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Assessing the Impact of Patient Navigation: Prevention and Early Detection Metrics

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Abstract

Background—The lack of comparable metrics to evaluate prevention and early detection patient navigation programs impedes our ability to identify best practices.

Methods—The Prevention and Early Detection Workgroup of the Patient Navigation Leadership Summit was charged with making recommendations for common metrics specific to the prevention and early detection phase of the cancer care continuum. The workgroup began with a review of existing literature to characterize variability in published navigation metrics; then through discussion and group consensus developed a list of priority recommendations.

Results—Recommendations for researchers and program evaluators include:

1. Clearly document key program characteristics;
2. Use a set of core data elements to form the basis of your reported metrics; and
3. Prioritize data collection using methods with the least amount of bias

Conclusion—If navigation programs explicitly state the context of their evaluation and choose from among the core set of data elements, meaningful comparisons among existing programs should be feasible.

Keywords

patient navigation; prevention & control; early detection of cancer; cancer screening; program evaluation; measures

Introduction

Cancer control begins with primary and secondary prevention efforts which aim to reduce cancer incidence and advanced disease, respectively. The evidence is clear that certain cancers — those caused by tobacco use, viruses, or sun exposure, for example — can be

prevented completely. Regular use of proven screening modalities, such as Pap tests for cervical cancer and colonoscopy for colorectal cancer, also result in prevention through the removal of precancerous lesions. Other screening tests can detect cancers of the breast, colon, rectum, cervix, prostate, oral cavity, and skin at early stages and translate into a direct mortality benefit when abnormal screening is followed by prompt diagnosis and treatment. Indeed, mounting evidence suggests that the delivery of prevention and early detection (PED) services are responsible for a substantial portion of the documented reduction in both cancer incidence¹ and mortality^{1, 2} in the United States.

It is also well documented that not all populations benefit equally from these prevention efforts, in part because our current healthcare delivery system does not provide consistent, high-quality care to all.³ Whether defined by age, gender, race, insurance status, geographic location, or co-morbid medical condition, certain populations face significant barriers to accessing timely and quality cancer PED services consistently, if at all.⁴⁻⁶ Patient Navigation, which targets barriers faced by vulnerable populations in accessing timely, quality cancer care,⁷ was designed to address the critical disconnect between the discovery and delivery of life-saving cancer care services. In fact, the first patient navigation program was started in Harlem, New York in order to increase the delivery of mammography screening to Black women who were too often presenting with advanced cancer as a result of a lack of screening.⁸ This groundbreaking work used lay navigators from the local community to help at-risk women overcome barriers to accessing screening and diagnostic services and resulted in profound improvements in breast cancer care.⁸ Since then a growing number of studies documenting the promise of navigation have resulted in its widespread adoption as a means to deliver PED services.⁹⁻¹⁵

As navigation becomes integrated into standard cancer care services across the country,¹⁶ the lack of comparable metrics to evaluate these programs in different settings with diverse target populations impedes our ability to identify best practices and realize the full potential of this promising intervention. Thus, we aim here to provide recommendations for researchers and program evaluators to consider adopting when measuring the impact of their PED navigation programs. The intent is to facilitate consistent use of priority metrics, including process and intermediate outcome measure, that document the type and quality of work performed by prevention and early detection Patient Navigators (PN) working in diverse settings. Through the use of such measures, public health and health reform policies may be generated to provide reimbursement for services that ensure the delivery of timely, quality cancer prevention.

Methods

In March 2010, the American Cancer Society hosted the first National Patient Navigation Leadership Summit, where it convened cancer clinicians, researchers and practicing public health experts to develop a national evaluation agenda for patient navigation. The Prevention and Early Detection (PED) Work Group was charged with making recommendations for common metrics specific to the prevention and early detection phase of the cancer care continuum. The work group comprised 10 individuals, representing community-based organizations, clinical programs and academia with decades of experience implementing and

evaluating patient navigation programs across diverse populations. The work group began with a review of existing literature to characterize variability in published metrics, then through discussion and group consensus developed a list of priority recommendations.

In early 2010 the Summit Planning Committee conducted a comprehensive review of the navigation literature to guide discussion at the March meeting. The PED work group updated the literature review in October of 2010. We searched the Pubmed database to identify original articles published any year, in English, using the key terms “patient navigation,” “patient navigator,” “navigation,” “navigator,” or “case management.” We also searched the references of each publication for additional relevant literature. In keeping with the scope of navigation as outlined by Dr. Freeman at the Summit, we included only intervention studies where navigators actively link patients to screening services. Educational or outreach navigation for the delivery of prevention education in community settings were excluded. We present here findings from the synthesis of thirty-two published articles we felt exemplified the breadth of published metrics. While not meant to be an exhaustive review of the extensive literature, the studies included are representative of the variability in existing metrics.

Findings from Literature Review

Most studies target breast and colorectal cancer, with fewer targeting cervical, lung and/or prostate cancer. Reported clinical outcome metrics fall into 2 discrete points along the continuum of cancer care: 1) Screening and 2) Diagnosis, while the remaining metrics focus on the processes specific to the navigation program. To date, no patient navigation intervention study has reported final endpoints such as survival or mortality. Rather, the current literature focuses mainly on intermediate clinical outcomes in the form of the delivery of recommended cancer prevention services. Only two studies^{17, 18} document a potential mortality benefit in the form of a stage shift at the time of diagnosis. As discussed below and summarized in Table 1, there exists wide variation in both the reporting of non-modifiable program characteristics as well as how study outcome metrics are defined and reported.

Screening

We reviewed twenty navigation studies that targeted cancer screening as an outcome. We include studies with community- and clinically-based navigators in urban^{19–25} and rural settings.^{14, 26} The studies targeted diverse populations, including American Indians,^{14, 15, 19, 26} Korean-Americans,²⁷ Chinese women,²⁸ Latinas,^{14, 29} Blacks,^{14, 26, 30, 31} non-English speaking,³² poor Whites,¹⁴ low-income,^{32–34} Few programs were comprehensive targeting multiple cancer sites,^{29, 30, 33} while most target only one disease-specific screening.^{14, 15, 19–28, 31, 32, 34–36} Even among studies targeting the same disease, eligibility criteria for inclusion in programs vary, including the age of participants and the time since their last screening. For example, one mammography screening navigation study included women 52–77 years who had not had a mammogram in the previous 2 years,²¹ while another included women over 40 years whose last mammogram was only 12 or more months prior.²⁶

Most studies document receipt of a screening test as the goal of navigation and report the outcome simply as a screening rate, defined as the proportion of eligible subjects who complete a recommended test, such as a mammogram, Pap test or colonoscopy, during the intervention period. The range of the intervention period across studies was wide, such that the time subjects were followed to assess the outcome varied from 6 months^{21, 24, 32–34}, to 3 years.³⁰ The most common follow-up period was six months.^{22, 23, 27, 29, 36} Two studies document adherence to recommended screening^{20, 33} as the goal of navigation and report the outcome as an adherence rate, defined as the proportion of eligible subjects who are up-to-date with a screening test as recommended by an existing guideline or standard. These two breast navigation studies differed in how they defined “adherent”; one utilized USPSTF guidelines,³³ another HEDIS criteria.²⁰ Only one study reports maintenance screening behavior³¹ which was defined as the percentage of annual mammograms that were actually obtained during the study period. Data collection methods were either self-reported behaviors^{13–15, 19, 27–29, 35} or objective evidence from medical record review.^{20–24, 26, 31–33, 36}

Diagnosis

Of the thirteen studies included targeting the diagnostic phase of the cancer care continuum, 12 targeted breast cancer diagnosis^{8–10, 12, 13, 17, 18, 31, 37–40} while only one targeted cervical cancer.¹¹ As above, we include studies with a range of program settings that target diverse populations. And similar to screening navigation studies, the range of the intervention period across studies was wide, and the time subjects were followed to assess the outcome varied. Studies report four clinical metrics at the point of diagnostic evaluation: (1) Receipt of diagnostic resolution,^{8–11, 38, 40} (2) time to diagnostic resolution,^{8, 37–39} (3) timely adherence to diagnostic resolution,^{9–13, 31, 37, 38} and less commonly (4) stage at diagnosis.^{17, 18}

Five studies report receipt of diagnostic resolution^{8–11, 38, 40} as the goal of navigation. These studies present this outcome simply as a resolution rate, defined as the proportion of eligible subjects who complete diagnostic testing during the intervention period. The majority of studies reviewed report timeliness of diagnostic care as the goal of patient navigation. These studies documented time in two distinct ways: either (1) the time to diagnostic resolution^{8, 37–39} as a continuous outcome or (2) the rate of timely adherence to diagnostic resolution as a dichotomous outcome.^{9–13, 31, 37, 38}

The most striking finding in reviewing these metrics is the lack of a consistent definition for what constitutes ‘diagnostic resolution’ or the diagnostic interval. Most studies use the date the abnormal screening test was performed as the index event or start date.^{9, 10, 31, 37, 38} However, there is widespread variability in the data point indicating diagnosis, diagnostic resolution or adherence to recommended follow up, ranging from the date of arrival to first diagnostic clinical visit¹² to the actual date a tissue sample was obtained.⁸ When tissue diagnosis is not recommended, studies vary in reporting how a ‘diagnostic resolution’ is determined. For example, one study reports the endpoint as “until negative mammogram, benign biopsy, 6 month follow-up test, or start of cancer treatment”¹⁰ while other studies

only include benign or malignant tissue as a diagnosis.³⁹ There is similar variability in how investigators define “timely” ranging from 60 to 180 days.^{9, 13}

The Patient Navigation Research Program, a collaborative multi-site research program designed to evaluate the efficacy of navigation after abnormal cancer screening, developed a set of “common” data points using the National Comprehensive Cancer Network (NCCN) guidelines as the major focus of clinical outcomes.⁴¹ While the results of this program are not yet published, the PNRP is the largest study to date on PED navigation. In their program, 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.

The two studies reporting breast cancer stage at diagnosis as the outcome similarly reported population level data to assess the impact of a navigation program targeting individuals.^{17, 18} While this suggests a potential impact of navigation, the methods used preclude a causative association to be determined.

Process metrics

In addition to intermediate clinical outcomes six studies included here report metrics that evaluate whether the intervention was implemented as intended. Five studies report navigator-documented barriers to care^{9, 10, 25, 31, 35}. One study, by Lasser et al, documents the median number of contacts per patient and mean hours of telephone outreach per patient³³. A descriptive study by Lin et al documented the types of barriers to care and time spent by the navigator.⁴² The PNRP is collecting the following process metrics in their multi-site program: barriers to care identified by navigator, actions taken by the navigator, and details of navigation encounters such as type of encounter and time spent.⁴¹ Only one³³ of these studies have examined the association between these process measures with their outcomes, which represents an area in critical need for further study.

Recommendations for PED Metrics

In keeping with the goal of having a core set of priority metrics for navigation programs to measure impact on individuals and populations, it would be ideal to have consistent study characteristics, including eligibility criteria, follow up time intervals and outcome metrics. Obviously, this is not possible for several reasons. First, there are certain program characteristics that are inherently non-modifiable such as program setting and the populations they serve. In addition, the specific needs of populations appropriately dictate the intended outcomes of navigation, the ideal mode of navigator contact or specific navigator activities. Finally, there is wide variability in the amount and type of resources available for evaluation efforts. Community programs wishing to conduct an evaluation of their program may well have fewer resources than an externally funded research project such as the PNRP. Regardless, the existing literature illuminates the need for one approach that may bring us closer to this ideal. That is, the need for consistency in reporting both modifiable and non-modifiable program characteristics. Stating these clearly will facilitate meaningful program comparisons even in the absence of common outcome metrics.

Therefore, our first recommendation is to clearly document the following set of program characteristics:

1) Program setting

At a minimum knowledge of geographic settings such as urban, rural, suburban is an important distinction. More importantly, the system setting is essential to know when considering replicating a program. Beyond describing whether a program is community versus clinically-based, some detail on the specific area within a clinical or community setting is important, such as in primary care versus radiology.

2) Eligibility criteria of navigated subjects

These programmatic elements are necessary in order to interpret the outcomes and their potential impact for other populations. Most important are age, race/ethnicity, primary spoken language and time since last screening.

3) Mode of navigation

The primary mode of delivering the navigation program is a minimal program element essential to comparing study findings. Specifically, did the navigator interact with their target community in person (in a community setting, in a clinical setting) or on the telephone?

4) Time interval of the follow up period at which outcomes are assessed

This detail is critical to interpreting the meaning of a defined outcome. For example, it would be important to know that two programs reporting a similar clinical outcome (ie: 90% of program participants completed their mammogram) have each measured their outcome at different time intervals (ie. one year versus 6 months).

Many of the observed differences in published PED outcomes are not in the data elements collected, rather in either the nomenclature used to describe them or the analyses used to report them. Thus, defining a core set of *data elements*, rather than firm outcome metrics is a much more realistic approach and comprises our second set of recommendations. Prioritizing the collection of these data elements will allow for the variability inherent in navigation programs that target different communities and systems of care while also allowing for meaningful comparisons. From these data elements, common metrics to represent prevention and early detection constructs can be created (see Tables 2, 3 and 4).

Table 2 displays recommendations for core data elements that may be used to create a set of common intermediate outcome metrics that fit within the constructs of screening outcomes, and potential analysis options for use in reporting. The first construct is Receipt of the screening test. Documenting the core data elements to measure this construct allows for the reporting of dichotomous outcome metrics like “completion of screening test (yes/no)” or “timely completion of screening test (yes/no)” as well as the continuous outcome of “time to complete screening”. Either of these metrics may be reported using any or all of the common data points outlined in Table 2. This measure is limited when comparing programs with different eligibility criteria and follow up time periods. Thus, a more comparable

construct to consider is Adherence to recommended screening, which requires of course that a screening guideline (such as the USPSTF) be stated explicitly. This common metric allows for programs to compare their adherence rates across different populations. Because the full benefit of screening on survival is dependent on the longitudinal use of “routine” screening tests, there should be an emphasis towards documenting screening maintenance over time.

Table 3 displays recommendations for core data elements that may be used to create a set of common intermediate outcome metrics that fit within the constructs of diagnostic outcomes, and potential analysis options for use in reporting. Common measures for the construct of diagnostic resolution include the dichotomous outcome metrics of “completion of diagnostic resolution (yes/no)”, “timely completion of diagnostic resolution (yes/no)” and the continuous outcome of “time to complete diagnostic resolution.” These metrics may be reported using any or all of the common data elements outlined in Table 3. Resources and program intent will create variability in which data elements programs are interested in and capable of collecting. The priority should be to have an explicit and consistent definition of diagnostic *resolution* and to collect the date corresponding with that definition, as recommended by the PNRP.⁴¹ When the diagnostic resolution is a diagnosis of cancer, metrics such as stage at diagnosis are also important to record. Table 3 lists available options in care delivery that may constitute diagnostic resolution, which all programs should aspire if resources allow. Another recommended construct that is often omitted from program evaluation is Adherence to recommended testing, as determined by documentation of the type of diagnostic test performed in approaching diagnostic resolution. This common metric, completion of appropriate test, is another measure of quality to ensure populations have access to appropriate diagnostic testing.

Our third set of recommendations call for a minimal set of process data elements (Table 4). Process measures are intended to measure whether navigation was delivered as planned or designed. Without these details, replication of programs with successful outcomes is not possible. Knowledge of the specific components of a navigation program are necessary to apply lessons learned from one program to the next. The PED Working Group identified three distinct phases of PED where processes of navigation may differ:

1. Outreach/promotion (helping community understand the need and availability of cancer screening)
2. Support during clinical visits
3. Tracking and follow up after clinical visit completed

At a minimum, programs should document which phase(s) of PED their navigators address, as this captures broadly the types of activities involved in the navigation program.

In addition, we strongly recommend that programs document the number of patients navigated (over some specified time period: daily, weekly or monthly) and the time spent with individual patients. From this information measures of caseload may be created. Mode of communication and whether an interpreter was used in an encounter is another important process measure. Documenting the date of last navigator encounter ensures a way to attribute the screening outcome to navigation. For example, we wouldn’t want to attribute a

screening outcome to navigation if there has been no contact with a navigator in the prior 12 months.

Considering that barriers to care are at the very center of the conceptual model of navigation, it is essential to measure them along with navigator activities, or actions, taken to address them. Creating an optimal set of patient-level barriers to care is challenging given the specific needs of diverse populations, as barriers in one community may be vastly different from barriers in another. Freund et al describe recommendations for barriers used by the PNRP⁴¹ and provide a framework for documenting navigation activities that would facilitate meaningful comparisons. The Native American Cancer Research Corporation (NACR) provides another example of documenting barriers and actions routinely used in their program.¹⁵ Finally, documenting healthcare utilization along the screening process is an alternative way of capturing benefits of navigation, such as reduction in rates of missed appointments.

Our fourth and final set of recommendations is related to data collection efforts. Data elements may be collected using patient self report, navigator logs, clinical data sources, and/or objective observation. At a minimum, programs should document their data source, given the limitations/strengths of these various sources. In a research context, it would be inappropriate to have navigators administer outcome assessments for their own patients as it would introduce potential bias. While it would be acceptable to have navigators document process measures, all programs should avoid using navigators to document clinical outcomes.

PN daily logs are an obvious source for process measures. Electronic programs can be used for those PN who have access to computers and/or the Internet. Tremendous effort should be made to ensure the layout consists of closed question format or checkboxes that address most prevalent responses with an “other” category that allows for text input. These lists or checkboxes should include space to document the amount of time the PN spent doing each task, or better yet checkboxes with time intervals.

Patient self-reported screening behaviors are often inaccurate.⁴³ and how the questions are asked may influence the responses. However, if patient self report is used, phrasing of questions should be drawn from standardized, validated instruments such as the National Health Interview Survey (NHIS), the Behavioral Risk Factor Surveillance System (BRFSS), or the National Medical Care Expenditure Survey (NMEPS). Likewise, there are differences in the types of responses when such instruments are administered face-to-face, over the phone, completed by the patient, use of CADI (Computer Aided Design Instrument) systems and/or through the Internet.⁴⁴

While objective observation methods of patients and navigators have been developed,⁴⁵ most programs will not have the resources to utilize them. With federal mandates requiring transition to electronic medical records, there is tremendous opportunity to utilize objective clinical data sources to measure these outcomes and should be the standard for navigation programs to aspire. For example, electronic medical records may be queried for the presence of screening reports or as a means to complete certain data points, while electronic

registration systems may be queried to report adherence outcomes for scheduled appointments.

Discussion

Patient navigation programs that target the prevention and early detection spectrum of care share similar goals, yet vary widely in how they document their success. Differences in program structure, population needs, outcomes of interest, and reported evaluation metrics make cross-study comparisons impossible. However, a review of the literature suggests that a common set of evaluation metrics relevant to multiple stakeholders can be developed. Based on a synthesis of existing navigation literature and expert consensus, we present here a set of four recommendations related to measuring and reporting PED navigation program success so that dissemination of the evidence may be used to delineate best practices in the design of care processes across diverse settings.

Our recommendations call for a core set of quality indicators that measure the intent of navigation – to bridge the critical disconnect between the discovery and delivery of life saving cancer care services. Knowledge of basic program characteristics is the starting point to contextualize comparisons between programs. While clinical outcome measures of quality (e.g., stage of diagnosis or mortality) are generally more difficult or not feasible to measure, we provide a framework of core data elements that may be used to report a common set of intermediate clinical metrics. Equally important, we provide recommendations for collecting and reporting process measures (activities performed while receiving care) which are the most frequently used quality indicators,^{46, 47} because they are sensitive, unambiguous, and easily measured.^{48–50} Our review of the literature highlights the lack of evidence linking these processes to clinical outcomes, making these data elements of high priority for future study as process measures should be associated to outcome measures for effective quality assessment.^{51, 52}

Priorities should focus on defining the needs and demographics of the target population, which in turn should drive the expected outcomes of the intervention. As long as programs explicitly state the context of their evaluation and choose from among the core set of data elements, meaningful comparisons among existing programs should be feasible. While methods for collecting these metrics will depend upon resources and existing infrastructure, programs should aspire for rigor with objective sources when possible. When objective electronic data are not available, sites need creativity to determine the best way to retrieve the information, either from manual chart abstraction or navigator documentation. These recommendations are a first step towards adopting a minimal dataset for PED navigation programs, as has been done by other population based approaches to improving quality care.⁵³

Navigation is emerging as an expected "standard" for cancer programs,⁵⁴ yet the literature has yet to provide consistent insight into activities or processes of navigation that are linked to favorable outcomes. We demonstrate here the growing body of knowledge regarding the impact of prevention and early detection navigation on cancer care would benefit from some thoughtful standardization. In keeping with recommendations from the 2001 IOM report to

deliver patient-centered care that is timely, efficient and equitable³ it is imperative that we evaluate the ability of PED patient navigation programs to realize that potential. Only then can we “apply evidence to health care delivery” as recommended. The responsibility for the analysis and synthesis of this medical evidence falls on all of us involved in the delivery of these services.

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Table 1

Variability in Prevention and Early Detection Metrics

Screening										
Study	Setting	Disease	Eligibility Criteria	Navigation mode	Outcome Metric	Process Metric	Follow-Up Period	Data Collection		
Burhansstipanov L, 2010	Urban Community	Breast	Age 39 Last mammo > 18 months	Face-to-face Telephone	Receipt of screening mammo	NR	NR	Self-report		
Burhansstipanov L, 2000	Urban Community	Breast	Age 39 Last mammo > 18 months	Face-to-face Telephone	Receipt of screening test	NR	NR	Self-report		
Ford, 2006	Urban Clinical	Prostate Lung Colorectal	Age 55	Telephone	Receipt of screening test (Next scheduled test)	NR	Time to next trial screening	Medical Record Review		
Dietrich, 2006	Urban Clinical	Breast Cervical Colorectal	Age 50 – 69 Overdue at least 1 cancer screening	Telephone	Adherence to recommended screening	NR	18 months	Medical record review		
Fernandez, 2009	Rural Community	Breast Cervical	Age 50 Farm worker status	Face-to-face	Receipt of mammo, pap test	NR	6 months	Self-report Medical record review for validity		
Wang, 2010	Urban Community	Cervical	Age 18+ Last pap > 12 months	Face-to-face	Receipt of pap test	NR	12 months	Self-report		
Dignan, 2005	Urban Community	Breast	Age 40+ Last mammo > 18 months	Face-to-face Telephone	Receipt of mammo	NR	12 months	Self-report		
Han, 2009	NR Community	Breast	Age 40+ Last mammo > 24 months	Face-to-face Telephone	Receipt of mammo	NR	6 months	Self-report		
Paskett, 2006	Rural Community	Breast	Age 41 Last mammo > 12 months	Face-to-face follow-up telephone calls	Receipt of mammo	Barriers	12 months	Medical record review		
Phillips, 2010	Urban Clinical	Breast	Age 51 – 70 Last mammo > 18 months	Telephone	Adherence to recommended screening	NR	24 months	Medical record review		
Weber, 1997	Urban Clinical	Breast	Age 52 – 77 Last mammo > 24 months	Telephone	Receipt of mammo	NR	10 months	Medical record review		
Clark, 2009	Urban Clinical	Breast	Age 18 – 75	Telephone	Receipt of mammo/Maintenance screening behavior Timely adherence to diagnostic resolution	NR	3 years	Medical record review		
Ma, 2009	NR Community	Colorectal	Age 50+ ACS guidelines for last CRC screening	Face-to-face	Receipt of CRC screening	Barriers	12 months	Self-report Verified with physician's office		

Screening									
Study	Setting	Disease	Eligibility Criteria	Navigation mode	Outcome Metric	Process Metric	Follow-Up Period	Data Collection	
Jandorf, 2005	Urban	Colorectal	Age 50+ FOBT > 1year FS or Barium Enema >5 years Colonoscopy >10 years	Telephone	Receipt of CRC screening	NR	6 months	Medical record review	
Lasser, 2009	Urban	Colorectal	Age 52 – 80 No CRC screening	Telephone	Receipt of CRC screening	Number of contacts Hours of contact	6 months	Medical record review	
Myers, 2008	NR	Colorectal	Age 50 – 79 Last practice visit < 24 months	Telephone	Receipt of CRC screening	NR	6 months	Self-report Medical record review	
Pereac-Lima, 2008	Urban	Colorectal	Age 52 – 79 FOBT > 1year FS or Barium Enema >5 years Colonoscopy > 10 years	Telephone	Receipt of CRC screening	Barriers	9 months	Medical record review	
Nash, 2006	Urban	Colorectal	All colonoscopies	NR	Receipt of colonoscopy	NR	11 months	Medical record review	
Diagnosis									
Study	Setting	Disease	Eligibility Criteria	Navigation mode	Outcome Metric	Process Metric	Follow-Up Period	Data Collection	
Oluwole, 2003	Urban	Breast	Age: None Clinic patients	NR	Stage at diagnosis	NR	Retrospective, cross-sectional	Medical record review	
Gabram, 2008	Urban	Breast	Age: None Clinic patients	NR	Stage at diagnosis	NR	Retrospective, cross-sectional	Medical record review	
Ferrante, 2007	Urban	Breast	Age: 21 BIRADS 4 & 5	Telephone Face-to-face	Timely adherence to diagnostic resolution Time to diagnostic resolution	NR	60 day interval Follow-up period unclear	Medical record review	
Palmieri, 2009	Urban	Breast	Age: None 200% FPL	NR	Timely adherence to diagnostic resolution Receipt of diagnostic resolution	NR	60 day interval NR	Medical record review	
Ell, <i>Cancer Pract</i> , 2002	Urban	Breast	Age: None Prescribed follow-up screening/diagnostic test	Telephone	Receipt of diagnostic resolution Timely adherence to diagnostic resolution	Barriers	NR ACR 4& 5: 60 day interval ACR 3: 240 day interval	Appointment records Self-report	
Ell, 2007	Urban	Breast	Age: None ACR 3-5	Telephone	Receipt of diagnostic resolution Timely adherence to diagnostic resolution	Barriers	8 months ACR 4&5: 60 days ACR 3: 240 days	Medical record review	
Ell, <i>J Women's Health Gend Based Med</i> 2002	Urban	Cervical	Age: None LGSIL & HGSIL Prescribed follow-up screening/ diagnostic test	Telephone	Receipt of diagnostic resolution Timely adherence to diagnostic resolution	NR	12 months 30 day interval	Medical record review	
Battaglia, 2007	Urban	Breast	Age: >18 Referred for evaluation	Telephone	Timely adherence to diagnostic resolution	NR	ys	Medical record review Self-report	

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Screening									
Study	Setting		Disease	Eligibility Criteria	Navigation mode	Outcome Metric	Process Metric	Follow-Up Period	Data Collection
Bastani, 2010	Urban	Clinical	Breast	Age: None Referred to Surgery or Radiology for breast abnormality	Telephone	Timely adherence to diagnostic resolution	NR	6 months	Medical record review

* NR = Not recorded

Table 2

Recommended common data elements for Screening Metrics

Construct	Common Metrics	Core Data Elements	Analysis Strategies
Receipt of screening test	Completion of screening test (<i>Yes/No</i>) Timely completion of screening (<i>Yes/No</i>) Time to complete screening (<i># days</i>) Kept appointment rates	A. Date enrolled into navigation B. Date referred for screening C. Date test scheduled D. Date test completed E. Date test results are read/reported F. Date patient informed of test result Scheduled appointment status for each appointment: arrive, no show, reschedule, cancel	Define "completion" i.e., "Yes" = a date is entered for D. Date test completed Define "time to complete screening" ie: Identify time intervals: # of days from A → B → C → D → E → F, A → F, or any combination Define "timely" (i.e. NCCN guidelines) Define "kept appointment" & "not kept appointment" i.e. cancel vs reschedule vs no show
Adherence to single recommended screening	Did not keep appointment rates Number of re-scheduled appointments	C. Date most recent screening test completed	Track for each scheduled appointment Analyzed at patient, provider, or practice level
Adherence to recommended screening longitudinally	Adherent to routine recommended screening (<i>Yes/No</i>)	A. Name of professional guidelines that defines recommended screening maintenance (ie: USPSTF, NCCN) B. Date current screening test completed C. Date most recent screening test completed D. Date past screening tests completed	Define "adherent" i.e. "Yes" = completed a series of tests over specified time period Clearly document time of follow up period

•USFSTF= United States Preventive Services Task Force, NCCN= National Comprehensive Cancer Network

•HEDIS= Healthcare Effectiveness Data and Information Set

Table 3

Recommended common data elements for Diagnostic Metrics

Construct	Common Metrics	Core Data Elements	Analysis Strategies
Receipt of diagnosis or resolution of screening abnormality	Completion of diagnostic resolution (<i>Yes/No</i>) Time to completion of diagnostic resolution ⁴² (# days) Timely completion of diagnostic resolution (<i>Yes/No</i>) Kept appointment rates	A. Date index screening test performed B. Date patient informed of test result C. Date enrolled into navigation clinical evaluation D. Date of first scheduled diagnostic test/ clinic visit E. Date of completion of first diagnostic test/clinic visit F. Date of final scheduled diagnostic test/ clinic visit G. Date of diagnostic resolution = date final test performed H. Date diagnostic test read/reported I. Date patient informed of test results Scheduled appointment status for each appointment: arrive, no show, reschedule, cancel	Define “diagnostic resolution” ie. “Yes”= a date exist for the F. “date of diagnostic resolution” Define “time to completion” ie: Identify time intervals: # of days from A → B → C → D → E → F → G → H, → I A → I, or any combination Define “timely” ie: 30, 60, 90, 120, 180 days Define “kept appointment” & “not kept appointment” i.e. cancel vs reschedule vs no show
Adherence to recommended diagnostic testing	Did not keep appointment rates Number of re-scheduled appointments		Track for each scheduled appointment Analyzed at patient, provider, or practice level
Stage at diagnosis	Stage 0–4	TNM Classification of Malignant Tumors cancer staging criteria	*ACJJ Staging Manual ⁵⁵

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Table 4

Recommended common data elements for Process Metrics

Construct	Common Metrics	Core Data Elements	Analysis Strategies
Phase of cancer care that navigation program target	Phase of cancer care	<ol style="list-style-type: none"> 1 Outreach 2 Support during clinical visits 3 Tracking and follow up 	Check all that apply
Caseload	Navigator Caseload	# of patients navigated per navigator Time spent per patient (minutes, hours)	Define “caseload” within a specified timeframe (ie: weekly, monthly, annually) Consider accounting for time when defining caseload
Communication	Mode of communication	Encounter type: in person, phone, letter Interpreter used (<i>yes/no</i>)	Define “encounter” Track for each encounter Specify unit of analysis (per encounter, per patient)
Barriers	Number of barriers Type of barriers	Fitzpatrick scale PNRP Methods paper ⁴¹	Define “barrier” Track for each encounter
Actions	Number of actions Type of actions	PNRP Methods paper ⁴¹	Define “action” Track for each encounter