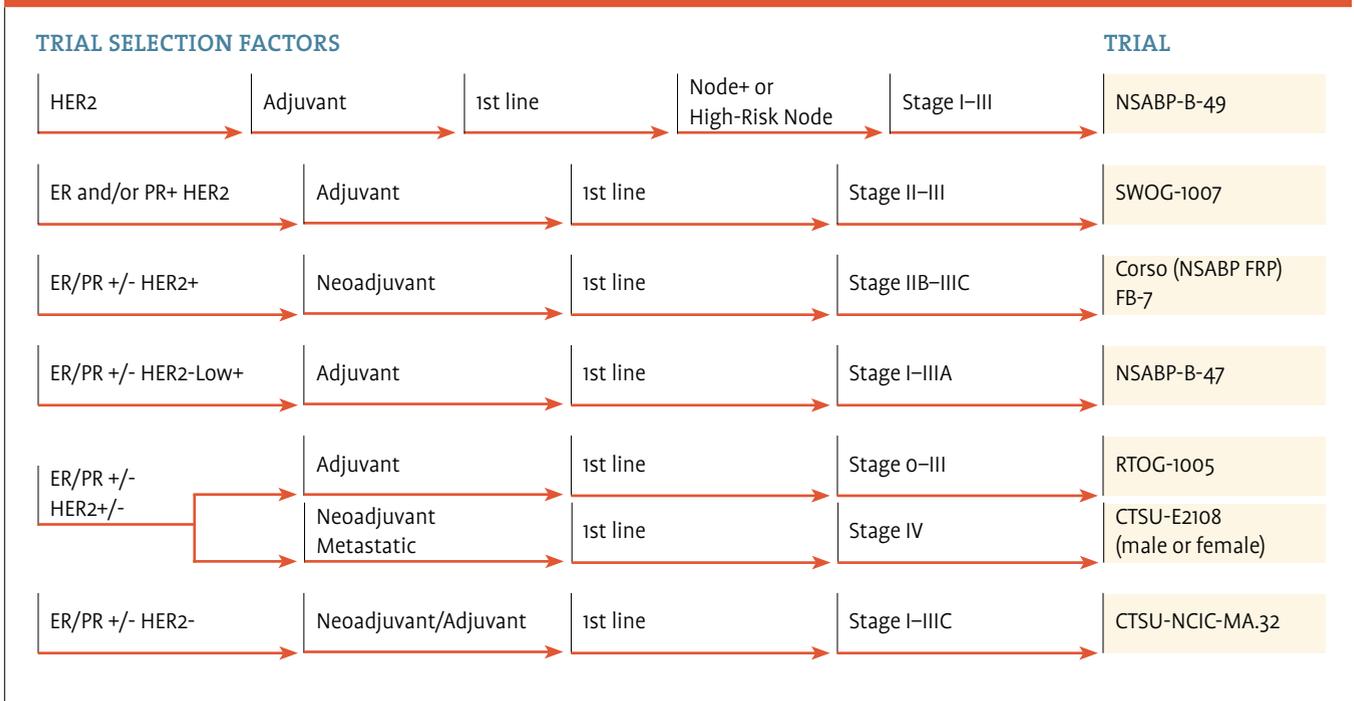
- Demystifying clinical trials by addressing myths and fears about cancer research
- Answering questions about clinical trials
- Communicating with physicians and research nurses
- Educating patients on the availability of specific trials
- Screening patients for trial eligibility
- Referring patients to the clinical research team.

Helping patients and families develop a comfort level about considering trial participation as a treatment option is an

Table 6. Spartanburg Patient Navigation Project

CLINICAL TRIAL FOCUS EXAMPLE	
<p>Trial: Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Adding New Drug TAK700 (RTOG 1115). Trial aim: Compare the effects of hormone therapy and TAK-700 plus radiation therapy with hormone therapy and radiation therapy to find out which is better.</p> <p>Target Population: High-risk African American (AA) males with prostate cancer.</p>	
BARRIER	STRATEGY
Travel and transportation.	Provide gas cards.
Educational level.	Educate AA males about clinical trials in general and this trial specifically.
Lack of trust.	Provide culturally relevant information regarding the risks/benefits of the trial.
Decisional choices.	Pre-educate patient about the multiple treatment options prior to provider consult.

Figure 3. Spartanburg Trial Matching Tool



important aspect of the navigator’s role. Two phrases to assist in this process are:

- *Clinical trials help us [providers] answer questions about how we can improve outcomes [for the patient’s specific cancer type]. This research may even benefit a family member in the future.*
- *I will help you through your treatment and this study.*

Requiring navigators to become actively involved with clinical trial accrual was a paradigm shift for the cancer center. The process was complex and took the commitment of leadership to encourage increased interactions between two traditionally separate departments. Although the process took time, Spartanburg attributes these additional factors to the successful shifts in processes and roles:

- The navigators’ strong core advocate role
- Data collection on navigator interventions, which helped track progress and celebrate successes
- Navigator attendance at investigator meetings
- The practice of partnering each navigator with a research nurse
- Collaboration between the directors of research and navigation.

The navigator’s expertise in laying the ground work for increasing patient comfort levels about enrolling in clinical trials continues to grow and is helping to increase accruals. Patients and families look to the navigator as the one who can guide them through

their cancer journey, which may include a clinical trial. Navigators use resources, such as the Trial Matching Tool (Figure 3, above), to look for available trials. This tool provides an easy method for the navigator to identify and discuss trials for which the patient may be eligible.

Going Forward

While experiences varied for the community hospitals that participated in NCCCP Navigation Project, the three programs described in this article have demonstrated that—despite some challenges—educating patient navigators and engaging them with research staff result in navigators who are better prepared to discuss clinical trials with patients. In turn, this education led to increased navigator awareness of treatment options and helped navigators decrease patient anxiety during treatment discussions with their providers, realizing one of the project’s aims: to empower patients to discuss relevant clinical trials with their physicians.

The sites who participated in the NCCCP Navigation Project value patient navigation and recognize the important role navigators can play in clinical trials. The programs continue to collect, share, and discuss the following metrics:

- Navigators’ level of engagement in clinical trials, including provision of clinical trial education or information
- The number of referrals by the navigator to the clinical research team
- The number of these referrals who are accrued to clinical trials.

These metrics help measure the impact of the navigators' efforts, potentially justifying their use in this area and supporting the navigation program's return on investment. Though the NCCCP Patient Navigation Project's focus was on feasibility, demonstration of navigator interventions on increasing clinical trial accrual, particularly in underserved and minority populations, is important to pursue in a controlled setting. The NCI-ASCO Clinical Trial Accrual Symposium recommended future studies to evaluate patient navigation and its impact on enhancing trial participation.⁵

In addition to studying navigation and its role in clinical trial accrual, the experiences of the three NCCCP sites described in this article demonstrate the need for the development of well-designed randomized clinical trials to study navigator interventions and determine optimal roles and the effectiveness of professional and lay navigators. These studies align with the expanded research agenda of the new NCI Community Oncology Research Program (<http://prevention.cancer.gov/ncorp>), which will include cancer care delivery research. Future research may also include the impact of navigation on healthcare utilization, cost, and patient satisfaction.

Diane St. Germain, RN, MS, and Eileen Dimond, RN, MS, are nurse consultants in the Division of Cancer Prevention at the National Cancer Institute, Rockville, Md. Kristi Olesen is the cancer accreditation coordinator and Christie Ellison, RN, BSN, OCN, CCRP, is the early-phase clinical trial coordinator at Sanford Cancer Center in Sioux Falls, S.D. Lianne Nacpil, MPH, CTR, is cancer registry manager at the Center for Cancer Prevention and Treatment at St. Joseph Hospital in Orange, Calif. Lucy Gansauer, RN, MSN, OCN, is director of the NCCCP at Gibbs Cancer Center of Spartanburg Regional Healthcare System, Spartanburg, S.C. Angela Carrigan, MPH, is a clinical data analyst and Kathleen Igo is a medical writer in the Clinical Research Directorate/Clinical Monitoring Research Program, Leidos Biomedical Research, Inc., (formerly SAIC-Frederick, Inc.) Frederick National Laboratory



Nurse navigator confers with radiation oncologist about a patient's case.

for Cancer Research, Frederick, Md. Maria Gonzalez, MPHc, BS, is currently the administrator at the Roy and Patricia Disney Family Cancer Center and was the manager for cancer research and co-PI at St. Joseph Hospital, Orange, Calif.

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