



Published in final edited form as:

*Cancer*. 2008 December 15; 113(12): 3391–3399. doi:10.1002/cncr.23960.

## The NCI Patient Navigation Research Program Methods, Protocol and Measures

**Karen M Freund, MD MPH,**  
Boston University School of Medicine

**Tracy A Battaglia, MD MPH,**  
Boston University School of Medicine

**Elizabeth Calhoun, PhD,**  
University of Illinois/Chicago School of Public Health

**Donald J. Dudley, MD,**  
University of Texas, Health Science Center, San Antonio

**Kevin Fiscella, MD MPH,**  
University of Rochester

**Electra Paskett, PhD,**  
Ohio State University, Comprehensive Cancer Center

**Peter C. Raich, MD, and**  
Denver Health and Hospital Authority

**Richard G. Roetzheim, MD on behalf of Patient Navigation Research Program Group**  
U. of South Florida and Cancer Prevention and Control, H. Lee Moffitt Cancer Center

### Abstract

**Background**—Patient, provider, and systems barriers contribute to delays in cancer care, lower quality of care, and poorer outcomes in vulnerable populations, including low income, underinsured, and racial/ethnic minority populations. Patient navigation is emerging as an intervention to address this problem, but navigation requires a clear definition and a rigorous testing of its effectiveness. Pilot programs have provided some evidence of benefit, but have been limited by evaluation of single-site interventions and varying definitions of navigation. To overcome these limitations, a nine-site National Cancer Institute Patient Navigation Research Program (PNRP) was initiated.

**Methods**—The PNRP is charged with designing, implementing and evaluating a generalizable patient navigation program targeting vulnerable populations. Through a formal committee structure, the PNRP has developed a definition of patient navigation and metrics to assess the process and outcomes of patient navigation in diverse settings, compared with concurrent continuous control groups.

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Corresponding author: Karen M Freund MD MPH, Boston University School of Medicine, 715 Albany Street, Crosstown 470, Boston MA 02118, Phone 617 638 8036, Fax: 617 638 8096, Karen.freund@bmc.org.

Additional Authors Listing:

The Patient Navigation Research Group

Charles L. Bennett MD, Northwestern University

Jack A Clark PhD, Boston University School of Public Health

Roland Garcia PhD, Center to Reduce Cancer Health Disparities, National Cancer Institute

Amanda Greene PhD, NOVA Research

Steven R. Patierno PhD, George Washington University Cancer Institute

Victoria Warren-Mears, PhD, RD, LD, Northwest Tribal Epidemiology Center

**Results**—The PNRP defines patient navigation as support and guidance offered to vulnerable persons with abnormal cancer screening or a cancer diagnosis, with the goal of overcoming barriers to timely, quality care. Primary outcomes of the PNRP are (1) time to diagnostic resolution, (2) time to initiation of cancer treatment, (3) patient satisfaction with care, and (4) cost effectiveness, for breast, cervical, colon/rectum, and/or prostate cancer.

**Conclusions**—The metrics to assess the processes and outcomes of patient navigation have been developed for the NCI-sponsored Patient Navigator Research Program. If the metrics are found to be valid and reliable, they may prove useful to other investigators.

### Keywords

breast cancer; cervical cancer; colorectal cancer; prostate cancer; navigation; case management; minority groups; medically underserved areas; vulnerable populations

## INTRODUCTION

In recent decades, advances in screening and treatment have resulted in improved cancer outcomes. <sup>1</sup> However, disparities in cancer outcomes according to race and income continue.<sup>2-4</sup> A recent focus in cancer research has been to understand the social, economic, cultural, behavioral, and systems barriers to receiving comprehensive cancer care in a timely fashion and to eliminate these persistent disparities.<sup>5-7</sup> Patient navigation represents one proposed remedy for disparities in cancer outcomes by intervening to address these barriers to care. <sup>8</sup> Several uncontrolled studies and small single-site trials have suggested that patient navigation may improve cancer outcomes. <sup>9-11</sup>

Patient navigation has been defined as the logistic and emotional support needed to achieve completion of diagnostic and treatment care. Individuals previously identified as case managers, patient advocates, community health workers, and schedule coordinators are now being placed under the umbrella of “patient navigation.” While the concepts of patient navigation can be used for multiple chronic and acute diseases<sup>12</sup>, the lack of common nomenclature with clearly defined job responsibilities makes comparison of different navigator models difficult.

Before patient navigation can be extended as a standard of cancer care, empirical evidence of its benefit and cost-effectiveness must be demonstrated. To date, there are no accepted measures of either the navigation process or its clinical and economic outcomes. Development and dissemination of process and outcome measures will allow communities and researchers to evaluate the results of these programs.

The Patient Navigation Research Program (PNRP) sponsored by the National Cancer Institute’s (NCI) Center to Reduce Cancer Health Disparities (CRHCD) is the first multi-center program to examine the role and benefits of patient navigation. To achieve this aim, the Steering Committee of the PNRP developed a definition of patient navigation and a series of common measures to assess outcomes of care with patient navigation. We present here the definitions and measures developed in order to assess the benefits of patient navigation.

## METHODS

### Overview of Program

Funded through the NCI with additional support from the American Cancer Society and Avon Foundation, the PNRP is a cooperative effort of nine sites across the United States.

Target communities include racial and ethnic minorities and those of low socioeconomic status who have either abnormal cancer screening or an incident diagnosis of breast, cervical, colorectal or prostate cancer. Investigators in each site will assess the outcomes in a group of patients receiving patient navigation, compared to a concurrent control group without navigation.

### **Definition of navigation and role of navigators**

The working definition of patient navigation was provided by the NCI's CRHCD in their request for applications.<sup>13</sup> In this definition, patient navigation refers to support and guidance offered to persons with abnormal cancer screening or a new cancer diagnosis in accessing the cancer care system, overcoming barriers, and facilitating timely, quality care provided in a culturally sensitive manner. Patient navigation is intended to target those who are most at risk for delays in care, including racial and ethnic minorities and those from low income populations. Furthermore, patient navigation targets specific time points in the cancer care continuum; we operationally define patient navigation as starting at the time of an abnormal screening result and ending at the determination that the screening test was a false positive or, for those individuals with a new cancer diagnosis, continuing through the completion of cancer treatment. The goal of patient navigation is to facilitate timely access to quality cancer care that meets cultural needs and standards of care for all patients.

Examples of navigation services include: arranging various forms of financial support, arranging for transportation to and childcare during scheduled appointments, identifying and scheduling appointments with culturally sensitive caregivers, coordinating care among providers, arranging for interpreter services, ensuring coordination of services among medical personnel, ensuring that medical records are available at each scheduled appointment, and providing other services to overcome access barriers encountered during the cancer care process including linkage to community resources. Navigators work to address health literacy and to train patients to advocate for themselves in the health care system. They are also trained to provide emotional support to patients during this stressful period. Navigators may also identify systems issues that serve as barriers to many patients, and work towards reduce the complexity to the patient of the multidisciplinary approach to care.

The concept of patient navigation is based upon the care management or case management model, which has four components.<sup>14</sup> The first is case identification, which is a systematic approach to the identification of those individuals with abnormal cancer screening in need of follow-up care or incident cancers. The second is identifying individual barriers to receiving care. Navigators contact patients and elicit information about the barriers to completion of recommended care. The third is developing an individualized plan to address the barriers that are identified. The fourth is tracking, which is a systematic method of following each case through resolution of the problem. In the case of cancer navigation, this is to resolution of a diagnostic evaluation when a benign condition is diagnosed or follow-up to completion of primary therapy when a cancer or pre-malignant condition is diagnosed.

The navigator will focus on assisting patients and coordinating care of the patients among providers, community, and the patients and their families. Given that patient navigators are working primarily with racial/ethnic minority and low-income patients, cultural competence is a key feature. Cultural and linguistic competence is a set of congruent behaviors, attitudes, and policies that enable effective work in cross-cultural situations.<sup>15</sup>

PNRP sites vary in the prior training, skill sets, and educational background of navigators and include lay community peers, health educators and advocates, medical assistants, social workers, and nurses. The study has set a minimum requirement of a high school diploma or

General Education Diploma. In an effort to achieve a core set of knowledge, skills, and competencies across navigators, a standardized training has been developed. The curriculum focuses on basic information about cancer and its diagnosis and treatment, professionalism, understanding barriers to care, communication skills, cultural competency, ethical conduct of human subjects research, and developing a local network of resources to support patients.  
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### **Cancers of Interest**

The PNRP program chose breast, cervical, colorectal, and prostate cancer for several reasons. Each is prevalent, particularly in low-income populations, accounts for significant morbidity and mortality, and there exists evidence of racial and ethnic outcome disparities.<sup>2</sup> For these cancers there is a commonly used screening test and evidence of better outcomes with earlier stage disease for cervical, breast and colorectal cancer, 17-18 with trials underway to assess the benefits of prostate cancer screening.<sup>19</sup> Each of the 9 sites is addressing one or more of the cancers in specific underserved populations (see Table 1).

### **Definition of metrics and methods**

Key variables necessary to answer the primary outcome questions were required of all sites and form the minimal or “common” dataset for all sites to collect. Multiple secondary analyses and sub-questions have emerged. As each of these questions arose, common metrics were chosen for these additional “optimal” elements, so that the sites collecting this additional information could pool their data for analyses of secondary outcomes and research questions. Metrics were developed by use of those guidelines that exist within the medical literature or by consensus of the steering committee. The National Comprehensive Cancer Network (NCCN) guidelines formed the major focus of the clinical guidelines on management for both screening abnormalities and diagnostic management decisions.<sup>20-23</sup> The steering committee also reviews relevant changes in guidelines during the course of the study.<sup>24</sup>

### **Eligibility and Exclusion Criteria**

Table 2 lists the screening abnormalities and diagnostic categories eligible for inclusion into the study. For each cancer, abnormal findings on screening studies that require additional testing are included. For each disease, clinical findings suspicious for cancer, for example, a breast mass or suspicious cervical lesions that result in referral to a disease specialist, will also serve as entry criteria. Lastly, a patient can enroll if presenting with a cancer diagnosis without prior treatment.

Exclusion criteria include prior history of cancer other than non-melanoma skin cancer, as patients who have already experienced the multidisciplinary complexity of cancer treatment may be more likely to be able to navigate the system. Patients with prior abnormal cancer screenings, but without a cancer diagnosis are eligible. Patients who have received patient navigation for a cancer screening abnormality are excluded, as the benefits of their prior navigation may confound the current intervention. Patients who have experience with case coordination for another disease process, such as mental health or diabetes care management are not excluded; however, information about their prior care coordination will be collected. Women who are pregnant at study entry are excluded, as delays in care influenced by pregnancy status, such as postponing cervical biopsy for cervical lesions until after delivery, will confound comparisons of the course of follow-up care.

## Methods of case and control allocation

The issue of allocating subjects to intervention versus control arms for an intervention that seems intuitively beneficial has ethical considerations. However, none of the sites in the program had pre-existing navigation services, nor were there other resources available for navigation, therefore the control groups were not denied a service that would otherwise be available to them. Each site has developed a method of allocation of cases and controls in order to address scientific rigor and logistic needs of working with community partners, within the context of these ethical concerns, and all were approved by their institutional IRB. Several sites will conduct randomized clinical trials, with randomization at the individual level at each site. Some sites have reported community concerns about not providing all eligible patients the opportunity for entry into the navigation arm, and several sites have expressed concern about contamination when attempting individual randomization. Several sites that are recruiting from multiple community health care centers have opted to randomize each clinical site to either case or control status as a way to address the above concerns. One site, in response to community concerns and buy-in for the project, has allocated each site as a navigation site for one type of cancer and control status for another cancer. Some sites have provided a minimal education intervention to the control arm, to facilitate buy-in from providers and subjects.

**Timeliness of Diagnosis**—Four primary outcomes were selected that are clinically relevant and for which disparities in care among racial and ethnic minorities and/or low-income individuals have been documented (Table 3). The ultimate outcome of an effective cancer intervention is reduction in morbidity and mortality. Delays in follow-up of abnormal cancer screening can often result in increased patient morbidity and mortality.<sup>25, 26</sup> Our first outcome measures will be the intermediate outcome of time to completion of diagnostic evaluation, as we do not have the power or the longitudinal design in this study to measure cancer-specific mortality. Screening abnormality is defined in our study as the date that the screening test was conducted, for example, the date of an abnormal clinical breast examination or the date that a prostate specific antigen or cervical cytology specimen was collected. We chose this definition because the date of report of the abnormal result, date of physician notification, or date of patient notification can reflect delays. Diagnostic resolution is defined as completion of the diagnostic test that results in a diagnosis or clinical evaluation that determines that no further evaluation is indicated. For example, a colonoscopy with biopsy confirming a malignant polyp or a colonoscopy in which no malignant lesion is identified would both serve as a diagnostic resolution.

**Timeliness of Cancer Treatment**—Subjects can enter the cancer treatment phase of the study either from the diagnostic phase, when a cancer diagnosis is established, or as a new subject with an untreated cancer. We will record the date at which the diagnostic test was performed that established the cancer diagnosis and the date at which cancer treatment was initiated; for example, date of biopsy of a polyp and date in which a partial colectomy is performed.

**Quality of Life and Patient Satisfaction**—The news of a positive screening test for cancer is likely to cause immediate quality of life changes, including emotional distress. We selected the Impact of Events Scale (IES) as a common validated measure of health-related quality of life,<sup>27</sup> that is widely used in cancer studies. The IES addresses the distress, intrusive thoughts, and misgivings precipitated by the troublesome event of an abnormal screening result or a diagnosis of cancer and can also be adapted to refer to a specific screening test result or diagnosis of cancer without altering its meaning or measurement properties. The IES will be collect at both the post-screening follow-up and post-diagnosis treatment phases of patients' experiences.

To measure patient self-efficacy in dealing with cancer and related health services we chose the newly developed Communication and Attitudinal Self-Efficacy Scale (CASE) measure. 28 CASE was validated in a diverse population of general oncology patients. The CASE has two forms: generic and cancer-focused. The former assesses self-efficacy in dealing with health care in ways that are relevant to follow-up after a positive screening. The latter form specifically assesses self-efficacy in dealing with the health care challenges following a cancer diagnosis.

While there are many measures of patient satisfaction, we found none that was specifically relevant to the expected experiences of care and the perceptions of the study participants experiencing navigation. We are developing a navigation-focused measure that will assess satisfaction with aspects of care in which navigation may be expected to have an impact. To do this, we have adapted domains and items from existing measures and developed new items, based on the combined expertise of the nine research teams. The resulting 29-item instrument addresses three major domains of patient satisfaction with clinical encounters: interpersonal process, outcomes, and structural/access issues. We are currently conducting psychometric evaluation to validate this new instrument, with data from the first 500 subjects surveyed by the nine sites.

In addition to satisfaction with care, we are developing a measure of satisfaction with the navigator, consisting of two scales. One scale includes 26 items that assess a subject's perceptions of the effectiveness of his or her navigator's efforts in overcoming specific barriers to care following a positive screening test or diagnosis, such as scheduling appointments, completing forms, and dealing with child care issues. These items correspond to the content of training that navigators receive and the specific list of barriers to care they are trained to investigate and address. The second scale consists of nine items that assess the patient's subjective satisfaction with the interpersonal relationship with the navigator. This new scale will also be subjected to validation with data from initial subjects.

We determined that the time frame for measuring patient satisfaction and quality of life would be within 3 months of completion of a diagnostic evaluation for patients with abnormal screening and within 3 months of initiation of cancer treatment for patients with cancer. This time frame was chosen to reflect the logistical issues of reaching patients to complete the inventory of items, while remaining within a time period in which the impact of events and their satisfaction with the care they received would remain current issues.

**Cost Effectiveness Analysis**—A cost effectiveness analysis will compare the costs of care using a patient navigation model with usual care, against estimates of Quality of Life Years. A societal view of costs will be used, to include estimates of start up costs for navigation programs, training costs, fixed and variables cost of the program, as well as health care expenditures, and patient out-of-pocket costs associated with their medical care. Patient utilities will be derived from a subset of patients in the navigated and control arm, using generic multiattribute utility instruments. The timeframe of the study is too short to directly measure survival time, this will be inferred from the distribution of stage at diagnosis in each group.

## Secondary outcomes

### Completion of Therapy

Many sites will collect data on therapy completion, and allow us to examine whether navigation improves rates of completion of radiation and chemotherapy. Since current data suggest that timing of therapies may play a role in effectiveness, and delays or incomplete



therapy may impede effectiveness; 29–30 these data will address this potential benefit of navigation.

### Quality of Care

By collecting details on staging of each cancer diagnosis and on the therapies completed by patients, and using evidence-based guidelines on therapeutic choices, 20–23 we can make some assessments of quality of care. For example, we can examine proportions of eligible women with estrogen receptor positive breast tumors in the navigated and control arms who are offered and who receive hormonal therapy.

### Process of Patient Navigation

Understanding the content of the work of navigation is critical to document the exact nature of the intervention, that is, the work activities of the navigators. Also, in order for other studies to compare their findings with the PNRP, there is a need for common metrics to measure navigation. Currently, no such metrics exist. We propose the following methods for other researchers to implement when evaluating patient navigation programs.

We have developed a common patient log for navigators to complete to document their work with patients. The log is based upon each direct contact with the patient and the activities performed on behalf of the patient. The nature of each patient contact (e.g., by phone, email, or in person, and at what site) and the duration of the encounter are recorded. Navigators will document barriers to care from a pre-defined list and actions taken by navigators to address these barriers. Variables also include the navigator estimate of total time to address each case. These variables will allow us to compare the barriers to care across sites, identify barriers that are not overcome, and identify which actions are associated with improvements in outcomes with navigation (see Table 4).

We are collecting information about the navigators themselves, including prior training and experience and their personal and family experience with cancer. The demographic data collected about the navigators are analogous to those collected on patients, including race and ethnicity, gender, language, health insurance, housing, and family dependents. These variables will allow us to assess if specific characteristics of navigators are associated with successful navigation and whether congruence on demographic characteristics between navigators and patients promotes improved care.

We plan direct observation of the activities of navigators to assess the content of their activities. Each navigator will be assessed twice yearly on an 8-point competency checklist, to assure that minimum standards are met across the nine sites. We hypothesize that the effectiveness of the patient navigator is related to networking of resources available to the navigator to assist in care. This requires that the navigator have access to a network of resources to support the patient's needs. We, therefore, are developing a new structured observation protocol, using concepts from task and social network analysis,<sup>31–33</sup> that will assess through direct observation of the navigators two dimensions: the individuals and organizational entities with whom the navigator interacts, and the type of task carried out in support of the navigated patient.

Each of the nine research sites is conducting the intervention in multiple health care settings. Information is collected annually on each clinical care center: geographic location, annual clinical volume, race and ethnicity of patients seen, and onsite services related to cancer screening and diagnosis. Other optional variables are collected by some of the sites for subset analyses. These include comorbidity using the Charlson Comorbidity Score<sup>34</sup> and family history of cancer. Literacy is assessed using the Rapid Estimate of Adult Literacy in

Medicine (REALM)<sup>35</sup> or by self-report of problems in reading instructions and health information.<sup>36</sup>

## DISCUSSION

Patient Navigation was a term first used to describe case management of patients in need of cancer screening or with cancer screening abnormalities.<sup>8</sup> This term is now being widely used to describe a broad array of roles and functions, from traditional administrative assistant positions, community outreach workers, social workers, nurses, and patient advocates.<sup>9</sup> The diversity of job and role descriptions, coupled with little data on the outcomes of these programs, hampers the incorporation of these roles as part of reimbursed, routine care available to select or all populations. While several state and national bills have already approved funding for patient navigation programs,<sup>37–39</sup> incorporation into Medicare or Medicaid services of more widespread patient navigation systems for vulnerable populations requires stronger evidence of its benefits and costs.

The NCI Patient Navigation Research Program is unique in examining the outcomes of care in patient navigation for persons across four different types of cancer, and across multiple diverse clinical care sites and populations. The study will assess the ability of patient navigation to facilitate timely and quality care from the initial cancer screening abnormality through the completion of initial cancer therapy. By developing a core training program, this program will develop curricula we anticipate will be useful for navigator programs throughout the country. By recording and linking patient navigation activities between the navigator and each patient, we will be able to conduct secondary analyses on the effectiveness of navigation as a function of work load, activities of the navigator and provide critical information on the optimal caseload for a navigator.

The PNRP emphasizes the importance of beginning measurement of time in care at the point of abnormal screening. To encompass all potential delays in care, we have defined our endpoints as time until definitive diagnosis and time to initiation and completion of initial therapies. Our study will not have power to assess changes in stage of diagnosis or survival benefits of navigation. Benefits of navigation will be inferred from improvements in timeliness of care, and completeness of treatment. Other studies have documented that timeliness and completion of recommended therapy are associated with improvements in survival, especially in the elderly.<sup>29, 30, 40</sup> Our research study does not address the issues of screening, nor of survivorship following treatment.

The limitations of our methodology reflect the limitations inherent in research addressing dissemination of programs within community settings. The cooperative group includes both randomized clinical trials, which assign subjects to the intervention and control groups, and quasi-experimental designs, with assignment based upon site of care. These differences reflect community and local needs when conducting community-based participatory research. Each methodology has its strengths and weaknesses in addressing the questions of interest in the research project. The randomized trial methodologies benefit from balance of known and unknown confounders between the two groups studied, but is limited in the generalizability to those subjects able to be reached and willing to be randomized. Those sites that include all subjects based upon site of care risk confounding by site of care; however, by designing the intervention as a new standard of care that allows collection of data on all eligible subjects, they benefit in generalizability by the inclusion of those very subjects most difficult to reach and for whom the navigation intervention is designed to provide support. A second major limitation is the lack of power to address stage at diagnosis and survival outcomes and the need to utilize intermediate outcomes of timeliness of completion of care and patient satisfaction.



The multidisciplinary approach to cancer care has resulted in significant survival gains, but at the cost of increased complexity within the health care system. The persistent gap in translating these improvements in cancer care to vulnerable populations will result in persistent and even widening racial disparities in cancer outcomes, unless we develop and disseminate specific interventions to facilitate the process of care. Patient navigation represents a novel approach to addressing the barriers to completion of cancer care, in groups of patients vulnerable to inadequate care by virtue of their economic, cultural, educational, racial and/or ethnic status.

## Acknowledgments

Supported by NIH Grants U01 CA116892, U01 CA 117281, U01CA116903, U01CA116937, U01CA116924, U01CA116885, U01CA116875, U01CA116925, and American Cancer Society #SIRSG-05-253-01. The contents are solely the responsibility of the authors and do not necessarily represent the official views of the Center to Reduce Cancer Health Disparities, NCI.

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**Table 1**

Cancer Type and Populations Studied by National Site – NCI Patient Navigation Program

National Site	Cancer Type					Populations Addressed			
	Breast	Cervical	Colo-rectal	Prostate	African American	Hispanic	Asian	American Indian/ Native Alaskan	
Boston University Medical Center	X	X			X	X	X		
Denver Health and Hospital Authority	X		X	X	X	X	X	X	
H. Lee Moffitt Cancer Center	X		X		X	X			
Northwest Portland Area Indian Health Board	X	X	X	X				X	
Northwestern University			X	X	X	X			
University of Illinois/Access Community Health Network	X	X			X	X			
George Washington University	X				X	X			
Ohio State University	X	X			X	X			
University of Rochester School of Medicine and Dentistry	X		X		X				
University of Texas Health Science Center	X	X			X	X			

**Table 2**

## Patient Navigation Research Program Eligibility Criteria

Cancer site	Test	Abnormality
Breast – Screening Abnormality	Clinical Breast Exam	<ul style="list-style-type: none"> <li>Breast Mass</li> <li>Clinical Finding Suspicious For Cancer</li> </ul>
	Screening Mammogram	<ul style="list-style-type: none"> <li>BIRADS<sup>1</sup> 0, 3, 4, 5</li> </ul>
	Screening Ultrasound	<ul style="list-style-type: none"> <li>BIRADS 0, 3, 4, 5</li> </ul>
	Screening MRI <sup>2</sup>	<ul style="list-style-type: none"> <li>BIRADS 0, 3, 4, 5</li> </ul>
Breast Cancer	Pathology	<ul style="list-style-type: none"> <li>DCIS<sup>3</sup></li> <li>Invasive Cancer</li> </ul>
Cervical – Screening Abnormality	Cytology	<ul style="list-style-type: none"> <li>LGSIL<sup>4,5</sup>,</li> <li>HGSIL<sup>6</sup></li> <li>ASCUS<sup>7</sup>, HPV<sup>8</sup> positive</li> <li>ASCUS, no HPV testing</li> <li>AGUS<sup>9</sup></li> </ul>
	Clinical Exam	<ul style="list-style-type: none"> <li>Suspicious abnormality</li> </ul>
Cervical Cancer And Precancerous Lesions	Pathology	<ul style="list-style-type: none"> <li>CIN<sub>2</sub><sup>10</sup></li> <li>CIN<sub>3</sub><sup>11</sup></li> <li>Carcinoma in situ</li> <li>Invasive cervical cancer</li> </ul>
Colorectal – Screening Abnormality	Clinical History And Exam	<ul style="list-style-type: none"> <li>Blood in stool or rectal bleeding in patient 50 years or older</li> <li>Rectal mass</li> </ul>
	Hemoccult	<ul style="list-style-type: none"> <li>Positive FOBT<sup>12</sup></li> </ul>
	Sigmoidoscopy Or Colonoscopy	<ul style="list-style-type: none"> <li>Polyp</li> <li>Space –occupying lesion</li> </ul>
	Double Contrast Barium Enema	<ul style="list-style-type: none"> <li>Space –occupying lesion</li> </ul>
	Virtual Colonoscopy	<ul style="list-style-type: none"> <li>Space –occupying lesion</li> </ul>
Colorectal Cancer	Pathology	<ul style="list-style-type: none"> <li>CIS<sup>13</sup></li> <li>Invasive cancer</li> </ul>
Prostate Screening Abnormality	Clinical Exam	<ul style="list-style-type: none"> <li>Prostate Induration</li> <li>Prostate Nodule</li> <li>Prostate asymmetry</li> </ul>

Cancer site	Test	Abnormality
	PSA <sup>14</sup>	<ul style="list-style-type: none"> <li>• Abnormal PSA</li> <li>• Abnormal PSA velocity</li> </ul>
Prostate Cancer	Pathology	<ul style="list-style-type: none"> <li>• PIN<sup>15</sup> or CIS</li> <li>• Invasive Cancer</li> </ul>

<sup>1</sup> BIRADS Breast Imaging Reporting and Data System

<sup>2</sup> MRI Magnetic Resonance Imaging

<sup>3</sup> DCIS Ductal Carcinoma in Situ

<sup>4</sup> LGSIL Low Grade Squamous Intraepithelial Lesion

<sup>5</sup> For women 21 years of age and older

<sup>6</sup> HGSIL High Grade Squamous Intraepithelial Lesion

<sup>7</sup> ASCUS Atypical Cells of Undetermined Significance

<sup>8</sup> HPV Human Papilloma Virus

<sup>9</sup> AGUS - Atypical Glandular Cells of Undetermined Significance

<sup>10</sup> Cervical Intraepithelial Lesion 2

<sup>11</sup> Cervical Intraepithelial Lesion 3

<sup>12</sup> Fecal Occult Blood Test

<sup>13</sup> Carcinoma in Situ

<sup>14</sup> Prostate Specific Antigen

<sup>15</sup> Prostatic Intraepithelial Neoplasia



**Table 3**

## Outcomes to Evaluate Patient Navigation

<b>Primary Outcomes</b>	<b>Secondary Questions</b>
Time to Completion of Diagnosis	Time to Completion of Therapy
Time to Initiation of Primary Therapy	Quality of Care
Patient Satisfaction and Quality of Life	Navigator Characteristics
Cost Effectiveness	Task and Social Network Analysis

**Table 4**

## Data Elements in Navigator Tracking Log

<b><u>Date of Encounter</u></b>
<b><u>Length of Time</u></b>
Length of Direct encounter time with the patient (categorical by 15-minute intervals to >90 minutes)
Total navigation time to complete navigation activities outside the time spent with the patient (categorical by 15-minute intervals to > 240 minutes)
<b><u>Type of Patient Encounter</u></b>
In-Person Home Visit
In-Person clinic/hospital visit at site where navigator is based
In-Person at hospital or clinical site other than where navigator is based
In-Person at non clinical site (eg. Social service agency, support group)
Phone call with patient
Written message to patient (letter, email)
<b><u>Barriers</u></b>
Transportation
Housing
Social/Practical Support
Language/Interpreter
Literacy
Childcare Issues
Adult Care
Location of Health Care Facility
Insurance Issues
Financial Problems
Employment Issues
Communication Concerns with Medical Personnel
Fear
Medical and Mental Health Comorbidity
Patient Disability
Out of Town/Country
Perceptions/Beliefs about Tests/Treatment
System Problems with Scheduling Care
Attitudes Towards Providers
Other Barrier Name
<b><u>Actions</u></b>
Referrals/Direct Contact
Accompaniment
Arrangements
Support

<b>Date of Encounter</b>
Records/Record Keeping
Education
Scheduling Appointments
Directly Contacting Family
No Actions Taken
Other