Metrics for Evaluating Patient Navigation During Cancer Diagnosis and Treatment

Crafting a Policy-Relevant Research Agenda for Patient Navigation in Cancer Care*

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BACKGROUND: Racial and ethnic minorities as well as other vulnerable populations experience disparate cancer-related health outcomes. Patient navigation is an emerging health care delivery innovation that offers promise in improving quality of cancer care delivery to those patients who experience unique health-access barriers. Metrics are needed to evaluate whether patient navigation can improve quality of care delivery, health outcomes, and overall value in health care during diagnosis and treatment of cancer. METHODS: Information regarding the current state of the science examining patient navigation interventions was gathered via search of the published scientific literature. A focus group of providers, patient navigators, and health-policy experts was convened as part of the Patient Navigation Leadership Summit sponsored by the American Cancer Society. Key metrics were identified for assessing the efficacy of patient navigation in cancer diagnosis and treatment. RESULTS: Patient navigation data exist for all stages of cancer care; however, the literature is more robust for its implementation during prevention, screening, and early diagnostic workup of cancer. Relatively fewer data are reported for outcomes and efficacy of patient navigation during cancer treatment. Metrics are proposed for a policy-relevant research agenda to evaluate the efficacy of patient navigation in cancer diagnosis and treatment. CONCLUSIONS: Patient navigation is understudied with respect to its use in cancer diagnosis and treatment. Core metrics are defined to evaluate its efficacy in improving outcomes and mitigating health-access barriers. Cancer 2011;117(15 suppl):3565-74. © 2011 American Cancer Society.

KEYWORDS: patient navigation, treatment adherence, quality of cancer care.

INTRODUCTION

Patient navigation is a health-access barrier-focused intervention,¹ becoming increasingly adopted as a health care delivery innovation to address disparate cancer-related health outcomes. Such disparities are well documented among minority and low-income patients, who often face multiple health-access barriers ranging from financial and logistical constraints in obtaining health care to cultural and trust issues that impede health care provision.²-¹¹ Recent policy events have imparted new urgency upon measurement of the potential impact of patient navigation on the quality of health care provision and outcomes. Specifically, the Affordable Care Act of 2010¹² (health care reform) seeks to identify effective care-delivery models that improve outcomes and quality of care at the level of policy, health care systems, and individual patient outcomes. When fully implemented, health care reform will expand insurance coverage to approximately 30 million previously uninsured individuals, a disproportionate number of whom will be ethnic/racial minorities and low-income individuals. These populations experience access barriers that go beyond lack of payment for health care coverage.³⁷,¹⁰,¹³ Therefore, barrier-focused interventions, such as patient navigation, may play an important role in improving quality and outcomes in the US health-care system.

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Contemporary cancer treatment involves a series of complex, often multimodal treatment regimens that even medically savvy and well-resourced patients can find challenging. Appropriate metrics and data sources must be defined that will allow researchers and administrators to determine if navigation can assist patients in managing the complexities of cancer care. These metrics and data must also be used to determine if navigation offers particular benefits in addressing the barriers to treatment among disadvantaged, low-income, or racial/ethnic minority patients. Appropriate metrics will not only define outcomes for cancer patients but also may be useful in other complex diseases, as well as patient-centered navigation.

The role of patient navigator was probably first practiced by knowledgeable and supportive clergy or culturally specific healers (e.g., nuns, pastors, rabbis, medicine men), followed by nurses and social workers in expanded roles. The organized introduction of lay advocates into navigation programs is a relatively recent occurrence and reflects the need to recontextualize the patient’s health care experience within the frame of the social determinants of health as well as that of the disease processes. In oncology care, patient navigation arose to improve cancer screening, early detection, and timely follow-up among low-income and disadvantaged populations, and its success was measured based on its programs’ success at improving screening, detection, and reducing follow-up delays among these vulnerable populations. Over time, however, navigation programs have expanded their purview, and programs now aim—among other goals—to improve the delivery of care for cancer patients who may encounter a variety of barriers that preclude their receipt of optimal treatment. Our goal is to propose appropriate metrics that could be used to evaluate a navigation program’s utility in addressing barriers to the delivery of cancer care. In this article, we review the literature to document which metrics have been used in studies of treatment-focused navigation. We then discuss proposed metrics that could be used in future evaluation studies of treatment-focused navigation programs.

Review of the Current Literature

Although the published literature and systematic large-scale research on patient navigation continue to emerge, the vast majority of existing data showing improved cancer-related health outcomes with patient navigation involve programs that provide navigation during the screening and diagnostic resolution phases of early cancer management. Fewer studies examine the impact of patient navigation during cancer treatment itself. Below is a review of the relevant published studies evaluating patient navigation during cancer diagnosis and treatment.

Survival and stage-shift outcomes

The primary goal of any cancer-related health intervention is to improve survival. The early experience with patient navigation suggested that it does improve survival outcomes by affecting a stage shift toward earlier stage at presentation. The first study to demonstrate that patient navigation may potentially alter cancer survival outcomes for vulnerable populations arose from the original patient navigation effort developed by Freeman et al in Harlem. A 2003 report from this effort published by Oluwole et al showed that patient navigation in this setting affected a stage shift to fewer patients presenting with advanced-stage (stages III-IV) breast cancer (21% vs 49% prior to implementation of patient navigation; \( P < .001 \)). Correspondingly, the proportion of patients presenting with stages 0-I breast cancer increased from 6% to 41%. These data suggest that patient navigation conferred a survival advantage in this population. Similarly, Gabram et al showed improvement in stage at diagnosis with patient navigation among a largely African American population in Atlanta with increase in the proportion diagnosed with stage 0 (in situ) breast cancers (26% vs 12%) and decrease in the number of patients with stage IV breast cancer (9% vs 17%) in their navigated cohort.

Patient navigation and improvements in diagnostic follow-up

Upstream of stage distribution improvements, better follow-up on abnormal screening tests and more timely diagnostic resolution have also been associated with patient navigation. Freeman’s original patient navigation model showed that patient navigation significantly improved diagnostic resolution of suspicious screening tests (88% received biopsy with patient navigation vs 57% without patient navigation) among low-income women in Harlem undergoing screening mammography. Battaglia et al also showed that patient navigation among minority, low-income patients in Boston had 39% greater odds of timely diagnostic follow-up (defined as diagnostic follow-up within 120 days of originally scheduled appointment).

Others have also demonstrated similar care improvements associated with patient navigation by reducing time intervals between steps in early cancer management. Ferrante et al reported shorter times to diagnostic resolution among minority women in urban New
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Jersey who received patient navigation after abnormal mammograms, as well as a higher proportion of navigated patients experiencing diagnostic resolution at 60 days compared with a control group (94% vs 78%). Furthermore, they showed that navigated patients experienced a mean time to diagnostic resolution of 25 days compared with 43 days for the non-navigated group (P = .001). Similarly, Palmieri et al reported that time from abnormal mammogram to diagnostic resolution was ≤60 days for 81% of low-income patients in a Jacksonville, Florida, cancer center. This compares favorably with a Center for Disease Control prevention quality benchmark of 75% of patients experiencing diagnostic resolution within 60 days.21,22 Investigators in Canada have also shown that patient navigation decreased biopsy wait times after abnormal mammogram,23 and a patient navigation program at the University of Pittsburgh was associated with shorter intervals between date of referral and date of consult and between date of consult and date of start of treatment.24

Health services utilization including treatment adherence and interruption

Some investigators have shown that patients undergoing navigation have more favorable health services utilization or better treatment adherence during cancer treatment. For example, Fillion et al25 reported significantly fewer hospitalizations among head and neck cancer patients who received patient navigation compared with a historical control group who did not receive patient navigation services at their institution. Oluwole et al showed that low-income, minority women in Harlem who received patient navigation had higher rates of breast conservation (45% underwent mastectomy) compared with an earlier, prenavigation cohort whose mastectomy rate was 71%.17 Other investigators have focused on treatment adherence and interruptions. Ell et al26 reported high rates of treatment adherence to chemotherapy and radiation therapy regimens in a study of patient navigation during treatment for low-income women with breast and gynecologic malignancies. However, it should be noted that in this randomized study, there was no statistically significant increase in adherence rates between those receiving in-person patient navigation and enhanced usual care, which was defined as written resource navigation information. Another study24 found that in patients undergoing radiation therapy, patient navigation reduced the time from consult to start of treatment, whereas the treatment completion rates were similar and navigated patients actually missed more treatment days (1.86 days/patients vs 0.47 days/patient in the non-navigated group). Of note is that the navigation intervention was limited to the start of radiation treatment. Petereit et al27 showed that American Indian patients in rural South Dakota who received patient navigation throughout treatment experienced fewer days of treatment interruptions than a historical control cohort treated prior to the implementation of the patient navigation program.

Patient navigation utilization and barrier mitigation data

Few data are published regarding patient navigation service delivery metrics that inform resource utilization requirements necessary to implement patient navigation. Investigators at the University of Pittsburgh published data from their experience showing that navigators spent an average of 2.5 hours with patients recently diagnosed with cancer.28 They indicated that navigators spent more time with uninsured patients than with those who were insured. The most time-consuming barrier addressed by their navigators was financial problems, but other barriers that required significant time from navigators included transportation, end-of-life issues, dependent-care help, scheduling of appointments, and assistance with activities of daily living. Uninsured, unemployed, and low-education patients tend to present with greater comorbidities that increase the number of barriers encountered and may place additional time demands on navigators.29

Clinical trial participation

Studies have consistently demonstrated lower rates of clinical trial participation among minority, rural, and low-socioeconomic subpopulations.30-36 These differences in clinical trial opportunities may contribute to cancer-related disparities among underserved populations,10,37,38 and some investigators have begun to look at patient navigation as a tool to engage these patients in clinical trial participation. Investigators in rural South Dakota have shown that clinical trial enrollment among American Indian patients was 8% among patients receiving patient navigation throughout cancer treatment.39 This compares favorably with not only reported rates of trial participation for American Indians, which is <1%,30,32,35,40 but also with trial participation rates for the general population, which are approximately 3% nationally.30-33

Patient-reported outcomes

Patient-reported outcomes are important tools for measuring the quality of health care, and patient
navigation has been shown to be associated with improvements in some important patient-reported outcomes. Ferrante et al\textsuperscript{20} reported improvement in satisfaction with health care and decreased levels of anxiety among a cohort of urban, minority (predominantly African American and Hispanic) patients who underwent patient navigation through diagnostic resolution of abnormal mammogram results. Fillion et al\textsuperscript{25} in Canada also showed a significant improvement in satisfaction with care, especially with regard to doctor-related and waiting-time concerns, among patients who received services of a patient navigator during treatment for head and neck cancer.

**Rationale and Methods for Selection of Measures**

**Sociodemographic data and baseline cancer-related data**

Any assessment of navigation program outcomes must include the collection of basic demographic, racial/ethnic, and sociodemographic data as well as baseline disease-specific data about type and stage of cancer and whether treatment is of curative or palliative intent. Collection of detailed data regarding sociodemographic factors (e.g., income level, educational level, marital status, employment status, primary language spoken in the home, family/caregiver support) is important, as evaluating outcome measures in the setting of patient navigation must take into consideration the role of health-access barriers and social determinants of health. (See a dedicated review by Natale-Pereira et al of health disparities and patient navigation on pages 000-000, this issue.) Navigation focuses on identification and resolution of barriers or concerns in a timely fashion, so it is crucial to clearly define the specific date that navigation became available to a patient. Ideally, time data for all relevant cancer events would be captured (e.g., screening, pathology report availability, diagnosis, communication of diagnosis to patient). However, some programs, such as those that only provide patient navigation for cancer patients during treatment, may have more difficulty capturing this data with sufficient accuracy. Metrics for evaluation of patient navigation must be contextualized to reflect those aspects of diagnosis and treatment in which patient navigators may realistically be able to have an impact for the specific program being evaluated (e.g., if the navigator program is targeted more for the diagnostic phase of management, treatment-related metrics would not be relevant).

Sociodemographic and baseline cancer-related data should be recorded in standardized format. Programs should use US Census categories and methodologies for collecting data on race/ethnicity, education, and income. Cancer baseline data should be recorded according to National Cancer Institute (NCI) standards. Individual programs should, at their discretion, also record additional demographic or cancer-specific data as long as census and NCI standards are included to facilitate cross-program comparison.

**Metrics for patient navigation during diagnosis of cancer**

Timely diagnosis and staging are important aspects of effective cancer management and may improve survival outcomes. Navigation programs that seek to assist patients in timely adherence to screening, diagnostic follow-up, and staging workup recommendations should use “time-to” variables as shown in Table 1. An important data point in these analyses is the date of diagnosis of cancer, which should be designated as the date of pathologic confirmation of malignancy (biopsy date in most cases). Similarly, time-to variables for various steps in cancer treatment are often critical for providing the best-quality cancer care. Specifically, the time to initiation of cancer treatment from the date of diagnosis is a key interval that may be shortened among some access-challenged patients whose care is facilitated by a navigator. Examples of such important treatment-related/time-to intervals are shown in Table 1.

**Metrics for outcomes, treatment aspects, and care quality**

Tracking program success at reversing disparities among minority and low-income populations can be done via myriad potential metrics for investigating the role of patient navigation in improving quality of care. For example, quality metrics proposed for breast and colorectal cancer include: receipt of radiation therapy after breast-conserving surgery; receipt of adjuvant chemotherapy for stages II and III breast cancer; and receipt of adjuvant chemotherapy and radiation therapy as clinically appropriate for colorectal cancer.\textsuperscript{41-44} However, investigators have documented that certain racial/ethnic and low-income subpopulations are less likely to receive appropriate adjuvant radiation therapy after breast-conserving therapy,\textsuperscript{45} appropriate adjuvant chemotherapy for breast cancer,\textsuperscript{46} or appropriate adjuvant radiation therapy and chemotherapy for rectal cancer,\textsuperscript{47} and are more likely to have unmet symptom-management needs after treatment for breast cancer.\textsuperscript{48} Some of these studies were done in
Medicare-covered populations, so ability to pay cannot alone explain the inequities. Other potential access and treatment-adherence barriers that contribute to disparate provision of cancer care can be identified and potentially addressed by patient navigators as this is their purpose on the health care team.\(^1\) Tracking rates of guideline-concordant treatment and treatment adherence among navigated patients with certain cancers can be used to compare with historical controls or published rates to gauge the impact of a patient navigation intervention. Table 2 describes some potential metrics, based on recommended quality measures or guideline recommendations, to be tracked in navigated cohorts. Tracking of treatment adherence and interruptions has obvious implications for cancer care quality in that completion of a recommended regimen with few if any interruptions is more likely to be effective than treatment that is either incomplete or unnecessarily protracted due to logistical or non-medical reasons. For example, survival and control rates for some cancers, such as head and neck cancer and cervical cancer, are adversely impacted by radiation therapy interruptions.\(^49\),\(^51\) Patient navigators may be able to assist patients at risk of missing treatments due to access barriers, and metrics that evaluate interruptions and adherence provide insight into the role of patient navigation in improving cancer care quality.

Metrics regarding care coordination should be recorded and may serve as indicators of high-quality care. Specifically, records should be kept regarding whether primary care providers were identified, notified, and provided with a record of cancer treatment, such as through treatment summaries and care plans. Another potential metric that may indicate well-integrated care would be whether a patient’s management was discussed at a multidisciplinary conference.\(^32\) It should be noted whether adjuvant therapies were coordinated and appropriately timed in relevant cancers such as cervical, head and neck, or colorectal malignancies, at which chemotherapy and radiation start dates must be coordinated to optimize cancer care. Other metrics of interest and that are reflective of the patient-centered medical home model of care\(^53\) include monitoring the receipt of ancillary care services (eg, nutrition, social work, physical therapy) and medications and devices.

**Patient-reported metrics on care processes**

Satisfaction with health care received and patient-provider interactions are important general measures of cancer care. These patient-reported measures are often best assessed through validated instruments specific to these conceptual domains of care-quality assessment. Other specific patient-reported measures include pain
# Table 2. Core Metrics for Patient Navigation During Cancer Treatment

<table>
<thead>
<tr>
<th>Domains</th>
<th>Metrics</th>
<th>Notes on Operationalization of These Metrics</th>
<th>Quality/Benchmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goals of treatment</td>
<td>Paliative vs curative intent established</td>
<td>Provides data regarding possible goals for treatment that can be tracked as appropriate depending on disease status</td>
<td>Institutional-specific baseline*</td>
</tr>
<tr>
<td>Timeliness of care</td>
<td>Consult with oncology provider to first treatment date</td>
<td>Calculated as time in days between dates</td>
<td>Institutional-specific baseline</td>
</tr>
<tr>
<td></td>
<td>Time intervals between modalities (surgery to radiation, chemotherapy to surgery/radiation)</td>
<td>Calculated as time in days between dates</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Concordant start dates of radiation therapy and chemotherapy (when indicated/relevant)</td>
<td>Yes/no</td>
<td></td>
</tr>
<tr>
<td>Treatment adherence</td>
<td>Recommended surgery performed, guideline adherent</td>
<td>Yes/no</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Recommended chemotherapy received/completed</td>
<td>Yes/no</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Recommended radiation therapy received/completed</td>
<td>Yes/no</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Radiation therapy treatment days missed</td>
<td>Not including weekends/holidays</td>
<td>Institutional-specific baseline</td>
</tr>
<tr>
<td></td>
<td>Reasons for radiation therapy days missed</td>
<td>Particular attention to reasons not related to medical indications for omission of radiation treatment; data can be used to tailor barrier tracking and resolution</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chemotherapy cycles missed/omitted</td>
<td>Particular attention to whether reasons outside of medical indications resulted in cycles omitted; data can be used to tailor barrier tracking and resolution</td>
<td></td>
</tr>
<tr>
<td>Guideline adherence</td>
<td>On-treatment appointments missed</td>
<td>Yes/no</td>
<td>Institutional-specific baseline</td>
</tr>
<tr>
<td></td>
<td>Staging workup/tests completed</td>
<td></td>
<td>Benchmark should be 100%; can compare with institutional-specific baseline</td>
</tr>
<tr>
<td></td>
<td>BCT vs mastectomy for BCT-eligible breast cancer patients</td>
<td>Especially in settings/populations where barriers exist as to receipt of a course of radiation therapy as part of BCT</td>
<td>Institutional-specific baseline</td>
</tr>
<tr>
<td></td>
<td>Receipt of adjuvant chemotherapy for colorectal cancer patients (when appropriate)</td>
<td>Yes/no</td>
<td>Institutional-specific baseline</td>
</tr>
<tr>
<td></td>
<td>Receipt of adjuvant hormone therapy when appropriate (breast, prostate cancer patients)</td>
<td>Yes/no</td>
<td>Institutional-specific baseline</td>
</tr>
<tr>
<td>Health services utilization</td>
<td>Standard of care delivered, NCCN guideline adherence</td>
<td>For programs where navigators have clinical knowledge/training</td>
<td>Institutional-specific baseline</td>
</tr>
<tr>
<td></td>
<td>Unplanned hospitalizations (preventable; eg, noninfectious)</td>
<td>For analyses, can adjust for reasons for hospitalization when comparing to a control cohort</td>
<td>Institutional-specific baseline</td>
</tr>
<tr>
<td></td>
<td>ER visits</td>
<td></td>
<td>Institutional-specific baseline</td>
</tr>
<tr>
<td></td>
<td>Trial availability</td>
<td>Yes/no</td>
<td></td>
</tr>
<tr>
<td>Clinical trial participation</td>
<td>Trial participation</td>
<td>Yes/no</td>
<td></td>
</tr>
</tbody>
</table>

(Continued)
management, symptom inventories, trust, anxiety, and depression scales. Table 3 includes some examples of scales for measuring patient-reported outcomes for various domains relevant to patient navigation in cancer care.

### Patient navigation through survivorship and end-of-life care

Some patient navigation programs may include navigation related to the quality of life during treatment and survivorship, as well as issues related to end-of-life care. A thorough review of patient navigation in end-of-life care is provided by Hauser et al on pages 000-000, this issue, and a similar article discussing patient navigation during survivorship care is provided by Pratt-Chapman et al on pages 000-000, this issue.

## DISCUSSION

Data collection to measure the impact of patient navigation on cancer care presents inherent challenges to any resource-intensive research and service effort. In some programs, separate data collection and data management staff may not be
available to record metrics. In some programs, the patient
navigator will be the individual collecting data, especially
patient-reported outcomes data such as symptoms data,
quality of life data, or barrier information, because it will be
the navigator's role to help assist with identified barriers and
issues. Therefore, when choosing the number and extent of
metrics to be tracked, there is a need for balance between
which data that navigators/staff can reasonably collect while
maintaining the ability to render needed services to popula-
tions with multiple barriers. Another potential consider-
ations in determining appropriate metrics for patient
navigation programs arises in the arena of measuring guide-
line adherence metrics in navigated populations. Patient
navigators are not trained medical professionals, and there is
an inherent limit on the ability of the patient navigator to
direct physician behavior in terms of guideline recom-
endation practices, i.e., it is not the patient navigator's role to
police physician communication and recommendations. In
some programs, patient navigators may be more integrated
into the medical team and have more agency with others
with respect to medical treatment planning decisions
Decisions to use guideline adherence and corresponding analysis
of those metrics must be contextualized to reflect the defini-
tion of patient navigation within the program being eval-
uated. Some programs may seek to develop measures of the
extent to which navigator efforts succeed in empowering
patients to be more effective and informed advocates for
their own cancer care needs and preferences.

Finally, patient navigation among many vulnerable
populations involves culturally tailored programs to fit the
needs of patients who often have many access barriers. This
makes comparison of data collected in these populations
logistically and statistically challenging. Specifically, to
whom do you compare the metrics in the navigated popula-
tion? The gold standard for comparison of outcomes when
a new care innovation is introduced is a randomized trial.
However, in many populations it may not be feasible or eth-
cial to offer a control arm of non-navigated patients because
of concerns among patients, communities, or staff that nav-
gitation services constitute resources or assistance that should
not be withheld simply to allow for research goals to be
met. In such cases, comparison with historical controls may
be an acceptable option. However, not all health care sys-
tems offer data on historical controls. Use of national regis-
try or survey data for various health indicators, disparities,
or care utilization rates may offer rough guides for compari-
son. However, population-based data may underrepresent
local care quality inequities or deficiencies, especially for
some racial/ethnic or socioeconomic subpopulations (such
as those often served by patient navigation programs), and
thus might also underestimate the impact that patient navig-
ation may have on selected metrics. Lastly, analyses of
reported outcomes must take into account cultural, fi-
nancial, familial, and educational aspects (e.g., through
adjusted modeling of results when possible) of the popula-
tion in which the navigation intervention is being studied.

Conclusions
Patient navigation programs are becoming increasingly
widespread as a health-access, barrier-focused intervention
to overcome disparate cancer-related health outcomes
among certain vulnerable populations, as well as for
patients in general. More evidence is needed to establish
that patient navigation consistently improves outcomes and
quality of cancer care delivery. Changes planned
under federal health care reform in reimbursement and
coverage make it even more important to measure the
quality of care provided to minority and low-income popu-
lations and to identify methods to better deliver care to
these populations. Therefore, there is heightened need to
identify metrics to elucidate the role, if any, that patient
navigation may play in improving cancer-related health
care delivery, especially for vulnerable populations.

Core metrics for evaluating patient navigation during
cancer diagnosis and treatment should include those that
are likely to be impacted by the patient navigation interac-
tion and reflect improved access to cancer care, as well as
the provision and completion of uninterrupted treatment.
Furthermore, metrics that document reduction in prevent-
able hospitalizations and emergency room visits are also
desirable. These metrics will provide the most guidance as
to the value that patient navigation may add to the provi-
sion of high-quality care for all patients with cancer.

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