

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 these 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.^{3-7,10,13} 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 (eg, 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.¹⁴ 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,^{15,16} 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.¹⁴ A 2003 report from this effort published by Oluwole et al¹⁷ 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 al¹⁸ 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 model¹⁴ 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 al¹⁹ 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 al²⁰ reported shorter times to diagnostic resolution among minority women in urban New

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 al²⁰ 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 al²⁵ 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 (eg, 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 (eg, 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 (eg, 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.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,⁴⁵ appropriate adjuvant chemotherapy for breast cancer,⁴⁶ or appropriate adjuvant radiation therapy and chemotherapy for rectal cancer,⁴⁷ and are more likely to have unmet symptom-management needs after treatment for breast cancer.⁴⁸ Some of these studies were done in

Table 1. Core Metrics for Patient Navigation During Diagnosis and Early Cancer Management

Domains	Metrics	Notes on Operationalization of These Metrics	Quality/Benchmark
Diagnostic resolution	Date of abnormal screening test Date of abnormal test or symptom (if not screen detected) Date of pathologic diagnosis (biopsy date in most cases) Date of pathology reading Date of notification of the patient of diagnosis Percent diagnostic resolution	Percent of patients with diagnostic resolution at 30, 60, 120 days	Institutional-specific baseline ^a
Timeliness of care	Interval from symptom to provider evaluation (if not screen detected) Screening test to diagnostic resolution Diagnostic confirmation to patient notification Diagnostic confirmation to consult with oncology specialist Diagnosis date to first treatment date Percent with treatment initiation	Calculated as time in days between dates Percent of patients initiated on treatment within 30, 60, 90 days	Institutional-specific baseline Institutional-specific baseline Institutional-specific baseline Institutional-specific baseline Institutional-specific baseline Institutional-specific baseline
Patient education	Cancer care education provided to the patient	Yes/no	Institutional-specific baseline
Continuity of care	Primary care provider notification/records sharing Lost to follow-up	Yes/no Yes/no	Institutional-specific baseline Institutional-specific baseline

^a Institutional-specific baseline can be determined from review of records for historic cohort with preference for a race- and sex-matched cohort whenever possible.

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.⁵² 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 care⁵³ 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

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

(Continued)

Table 2. (Continued)

Domains	Metrics	Notes on Operationalization of These Metrics	Quality/Benchmark
			not available, rates published in the literature for similar populations can be used for comparison
Care coordination	Reason for non-participation in clinical trial if offered/patient eligible	Data can be used for barrier tracking and resolution	
	Integration of adjuvant therapies where appropriate	Yes/no	Institutional-specific baseline; benchmark goal of 100%
	Ancillary services recommended/received (eg, nutrition, social work, physical therapy)	Yes/no	Institutional-specific baseline
Clinical outcomes	Medication and devices prescribed/received	Yes/no	Institutional-specific baseline; benchmark goal of 100%
	Stage at presentation		Institutional-specific baseline; when institutional baseline is not available, rates published in the literature for similar populations with same cancer subtype can be used for comparison
	Date of last follow-up	Needed for calculation of survival and recurrence outcomes	
	Survival data Recurrence data		Institutional-specific baseline Institutional-specific baseline

Abbreviations: BCT, breast-conservation therapy; ER, emergency room; NCCN, National Comprehensive Cancer Network; RT, radiation therapy.

^aInstitutional-specific baseline can be determined from review of records for historic cohort with preference for a cancer subtype-, race-, and sex-matched cohort whenever possible.

Table 3. Patient-Reported Outcomes Metrics

Domain	Scale	Description	Status/Notes
Patient satisfaction with cancer-related care	CAPHS, cancer supplement	Focuses on follow-up for cancer; available in software package	Under development
Patient satisfaction with navigation	PSN-Y	Focuses specifically on navigation; available in software package	Validated; awaiting publication
Functional health status	FACIT/FACT	Strong psychometrically; available in software package	Sensitivity to navigation
Functional health status and symptoms burden	PROMIS	Cognitively tested, well validated, computer assisted; available online; available in software package	
Symptoms	FACIT/symptoms	Strong psychometrically; available in software package	
Coping skills	MOCS	Confidence in handling issues; validated	
Comorbidity	Charlson Comorbidity Index	Widely used; validated	

Abbreviations: CAPHS, Consumer Assessment of Healthcare Providers and Systems; FACIT, Functional Assessment of Chronic Illness Therapy; FACT, Functional Assessment of Cancer Therapy; MOCS, measure of current status; PROMIS, patient reported outcomes measurement information system; PSN I, patient satisfaction with interpersonal relationship with navigator measure.

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 populations with multiple barriers. Another potential consideration in determining appropriate metrics for patient navigation programs arises in the arena of measuring guideline 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 recommendation practices, ie, 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 than 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 definition of patient navigation within the program being evaluated. 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 population? 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 ethical to offer a control arm of non-navigated patients because of concerns among patients, communities, or staff that navigation 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 systems offer data on historical controls. Use of national registry or survey data for various health indicators, disparities, or care utilization rates may offer rough guides for comparison. 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 navigation may have on selected metrics. Lastly, analyses of reported outcomes must take into consideration cultural, financial, familial, and educational aspects (eg, through adjusted modeling of results when possible) of the population 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 populations 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 interaction and reflect improved access to cancer care, as well as the provision and completion of uninterrupted treatment. Furthermore, metrics that document reduction in preventable 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 provision of high-quality care for all patients with cancer.

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REFERENCES

1. Dohan D, Schrag D. Using navigators to improve care of underserved patients: current practices and approaches. *Cancer*. 2005;104:848-55.

2. Smedley B, Stith A, Nelson A. Unequal treatment: confronting racial and ethnic disparities in health care. Washington, DC: National Academies Press; 2003.
3. Blackman DJ, Masi CM. Racial and ethnic disparities in breast cancer mortality: are we doing enough to address the root causes? *J Clin Oncol*. 2006;24:2170-2178.
4. Bruner DW, Jones M, Buchanan D, Russo J. Reducing cancer disparities for minorities: a multidisciplinary research agenda to improve patient access to health systems, clinical trials, and effective cancer therapy. *J Clin Oncol*. 2006;24:2209-2215.
5. Doescher MP, Saver BG, Franks P, Fiscella K. Racial and ethnic disparities in perceptions of physician style and trust. *Arch Fam Med*. 2000;9:1156-1163.
6. Freeman HP. Poverty, culture, and social injustice: determinants of cancer disparities. *CA Cancer J Clin*. 2004;54:72-77.
7. Geiger H. Racial and ethnic disparities in diagnosis and treatment: a review of the evidence and consideration of causes. In: Smedley B, Smith A, Nelson A, eds. *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*. Washington, DC: National Academies Press; 2003:415-454.
8. Glanz K, Croyle RT, Chollette VY, Pinn VW. Cancer-related health disparities in women. *Am J Public Health*. 2003;93:292-298.
9. Guadagnolo BA, Cina K, Helbig P, et al. Assessing cancer stage and screening disparities among Native American cancer patients. *Public Health Rep*. 2009;124:79-89.
10. Shavers VL, Brown ML. Racial and ethnic disparities in the receipt of cancer treatment. *J Natl Cancer Inst*. 2002;94:334-357.
11. Ward E, Jemal A, Cokkinides V, et al. Cancer disparities by race/ethnicity and socioeconomic status. *CA Cancer J Clin*. 2004;54:78-93.
12. America's Affordable Health Choices Act of 2009, HR 3200, 111th Cong (2009-2010).
13. Guadagnolo BA, Cina K, Helbig P, et al. Medical mistrust and less satisfaction with health care among Native Americans presenting for cancer treatment. *J Health Care Poor Underserved*. 2009;20:210-226.
14. Freeman HP, Muth BJ, Kerner JF. Expanding access to cancer screening and clinical follow-up among the medically underserved. *Cancer Pract*. 1995;3:19-30.
15. Wells KJ, Battaglia TA, Dudley DJ, et al. Patient navigation: state of the art or is it science? *Cancer*. 2008;113:1999-2010.
16. Freund KM, Battaglia TA, Calhoun E, et al. National Cancer Institute Patient Navigation Research Program: methods, protocol, and measures. *Cancer*. 2008;113:3391-3399.
17. Oluwole SF, Ali AO, Adu A, et al. Impact of a cancer screening program on breast cancer stage at diagnosis in a medically underserved urban community. *J Am Coll Surg*. 2003;196:180-188.
18. Gabram SG, Lund MJ, Gardner J, et al. Effects of an outreach and internal navigation program on breast cancer diagnosis in an urban cancer center with a large African-American population. *Cancer*. 2008;113:602-607.
19. Battaglia TA, Roloff K, Posner MA, Freund KM. Improving follow-up to abnormal breast cancer screening in an urban population. A patient navigation intervention. *Cancer*. 2007;109(2 Suppl):359-367.
20. Ferrante JM, Chen PH, Kim S. The effect of patient navigation on time to diagnosis, anxiety, and satisfaction in urban minority women with abnormal mammograms: a randomized controlled trial. *J Urban Health*. 2008;85:114-124.
21. Department of Health and Human Services Centers for Disease Control and Prevention. National Breast and Cervical Cancer Early Detection Program publications: Overview of the program management chapter of the NBCCEDP policies and procedures manual. Available at: <http://www.cdc.gov/cancer/dcpc/publications/nbccedp.htm>. Accessed May 24, 2010.
22. Department of Health and Human Services Centers for Disease Control and Prevention. National Breast and Cervical Cancer Early Detection Program: screening program data. Available at: <http://www.cdc.gov/cancer/nbccedp/data/>. Accessed May 24, 2010.
23. Psooy BJ, Schreuer D, Borgaonkar J, Caines JS. Patient navigation: improving timeliness in the diagnosis of breast abnormalities. *Can Assoc Radiol J*. 2004;55:145-150.
24. Schwaderer KA, Proctor JW, Martz EF, Slack RJ, Ricci E. Evaluation of patient navigation in a community radiation oncology center involved in disparities studies: a time-to-completion-of-treatment study. *J Oncol Pract*. 2008;4:220-224.
25. Fillion L, de Serres M, Cook S, Goupil RL, Bairati I, Doll R. Professional patient navigation in head and neck cancer. *Semin Oncol Nurs*. 2009;25:212-221.
26. Ell K, Vourlekis B, Xie B, et al. Cancer treatment adherence among low-income women with breast or gynecologic cancer: a randomized controlled trial of patient navigation. *Cancer*. 2009;115:4606-4615.
27. Peteret D, Molloy K, Reiner M, et al. Establishing a patient navigator program to reduce cancer disparities in the American Indian communities of western South Dakota: initial observations and results. *Cancer Control*. 2008;15:254-259.
28. Lin CJ, Schwaderer KA, Morgenlander KH, et al. Factors associated with patient navigators' time spent on reducing barriers to cancer treatment. *J Natl Med Assoc*. 2008;100:1290-1297.
29. Raich P, Valverde P, Thorland W, et al. The relationship between patient co-morbidities and perceived barriers in a group of underserved patients with cancer or at risk for cancer. Poster presented at: 30th Annual Meeting of the Society of Behavioral Medicine; April 22-25, 2009; Montreal, Canada.
30. Sateren WB, Trimble EL, Abrams J, et al. How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. *J Clin Oncol*. 2002;20:2109-2117.
31. Maurer LH, Davis T, Hammond S, Smith E, West P, Doolittle M. Clinical trials in a rural population: professional education aspects. *J Cancer Educ*. 2001;16:89-92.
32. Murthy VH, Krumholz HM, Gross CP. Participation in cancer clinical trials: race-, sex-, and age-based disparities. *JAMA*. 2004;291:2720-2726.
33. Swanson GM, Bailar JC 3rd. Selection and description of cancer clinical trials participants—science or happenstance? *Cancer*. 2002;95:950-959.
34. Baquet CR, Commiskey P, Daniel Mullins C, Mishra SI. Recruitment and participation in clinical trials: socio-demographic, rural/urban, and health care access predictors. *Cancer Detect Prev*. 2006;30:24-33.
35. Stewart JH, Bertoni AG, Staten JL, Levine EA, Gross CP. Participation in surgical oncology clinical trials: gender-, race/ethnicity-, and age-based disparities. *Ann Surg Oncol*. 2007;14:3328-3334.
36. Gross CP, Filardo G, Mayne ST, Krumholz HM. The impact of socioeconomic status and race on trial

- participation for older women with breast cancer. *Cancer*. 2005;103:483-491.
37. Peterit DG, Rogers D, Govern F, et al. Increasing access to clinical cancer trials and emerging technologies for minority populations: the Native American Project. *J Clin Oncol*. 2004;22:4452-4455.
 38. Espey DK, Wu XC, Swan J, et al. Annual report to the nation on the status of cancer, 1975-2004, featuring cancer in American Indians and Alaska Natives. *Cancer*. 2007;110:2119-2152.
 39. Guadagnolo BA, Peterit DG, Helbig P, et al. Involving American Indians and medically underserved rural populations in cancer clinical trials. *Clin Trials*. 2009;6:610-617.
 40. Rochon PA, Mashari A, Cohen A, et al. The inclusion of minority groups in clinical trials: problems of under representation and under reporting of data. *Account Res*. 2004;11:215-223.
 41. Schneider EC, Malin JL, Kahn KL, Emanuel EJ, Epstein AM. Developing a system to assess the quality of cancer care: ASCO's national initiative on cancer care quality. *J Clin Oncol*. 2004;22:2985-2991.
 42. Malin JL, Schneider EC, Epstein AM, Adams J, Emanuel EJ, Kahn KL. Results of the National Initiative for Cancer Care Quality: how can we improve the quality of cancer care in the United States? *J Clin Oncol*. 2006;24:626-634.
 43. Prosnitz RG, Patwardhan MB, Samsa GP, et al. Quality measures for the use of adjuvant chemotherapy and radiation therapy in patients with colorectal cancer: a systematic review. *Cancer*. 2006;107:2352-2360.
 44. Patwardhan MB, Samsa GP, McCrory DC, et al. Cancer care quality measures: diagnosis and treatment of colorectal cancer. *Evid Rep Technol Assess (Full Rep)*. 2006;138:1-116.
 45. Smith GL, Shih YC, Xu Y, et al. Racial disparities in the use of radiotherapy after breast-conserving surgery: a national Medicare study. *Cancer*. 2010;116:734-741.
 46. Bhargava A, Du XL. Racial and socioeconomic disparities in adjuvant chemotherapy for older women with lymph node-positive, operable breast cancer. *Cancer*. 2009;115:2999-3008.
 47. Morris AM, Billingsley KG, Hayanga AJ, Matthews B, Baldwin LM, Birkmeyer JD. Residual treatment disparities after oncology referral for rectal cancer. *J Natl Cancer Inst*. 2008;100:738-744.
 48. Yoon J, Malin JL, Tisnado DM, et al. Symptom management after breast cancer treatment: is it influenced by patient characteristics? *Breast Cancer Res Treat*. 2008;108:69-77.
 49. Peterit DG, Sarkaria JN, Chappell R, et al. The adverse effect of treatment prolongation in cervical carcinoma. *Int J Radiat Oncol Biol Phys*. 1995;32:1301-1307.
 50. McCloskey SA, Jaggernauth W, Rigual NR, et al. Radiation treatment interruptions greater than one week and low hemoglobin levels (12 g/dL) are predictors of local regional failure after definitive concurrent chemotherapy and intensity-modulated radiation therapy for squamous cell carcinoma of the head and neck. *Am J Clin Oncol*. 2009;32:587-591.
 51. Rades D, Stoeckl M, Kazic N, et al. Locally advanced stage IV squamous cell carcinoma of the head and neck: impact of pre-radiotherapy hemoglobin level and interruptions during radiotherapy. *Int J Radiat Oncol Biol Phys*. 2008;70:1108-1114.
 52. Rose C, Stovall E, Ganz PA, Desch C, Hewitt M. Cancer Quality Alliance: blueprint for a better cancer care system. *CA Cancer J Clin*. 2008;58:266-292.
 53. American Academy of Family Physicians. Joint principles of a patient-centered medical home released by organizations representing more than 300,000 physicians. Available at: <http://www.aafp.org/online/en/home/media/releases/2007/20070305pressrelease0.html> Accessed June 3, 2010.