

Rapid Evidence Product

Patient Navigation Models for Lung Cancer



Patient Navigation Models for Lung Cancer

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The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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Preface

Recognized for excellence in conducting comprehensive systematic reviews, the Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center (EPC) Program is expanding its portfolio to include Rapid Evidence Products. The program has begun to develop a range of Rapid Evidence Products to assist end-users in making specific decisions in a limited timeframe. The Scientific Resource Center (SRC) supports the activities of the EPC program, including piloting and producing Rapid Evidence Products.

In 2014, AHRQ EPCs produced a taxonomy of rapid evidence products produced by leading organizations around the world.^{a-c} This taxonomy now informs the development of Rapid Evidence Products. Based on level of synthesis, the report classified products as inventories, rapid responses, and rapid reviews. On one end of the spectrum, evidence inventories offer an assessment of the quantity and type of evidence without presenting results. On the other end, rapid reviews adapt and streamline traditional systematic review methods to provide a limited evidence synthesis.

To shorten timelines, reviewers must make strategic choices about which processes to abridge. Common adaptations to provide rapid evidence include: narrowly focusing questions, limiting the number of databases searched and/or modifying search strategies, using a single reviewer and/or abstractor with a second to provide verification, and restricting to studies published in the English language. However, the adaptations made for expediency may limit the certainty and generalizability of the findings from the review, particularly in areas with a large literature base. Transparent reporting of the methods used, the resulting limitations of the evidence synthesis, and the strength of evidence of included studies are extremely important. While tradeoffs will likely differ for each topic, they are described so readers can adjudicate the limitations of the findings and conclusions of the review.

While rapid evidence products are often sufficient for decisionmaking on their own, at other times they can uncover a large complex literature base that encourages end-users to seek a full review. Even in this instance, the rapid evidence review can provide a map of the evidence and assist decisionmakers in targeting resources to areas of highest interest and greatest potential value.

AHRQ expects that these rapid evidence products will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program.

If you have comments on this report, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

a. Hartling L, Guise J-M, Hempel S, et al. EPC methods: AHRQ End-user perspectives of rapid reviews. Rockville (MD): 2016. <https://www.ncbi.nlm.nih.gov/pubmed/27195347>

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c. Hartling L, Guise J-M, Hempel S, et al. Fit for purpose: perspectives on rapid reviews from end-user interviews. *Systematic Reviews*. 2017;6:32. doi: 10.1186/s13643-017-0425-7. PMID: PMC5316162.

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Patient Navigation Models for Lung Cancer

Structured Abstract

Background. Multiple patient navigation programs have been developed to address barriers to care (e.g., financial, logistical, and communication) across the cancer care continuum, but health systems are unsure which components of patient navigation are important and how to implement them. In addition the effectiveness of patient navigation programs to improve lung cancer outcomes is uncertain.

Purpose. To review recent literature on components of patient navigation programs addressing all types of cancer, the effectiveness of patient navigation programs on lung cancer outcomes, and the variable effectiveness of patient navigation programs on lung cancer outcomes based on patient characteristics. This report was developed to address the diverse research needs of a stakeholder group interested in the needs of people with lung cancer.

Methods. We searched for systematic reviews from 2015 to 2018 in PubMed®, CINAHL®, Cochrane Database of Systematic Reviews, Veterans Affairs Evidence-based Synthesis Program, Agency for Healthcare Research and Quality Effective Health Care Program, PubMed Health, and PROSPERO. We also searched for primary studies from 2013 to 2018 in PubMed and CINAHL. We extracted data from systematic reviews and primary studies, and synthesized results.

Findings. We identified four systematic reviews and six primary studies that focused primarily on breast, cervical, prostate, and colorectal cancer. Navigators' backgrounds varied from lay people to health care professionals, and training ranged from a few to several hundred hours. Navigation programs were both individual and team based, were delivered in diverse health care settings, and had more clearly defined entry criteria than exit criteria. Navigators performed multiple diverse services, including assisting patients to overcome health care system barriers, maintaining resource networks, and promotion of patient engagement. Only two completed studies evaluated the effectiveness of lung cancer patient navigation programs. One randomized clinical trial found that navigated patients were more likely to receive a screening chest computed tomography, and one observational study found that navigation was associated with increased satisfaction with care. No completed studies analyzed the effectiveness of lung cancer patient navigation programs based on patient characteristics.

Implications. Patient navigation programs for all cancer types are quite diverse with regard to navigators' characteristics and program structure. Future research studies should describe components in sufficient detail to facilitate implementation and determine which program is most effective for which health system. Lung cancer patients face unique challenges in managing their care, so additional studies on which components are important for lung cancer may be warranted.

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Appendix

Appendix A. Search Strategies

Background

Nearly 1.7 million new diagnoses of cancer are expected in the United States in 2018.⁴ Lung cancer will comprise 13 percent of these diagnoses and accounts for a quarter of cancer-related deaths.⁴ Although considerable progress had been made in the previous 20 years, the most recent 5-year survival rate for lung cancer remains under 20 percent.⁴

Patient navigation models have been adopted due to the complexity of treatment and necessary coordination of medical interventions throughout the continuum of cancer care. Patient navigation began in the United States in 1990 with a surgical oncologist, Harold Freeman, who wanted to address the disparities in breast cancer outcomes among African American women in Harlem.⁵ The primary aims of patient navigation are to eliminate financial, logistic, or communication barriers to the receipt of medical services by providing education and resources to patients.⁶ In 2005 the Patient Navigator and Chronic Disease Prevention Act was signed into law which authorized a demonstration grant program to provide patient navigator services to reduce barriers and improve health care outcomes.⁷ Additional guiding principles of patient navigation include a patient-centric delivery model, clear scope of practice, defined entry and exit criteria for navigation, and having a coordinator for the navigation system.⁵ Patient navigation models have been shown to improve cancer and patient-related outcomes including decreased time between diagnosis and treatment, increased adherence to care, and improved quality of life.⁶

Currently, there is no consensus on which patient navigation models are most effective. These models vary according to a number of factors including education, occupational background, and cultural competence of the individual employed as the patient navigator. A recent position statement by the Oncology Nursing Society states that effective navigation models use a variety of health care and non-health care personnel.⁶ However, there are very few studies directly comparing different models, and evidence has yet to be synthesized regarding relative effectiveness.⁸

History of Nomination

Patient navigation models for lung cancer was nominated to the Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center program by the Patient Centered Outcomes Research Institute (PCORI)-funded Stakeholder Engagement in Question Development (SEED) project, based at Virginia Commonwealth University. The SEED project brought together various stakeholders (patients, providers, and health systems) to identify high priority, patient-important topics for research. The nominator is interested in gaining a better understanding of the main components of patient navigation interventions, as well as whether these interventions positively impact lung cancer outcomes, in order to inform a broad research and policy agenda.

Questions

The questions for this nomination are:

1. What are the main components of patient navigation interventions for screening, diagnosis, treatment, and surveillance of any type of cancer?
 - a. Navigator characteristics (background [e.g., Registered Nurse, lay person], training, cultural competence)

- b. Team versus individual
 - c. Setting (single site versus health system)
 - d. Types of services delivered
 - e. Patient entry and exit criteria
2. What is the effectiveness of patient navigation interventions for improving lung cancer outcomes across the spectrum of care?
- a. Screening
 - b. Diagnosis
 - c. Treatment
 - d. Surveillance
3. Does the effectiveness of patient navigation interventions for improving lung cancer outcomes vary by geographic location (rural, suburban, urban), socioeconomic status, literacy, or race/ethnicity?

Methods

We conducted a literature scan and brief evidence synthesis in order to address the needs of our nominator. We first searched for systematic reviews (SRs) in PubMed and the Cumulative Index of Nursing and Allied Health Library (CINAHL) as well as Cochrane Database of Systematic Reviews, Veterans Affairs (VA) Evidence-based Synthesis Program, AHRQ Effective Health Care Program, PubMed Health, and PROSPERO from the past three years. We then searched for primary studies in PubMed and CINAHL from the past five years. We conducted a three-year SR search and a five-year primary study search in order to capture the most relevant and recent literature. Search strategies are available in Appendix A.

For Question 1, we included studies that explicitly described models for patient navigation or described services delivered as part of patient navigation. For Questions 2-3 we included studies that examined the effectiveness of patient navigation for improving lung cancer outcomes. For all questions, we only included quantitative studies.

We also searched for guidelines, grey literature, and clinical trials on patient navigation for cancer care. We spoke to a topic expert on patient navigation and looked at resources recommended by him.

To define the inclusion criteria for the questions, we specify the population, interventions, comparators, outcomes, and setting (PICOS) of interest (Table 1).

Table 1. Questions and PICOS

Questions	1. What are the main components of patient navigation interventions for screening, diagnosis, treatment, and surveillance of any type of cancer?	2. What is the effectiveness of patient navigation interventions for improving lung cancer outcomes across the spectrum of care?	3. Does the effectiveness of patient navigation interventions for improving lung cancer outcomes vary by geographic location (rural, suburban, urban), socioeconomic status, literacy, or race/ethnicity?
Population	Adults being screened for, at risk of, or diagnosed with any type of cancer	Adults being screened for, at risk of, or diagnosed with lung cancer	Adults being screened for, at risk of, or diagnosed with lung cancer
Interventions	Any patient navigation intervention	Any patient navigation intervention	Any patient navigation intervention
Comparators	N/A	Any comparator (including pre-post or separate control group)	Any comparator (including pre-post or separate control group)
Outcomes	N/A	<ul style="list-style-type: none"> • Rate of screening • Time to diagnosis • Time to treatment • Symptom management • Quality of life • Patient satisfaction • Mental health (e.g., depression, anxiety) • Survival • Harms 	<ul style="list-style-type: none"> • Rate of screening • Time to diagnosis • Time to treatment • Symptom management • Quality of life • Patient satisfaction • Mental health (e.g., depression, anxiety) • Survival • Harms
Setting	N/A	Community and health system	Community and health system

Abbreviations: N/A=not applicable; PICOS=Population, intervention, comparator, outcome, setting

Results

Question 1. What are the main components of patient navigation interventions for screening, diagnosis, treatment, and surveillance of any type of cancer?

Systematic Reviews and Primary Studies

We identified four SRs⁹⁻¹² that examined patient navigation across the cancer care continuum, including screening,^{9,10} diagnosis,^{11,12} and treatment.^{11,12} The main cancer types represented included breast,¹⁰⁻¹² colorectal,⁹⁻¹² prostate,¹¹ and cervical cancer.^{10,11} One SR included patients with a wide range of cancer types (including lung cancer).¹² Patient navigation programs targeted vulnerable patient groups, including those who are low-income,¹⁰ medically underserved,¹¹ part of racial/ethnic minority groups,^{9,10} or older.¹² Table 2 provides additional detail on these reviews.

Our search for primary studies identified six¹³⁻¹⁸ that described components of the Patient Navigation Research Program (PNRP) sufficiently to address Question 1. We highlight PNRP-related studies because the PNRP represents the single largest study of patient navigation to date: 10 different patient navigation programs across the country focused on breast, cervical, colorectal, and prostate cancers from 2005 to 2010.¹⁹ Three of our identified studies¹³⁻¹⁵ focused on seven of the PNRP sites, two^{16,17} focused on a scaled-up county-wide adaptation of the

PNRP, and one study¹⁸ examined navigators' work through field observations at nine PNRP sites.

Table 2. Systematic reviews relevant to Question 1

Study Information Author, Year <ul style="list-style-type: none"> • # Articles • Navigation Focus • Cancer Type 	Navigator Characteristics	Team Versus Individual	Setting (Single Site Versus Health System)	Types of Services Delivered	Patient Entry and Exit Criteria
Bush 2017 ¹¹ <ul style="list-style-type: none"> • SR of 16 articles • Diagnosis and treatment • Breast, cervical, colorectal, or prostate cancer 	Nine studies of lay navigators, four studies of nurses with oncology experience, seven studies of a team approach (lay person and a nurse or MSW). Some studies had bilingual navigators (English & Spanish).	Both individual and team	NR	<u>Diagnostic studies:</u> Structure of programs varied across studies; some used structured guide or assessment tools while other used logging system to record barriers or problems addressed during patient encounters. Common barriers included transportation, lack of insurance, coordination of health care appointments, language barriers, and general misunderstanding of the follow-up process. <u>Treatment studies:</u> NR	Diagnostic studies focused on medically underserved patients with abnormal cancer screening. Treatment studies focused on medically underserved patients diagnosed with cancer.
Domingo 2017 ⁶ <ul style="list-style-type: none"> • SR of eight articles • Screening • Colorectal cancer 	Professional or paraprofessional	NR	Federally qualified community health centers (FQHC)	Eight categories of navigation activities provided in studies including: <ul style="list-style-type: none"> • Screening education • Client reminders • Motivating/supporting patients • Scheduling appts • Translation assistance • Arranging transport • Ongoing barriers counseling • Teaching test instructions 	Minority FQHC clients

Study Information Author, Year <ul style="list-style-type: none"> • # Articles • Navigation Focus • Cancer Type 	Navigator Characteristics	Team Versus Individual	Setting (Single Site Versus Health System)	Types of Services Delivered	Patient Entry and Exit Criteria
Hou 2015 ⁷ <ul style="list-style-type: none"> • SR of 27 articles • Screening • Colorectal, cervical, and breast cancer 	Community-based navigators were recruited based on bilingual skills and length of residence in target community. Community and clinic-based navigators were culture/language concordant with patients. Length and intensity of navigator training ranged from 6-hour training to several hundred hours of programs.	NR	Community-based (15 studies in rural or urban areas, community-based service programs, local churches or academic institutions working with community advisory boards) vs. clinic/hospital-based (12 studies in primary care, hospitals, or health care orgs).	Roles and responsibilities: <ul style="list-style-type: none"> • Reaching out to patients via mail, phone, or face contacts • Up to 11 attempts or 2-3 weeks of calls were used in both settings. • Provide educational information • Host educational events • Provide barrier counseling • Share personal testimony • Provide logistic support • Serve as translator and advocate • Gather information on access to cancer care screenings Community navigators more likely to do face-to-face interactions, clinic-based navigators more likely to send out screening reminders or packages and educational materials.	Community-based navigators often identified racial/ethnic minority patients through community networks or churches. Clinic-based navigators often identified low income or mixed ethnic group patients through chart review, electronic client database, or referral by provider.

Study Information Author, Year <ul style="list-style-type: none"> • # Articles • Navigation Focus • Cancer Type 	Navigator Characteristics	Team Versus Individual	Setting (Single Site Versus Health System)	Types of Services Delivered	Patient Entry and Exit Criteria
Van Ee 2016 ⁹ <ul style="list-style-type: none"> • SR of 17 articles • Diagnosis and treatment • Breast, colorectal, or ovarian cancer or a range of cancer types (with lung as one type included) 	Patient navigation (PN) and patient activation (PA) primarily provided by nurses	Three PA interventions were delivered by an individual nurse or care manager, one PA intervention delivered by nurses with APNs available 24/7.	Individual cancer centers, VA medical centers, and a mix of community and public hospitals	Patient navigation models were not described in detail. Patient activation interventions focused on older adults aimed to improve at least one of the eight following care domains: <ul style="list-style-type: none"> • Timeliness of care • Health care utilization • Quality of life • Survival • Symptom and activity levels • Satisfaction with the intervention • Information and support related outcomes • Perception of provider's role Interventions ranged from transcription of encounter to phone contacts to home visits "Education, coordination, cognitive-behavioural strategies, clinical assessment and monitoring were among the strategies used to increase the self-efficacy of patients and the effectiveness of the care they received."	Older adults after the detection of a screening abnormality and before entering the palliative phase.

Abbreviations: APN=Advanced Practice Nurse; FQHC=Federally Qualified Health Center; MSW=Masters in Social Worker; NR=Not Reported; PA=Patient Activation; PN=Patient Navigation; SR=Systematic Review; VA=Veterans Affairs

Navigator Characteristics

Systematic Reviews

Patient navigation was delivered by both health care professionals⁹⁻¹² (including nurses^{10, 11} and social workers¹¹) and lay people.^{10, 11} The training provided to navigators was highly variable, with one SR¹⁰ describing a range from a single six-hour training session to several hundred hours of programs. Navigators were paired to patients in terms of culture¹⁰ and language.^{10, 11}

Primary Studies of the PNRP

Navigators were required to have a high school diploma or General Education Diploma (GED) at minimum.¹⁹ Education of navigators ranged from high school diploma^{13, 15} to masters level social¹⁵ work or public health.^{15, 17} About two-thirds of navigators had a college or graduate degree.¹⁸ Both lay and health care professionals (e.g., social workers^{13, 14}) delivered patient navigation. About half of navigators had additional professional training (e.g., nurse, social worker, medical assistant, radiation technologist, medical translation).¹⁸

Navigators had a combination of local instruction and PNRP biannual trainings and webinars on the role of navigators, cancer research, screening, culture and diversity, and removal of barriers.¹³ At one site, PNRP training was supplemented by project leaders observing navigators weekly.¹³ At the county-wide adaptation of the PNRP, navigators received 80 hours of on-the-job training (e.g., local resources, administration, case manager shadowing at the local health department, community partner training) in addition to the national PNRP trainings. Similar to the programs in the SRs, navigators were paired with patients by culture and language. One of the PNRPs included promotoras (lay community health workers who are members of the Hispanic community).¹⁴ Of note, navigators often had experience with cancer, as 14 percent were cancer survivors and 45 percent reported cancer in their family.¹⁸

Team Versus Individual

Systematic Reviews

Both individual and team-based interventions were described in two SRs^{9,11} while the other two SRs^{6,7} did not report this characteristic of navigator programs. Team-based interventions included pairing a lay person with a health care professional (such as a nurse or social worker) or pairing a nurse with an advanced practice nurse available to patients 24/7.⁹

Primary Studies of the PNRP

PNRP sites also described both individual and team-based navigator programs. The team-based interventions included pairing two lay people with two social workers.¹³ Another team approach paired a traditional navigator with a promotora (lay community health workers who are members of the Hispanic community) to specifically address cultural barriers of patients.¹⁴

Setting

Systematic Reviews

Navigation programs were delivered across diverse settings, including community (churches and community-based organizations),¹⁰ federally qualified health centers,⁹ individual cancer centers,¹² primary care clinics,¹⁰ and large medical centers.^{10, 12}

Primary Studies of the PNRP

The PNRP also delivered navigation in diverse settings including federally qualified health centers,¹⁵ ambulatory care centers,¹⁵ academic health systems,¹⁴ and treatment units¹⁸ (e.g., chemotherapy infusion units). Within each PNRP site, most navigators worked across multiple health care locations (2 to 12).¹⁸

Types of Services Provided

Systematic Reviews

Navigators provided a range of services, including discussion and help overcoming barriers⁹⁻¹¹ (including transportation^{9, 11} and translation⁹⁻¹¹), scheduling and coordinating appointments,^{9, 11} providing education and information on completing follow-up processes⁹⁻¹¹ (such as how to complete an at-home fecal occult blood test), as well as patient activation strategies^{9, 12} to promote patient engagement in care.

Primary Studies of the PNRP

While the PNRP had a common definition of patient navigation across sites, each site implemented navigation programs differently depending on their local staff and resources, and each site used a different study design. The PNRP defined patient navigation as support and guidance for vulnerable people with abnormal cancer screening or a cancer diagnosis, with the goal of overcoming barriers to timely, quality care in a culturally sensitive manner.¹⁹

The most comprehensive description of the myriad services delivered by patient navigators was found in a 2014 cluster analysis of field observations of 34 patient navigators at nine PNRP sites.¹⁸ Patient navigator tasks were divided into four main categories: navigating with individual patient by communication, supporting, instruction and coaching; facilitating care for patient via interaction with others; maintaining system of resources and relationships for patients; and information retrieval and medical record documentation. The analysis found six distinct patterns of work of patient navigators. Approximately 20 to 25 percent of navigators' total time was focused on one of three main work patterns: directly supporting patients through relatively long interactions (e.g., accompanying a patient to transfusion); interacting or coordinating with others for patients; or expediting care with patients, providers or clinical administrative staff. Interestingly, an additional one-quarter of their time was focused on tasks not interacting with patients: developing working relationships with community support agencies and medical record documentation.

Patient Entry and Exit Criteria

Systematic Reviews

In the SRs, overall patient entry criteria were clearer than exit criteria. For screening, navigators identified patients through patient databases or chart reviews^{9, 10} or community networks¹⁰ (such as churches). For diagnosis, navigation began after an abnormal screening test result.^{11, 12} For treatment, navigation began after a definitive diagnosis.^{11, 12} It was unclear when patients officially “exited” a navigation program, since most patients were only followed up to a given outcome (e.g., time to diagnostic resolution).

Primary Studies of the PNRP

Entry criteria were better described than exit criteria in the PNRP studies. For diagnosis, patients were referred to navigators after an abnormal screening test.¹⁴⁻¹⁶

Question 2. What is the effectiveness of patient navigation interventions for improving lung cancer outcomes across the spectrum of care?

Systematic Reviews

We did not identify any SRs examining the effectiveness of patient navigation interventions for improving lung cancer outcomes.

Primary Studies

We identified two completed studies (one randomized controlled trial [RCT]²⁰ and one mixed methods observational study²¹) and two ongoing studies^{22, 23} evaluating the effectiveness of navigation services on lung cancer outcomes. See Table 3.

Completed Studies

A U.S.-based RCT (n=1,200)²⁰ examined the effects of a lay navigator program to increase lung cancer screening among current smokers. Four part-time lay navigators helped patients identify and overcome barriers to screening, empowered patients to discuss risks and benefits of screening with their primary care provider, provided brief smoking cessation counseling, and followed up with the appropriate provider after screening. The intervention group had higher rates of chest computed tomography (CTs) and lung cancer screening CTs. Patients were grouped by their Lung CT Screening Reporting and Data System (Lung-RADS) results, where Lung-RADS 1 or 2 findings did not require follow-up and Lung-RADS 3 or 4 required additional imaging and/or procedures. Both intervention and control groups had similar Lung-RADS findings, number of diagnoses, and time to follow-up care for Lung-RADS 4 patients.

A Canada-based mixed-methods observational study (n=40)²¹ navigated patients with newly diagnosed lung cancer. Volunteer lay navigators contacted patients by phone, provided a tour of the cancer center, followed up with patients after the first visit with oncology, and provided an optional fourth contact if the patient’s needs were not met. Patients reported being satisfied with the program.

Table 3. Completed primary studies relevant to Question 2

Study Information Author, year • Study Type • Navigation Focus • Country	Population	Intervention/Comparator	Relevant Outcomes	Results
Percac-Lima 2018 ²⁰ <ul style="list-style-type: none"> • RCT • Screening • United States 	n=1,200 patients at five community health centers Eligibility criteria included current smokers aged 55-77 years old	<u>Intervention (n=400):</u> Lay navigators did the following: <ol style="list-style-type: none"> 1. Initial interview to determine smoking history/eligibility 2. Identify and help patients overcome barriers 3. Introduce shared decision-making 4. Empower patients to discuss risks and benefits of screening with PCP 5. Review CT lung cancer screening reports and contact provider about follow-up care 6. Provide brief smoking cessation counseling <u>Comparator (n=800):</u> Usual care	<ul style="list-style-type: none"> • Proportion of patients receiving chest CT scan for screening or diagnosis • Proportion of patients receiving lung cancer screening CTs • Results of screening CTs (Lung-RADS scale) • Lung cancer diagnoses • Time to follow-up of patients with Lung-RADS 4 	<ul style="list-style-type: none"> • A greater proportion of intervention patients had chest CTs compared with patients in control group (31% vs. 17%, p < 0.001). • Lung cancer screening CTs performed more often in intervention than control group (23.5% vs. 8.6%, p < 0.001). • Similar rates of Lung-RADS findings between intervention and control groups (p=0.72). Most had Lung-RADS 1 or 2 (no follow-up needed). • Intervention group had eight diagnoses of lung cancer vs. four in control (p-value NR). • Intervention group patients with Lung-RADS 4 findings had 20.1 days to follow up vs. 22 days in control (p-value NR).
Lorhan 2014 ²¹ <ul style="list-style-type: none"> • Mixed-methods observational (quantitative data from post-intervention survey) • Treatment • Canada 	n=40 patients with newly diagnosed lung cancer	<u>Intervention:</u> Volunteer lay navigators provided three steps with an optional fourth step: <ol style="list-style-type: none"> 1. Introduction phone call 2. Meet patient for tour of cancer center and discussion 3. Closure phone call after visit with oncologist 4. Additional support as requested by participants whose needs were not fully addressed <u>Comparator:</u> None	Satisfaction with program	Participants scored their satisfaction as 4.3 on a scale from one (not satisfied) to five (very satisfied).

Abbreviations: CT=Computed Tomography; Lung-RADS=Lung imaging reporting and data system; NR=Not Reported; PCP=Primary Care Physician; RCT=Randomized Controlled Trial

Protocols and Clinical Trials

Our search identified two ongoing studies.^{22, 23} One U.S.-based RCT²³ will examine the effectiveness of patient navigation for increasing lung cancer screening among a racially diverse, medically underserved population served by a safety-net health system. Patients (n=170) who are at high risk of cancer will be randomized to usual care or usual care plus navigation. Navigators will educate, motivate, and empower patients to schedule appointments for CT scans, inquire about interest in smoking cessation, remind patients about upcoming appointments, and follow up after the scan to refer patients to appropriate care. The RCT will measure adherence to cancer screenings, as well as patient attitudes and beliefs (including cancer worry, psychosocial distress, and patient satisfaction).

One U.S.-based randomized, open-label study²² (n≈200) will examine the effectiveness of nurse-led patient navigation in early stage non-small cell lung cancer (NSCLC) treatment in African Americans ages 21 and older. The primary outcome of interest is the receipt of lung-directed therapy with curative intent and, secondarily, time to therapy. Other secondary outcomes of interest include receipt of surgical/radiation oncology consultation, satisfaction with care, and time to death. The role of the nurse-led patient navigation is not well-defined in this study, but is generally to provide solutions of potential barriers to treatment and to engage in direct communication with patients at least once a week. See Table 4.

Table 4. Protocols and clinical trials relevant to Questions 2 and 3

Study Information Author, Year <ul style="list-style-type: none"> • Study Type • Navigation Focus • Country 	Population	Intervention/Comparator	Relevant Outcomes	Results (if Available)
Gerber 2017 ²³ <ul style="list-style-type: none"> • RCT protocol • Screening • United States 	n=340 medically underserved and racially diverse patients at high risk of lung cancer Eligibility criteria included age 55-77 years, smoking history ≥ 30 pack-years, quit within 15 years if former smoker	<u>Intervention:</u> Usual care plus navigation (navigators will educate, motivate, and empower patients to schedule appointments for CT scans, inquire about interest in smoking cessation, remind patients about upcoming appointments, and follow up after the scan to refer patients to appropriate care). <u>Comparator:</u> Usual care	Adherence to cancer screening Cancer worry Psychosocial distress Satisfaction with care	In process

Study Information Author, Year <ul style="list-style-type: none"> • Study Type • Navigation Focus • Country 	Population	Intervention/Comparator	Relevant Outcomes	Results (if Available)
Wake Forest University Health Services 2018 ²² <ul style="list-style-type: none"> • Randomized, Open-Label. ClinicalTrials.gov NCT01885455 • Treatment • United States 	n≈200 African Americans (21 years or older) with clinically suspicious or biopsy-proven, early stage non-small-cell lung cancer	<p><u>Intervention:</u> Nurse-led PN + standard therapy/usual care. PN will provide an NCI lung cancer booklet and encourage engagement with diagnosing physician. PN will contact each participant by telephone or in-person at least once per week. PNs identify and work to reduce barriers to treatment.</p> <p><u>Comparator:</u> Usual care, including complete staging work-up, surgical consultation, cardiac/pulmonary function testing, surgical resection, adjuvant therapy</p>	Receipt of lung-directed therapy with curative intent (LDTCI) Receipt of surgical and/or radiation oncology consultation Time to LDTCI Satisfaction with care received Time to death	Study is still recruiting. No results

Abbreviations: CT=Computed Tomography; LDCTI=Lung-Directed Therapy with Curative Intent; NCI=National Cancer Institute; PN=Patient Navigation; RCT=Randomized Controlled Trial

Question 3. Does the effectiveness of patient navigation interventions for improving lung cancer outcomes vary by geographic location (rural, suburban, urban), socioeconomic status, literacy, or race/ethnicity?

Systematic Reviews

We did not identify any SRs examining the effectiveness of patient navigation interventions for improving lung cancer outcomes for specific patient subgroups of geographic location, socioeconomic status, literacy, or race/ethnicity.

Primary Studies

Completed Studies

We did not find any completed studies which addressed lung cancer outcomes by patient subgroups of geographic location, socioeconomic status, literacy, or race/ethnicity.

Ongoing Studies

One U.S.-based randomized, open-label study²² (n≈200) will examine the effectiveness of nurse-led patient navigation in early stage NSCLC treatment in African Americans ages 21 and older. See Table 4 for additional information.

Ongoing Efforts

There are several ongoing efforts in the development and improvement of patient navigation programs. These efforts include guidelines, national standards used by health care systems and

government agencies, and volunteer-based grassroots efforts. The following is not a comprehensive list, rather examples found during this workup and identified during conversation with a patient navigation expert.

Guidelines

A 2012 United Kingdom National Institute for Health and Clinical Excellence (NICE) guideline on lung cancer requires that all people with known or suspected lung cancer have access to a clinical nurse specialist (the UK term for nurse navigator) who they can contact between visits. Furthermore the guideline requires that health systems track three quality metrics: the proportion of patients with known or suspected lung cancer who receive the name and contact number of a lung cancer clinical nurse specialist, the proportion of patients with lung cancer who had a lung cancer clinical nurse specialist at diagnosis, and the proportion of patient with lung cancer who were assessed by a lung cancer clinical nurse specialist.²⁴

Standards

The U.S.-based Commission on Cancer (CoC) updated their cancer care standards for hospitals and cancer centers in 2016. This commission, a program of the American College of Surgeons, "...recognizes cancer care programs for their commitment to providing comprehensive, high-quality, and multidisciplinary patient centered care."²⁵ Many government agencies (e.g., Centers for Medicare & Medicaid Services) and health care systems look to these standards to assist with quality reporting. Accreditation by the CoC does not require the hiring of a patient navigator, but rather provides a framework for reducing disparities and barriers to care. While comprehensive and multifaceted, the standards highlight the importance of a multidisciplinary team approach to cancer care, the use of a designated oncology nurse manager, community outreach for prevention and screening with follow-up, and the use of a community needs assessment to better target potential barriers of care in the community.

Toolkits

The Boston Medical Center (BMC), in a partnership with the Avon Foundation for Women, developed a patient navigation toolkit.²⁶ This navigation model was designed and studied^{27, 28} for breast cancer services but has been adopted to other oncological and chronic disease services in the BMC. The patients in the patient navigation group demonstrated higher mammogram adherence than in the control group ($p < 0.001$),²⁸ and were more likely to follow-up within 120 days of the initial appointment (39% greater odds, 95% confidence interval, 1.01–1.9).²⁷ This toolkit, using evidence- and experience-based examples, aims to help other health care systems develop patient navigation programs to reduce health disparities and improve health outcomes. This toolkit focuses on the logistics of launching a patient navigation program, and is therefore geared toward program and project managers, but provides valuable resources for conducting needs assessments and examples of patient navigator qualifications and job descriptions.

A Patient Navigation Manual for Latino Audiences: The Redes En Acción Experience²⁹ is a toolkit developed by a team of researchers, and studied in a network of six hospitals³⁰ (Redes En Acción: The National Latino Cancer Research Network, in San Francisco, San Diego, New York, Miami, Houston, and San Antonio [primary study site in San Antonio]). This patient navigation program demonstrated an increase in the percentage of Latinas initiating breast cancer treatment within 30 and 60 days of diagnosis compared to controls ($p = 0.045$ and $p = 0.021$,

respectively).³⁰ Like the BMC toolkit, this patient navigator manual was initially studied in breast cancer patients, and has since been adopted to other oncologic specialties. This toolkit has a primary emphasis on Latino populations, and related factors such as cultural competency and overcoming barriers to care.

Other Programs and Resources

The University of California (UC) system has a number of patient navigation programs, specific to individual university hospitals. UC San Francisco hosts a program called the Patient Support Corps, which relies on volunteer efforts from undergraduates (from UC Berkeley) and pre-medical interns (college graduates).³¹ These volunteers provide materials, services, and referrals to help those with cancer diagnoses review information, list questions they have about their diagnosis, and take notes and recordings of medical appointments. The UCLA Health Care Extender Program is also a volunteer program, wherein extenders are trained and then gain hands-on experience in the medical field, interact with patients and family, learn strategies to overcome barriers to care and difficult medical situations, and assist staff with their duties in the unit.³²

Most patient navigation programs require training for navigators. One of the most common training programs is provided by The Harold Freeman Institute.³³ The institute provides two-day training programs for patient navigators. This program emphasizes the elimination of barriers to timely care. The Harold Freeman Institute trains navigators to facilitate "...movement of an individual across the entire health care continuum from prevention, detection, diagnosis, treatment, and supportive, to end-of-life care."³³

Discussion

We found only two completed studies on patient navigation programs from the past 5 years addressing lung cancer at any point in the cancer continuum, one on lung cancer screening using paid lay navigators and one on newly diagnosed lung cancer patients using volunteer lay navigators. This limited evidence shows that patient navigation may improve rates of screening or diagnostic CTs, and that patients with newly diagnosed lung cancer may be satisfied with a volunteer patient navigation program. It will be important for future studies to address other important considerations, including if patients' screening decisions are aligned with their goals and preferences and comparing the effectiveness of volunteer lay navigators with paid lay navigators on the effectiveness of cancer outcomes as well as patient satisfaction.

Regarding all types of cancer, our findings from both SRs and PNRP-related studies confirms the wide variation among programs with respect to navigator characteristics (education, training, and cultural background), type of program (team versus individual), health care setting, and types of services provided. Entry criteria were often similar among programs (e.g., an abnormal screening test), but exit criteria were usually not defined. Most of the evidence we identified focused on breast, cervical, colorectal and prostate cancer.

This report found that navigators primarily deliver two types of services.¹⁸ First they work with patients, providers, staff and families to resolve problems and barriers to care. Second, they work to provide fixes to a broken health care system by facilitating communication and coordination between staff and systems to prevent lapses in care (e.g., transcribing medical records between medical systems).

Overall there is broad consensus on the general definition of patient navigation for cancer, mostly focusing on Harold Freeman's original vision of models to address barriers to care in a culturally sensitive manner for the most vulnerable patients as determined by race, language, income, or rural location.⁵ However, the specific details of how to implement a program are not agreed upon or prescribed by any guideline organizations at this time. Although it has been 28 years since Freeman's original conception, patient navigation programs have proliferated but there is no consensus on the ideal components.

Limitations of Review Methodology

This rapid evidence product used accelerated methods in order to complete the work on a rapid timeline for our nominator. Because our nominator was interested broadly in the components of navigation program and how to implement them, we determined that an evidence product with less scientific rigor was appropriate. We did not complete many steps of a traditional SR, including risk of bias evaluation. Therefore, these findings may have less certainty compared to those of an SR. We also may have missed studies since we narrowed the SR search to the past three years and the primary study search to the past five years. In addition, due to time constraints, we excluded qualitative studies, which limits our ability to explain why certain components of navigation programs work and the mechanism by which they improve patient's cancer care.

Implications for Future Research

While patient navigation interventions are a desired element of the continuum of all types of cancer care, it is important to highlight that there is no need to reinvent the wheel. Even though the evidence showing efficacy of these models and their application specifically to lung cancer is sparse, there is substantial evidence for effectiveness of patient navigation in other types of cancer. We previously mentioned interventions and toolkits that were initially designed for breast cancer care, but were later adapted for use in other cancer types. These evidence-based toolkits describe how to develop patient navigation models, which are intended to be frameworks on which tailored programs can be built. We recommend researchers conduct implementation studies to determine which model is the most effective for which cancer type in which health system.

We also recommend researchers describe patient navigation interventions in as much detail as possible, including navigators' duties, training, and characteristics. Despite a national research collaborative dedicated to patient navigation (e.g., the PNRP), studies were notable for their considerable lack of detailed descriptions on individual patient navigation programs. It was often difficult to determine what patient navigators actually did, beyond the general definition set forth by the PNRP program.¹⁹ The SRs on patient navigation programs for all cancers also did not provide granular descriptions. This lack of clarity makes it difficult to interpret the effectiveness results of the studies and difficult for others to replicate the navigator interventions.

Lung cancer presents certain challenges which may not be relevant for patients with other cancers, including that lung cancer often presents at an advanced stage with a more rapid and fatal course. In addition, lung cancer patients often have more physical and psychological needs and a significant portion of lung cancer patients may benefit from behavioral counseling (e.g.,

smoking cessation).³⁴ Therefore additional studies on lung cancer patient navigation may be warranted to determine the ideal adaptations of navigation programs for these patients.

Finally, we recommend recruiting diverse populations; including race, ethnicity, socioeconomic status, and geographic location; and analyzing results by subgroups. Of the limited evidence on lung cancer, only one ongoing RCT examined effectiveness in African Americans, and does not compare across subgroups of other races or ethnicities.²²

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Appendix A. Search Strategies

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, and Daily 1946 to July 18, 2018

Date Searched: July 19, 2018

Searched by: Information Specialist

#	Searches	
1	Patient Navigation/	
2	((lay or layperson or nurse* or patient* or peer* or "social work*" or volunteer*) adj3 navigat*).tw,kf.	
3	or/1-2	
4	exp neoplasms/ or exp cysts/ or exp hamartoma/ or exp neoplasms by histologic type/ or exp neoplasms by site/ or exp neoplasms, experimental/ or exp neoplasms, hormone-dependent/ or exp neoplasms, multiple primary/ or exp neoplasms, post-traumatic/ or exp neoplasms, radiation-induced/ or exp neoplasms, second primary/ or exp neoplastic processes/ or exp neoplastic syndromes, hereditary/ or exp paraneoplastic syndromes/ or exp precancerous conditions/ or exp pregnancy complications, neoplastic/	
5	(cancer* or neoplasm* or blastoma* or carcinoma* or metastat*).tw,kf.	
6	or/4-5	
7	exp Lung Neoplasms/ or Bronchial Neoplasms/ or Carcinoma, Bronchogenic/ or Multiple Pulmonary Nodules/ or Pancoast Syndrome/ or Pulmonary Blastoma/ or Pulmonary Sclerosing Hemangioma/ or Adenocarcinoma in Situ/ or Adenocarcinoma, Bronchiolo-Alveolar/ or Carcinoma, Non-Small-Cell Lung/ or Small Cell Lung Carcinoma/	
8	(adenocarcinoma or ((lung* or pulmonary or bronch*) adj3 (cancer* or neoplasm* or carcinoma*))).ti,kf.	
9	or/7-8	
10	and/3,6	
11	and/3,9	
12	(framework* or model* or theor* or concept* or principle* or taxonom* or measur* or evaluat* or barrier* or facilitat* or challenge* or opportunit* or metric*).ti,kf.	
13	and/10,12	This row general cancer models
14	and/11-12	This row lung cancer models
15	randomized controlled trial.pt.	
16	controlled clinical trial.pt.	
17	randomized controlled trials as topic/	
18	random allocation/	
19	double-blind method/	
20	single-blind method/	
21	clinical trial.pt.	
22	exp clinical trial as topic/	
23	(clin* adj25 trial*).ti,ab.	
24	((single* or doubl* or trebl* or tripl*) adj25 (blind* or mask*)).ti,ab.	
25	placebos/	
26	placebo*.ti,ab.	
27	random*.ti,ab.	
28	research design/	
29	comparative study/	
30	exp evaluation studies/	

#	Searches	
31	follow up studies/	
32	prospective studies/	
33	(control* or prospective* or volunteer*).ti,ab.	
34	or/15-33	
35	animals/ not humans/	
36	34 not 35	
37	and/10,36	This row general cancer trials with patient navigation trials
38	and/11,36	This row lung cancer patient navigation trials
39	Meta-Analysis as Topic/	
40	meta analy\$.tw.	
41	metaanaly\$.tw.	
42	Meta-Analysis/	
43	(systematic adj (review\$1 or overview\$1)).tw.	
44	exp Review Literature as Topic/	
45	or/39-44	
46	cochrane.ab.	
47	embase.ab.	
48	(psychlit or psyclit).ab.	
49	(psychinfo or psycinfo).ab.	
50	(cinahl or cinhal).ab.	
51	science citation index.ab.	
52	bids.ab.	
53	cancerlit.ab.	
54	or/46-53	
55	reference list\$.ab.	
56	bibliograph\$.ab.	
57	hand-search\$.ab.	
58	relevant journals.ab.	
59	manual search\$.ab.	
60	or/55-59	
61	selection criteria.ab.	
62	data extraction.ab.	
63	61 or 62	
64	Review/	
65	63 and 64	
66	Comment/	
67	Letter/	
68	Editorial/	
69	animal/	
70	human/	
71	69 not (69 and 70)	

#	Searches
72	or/66-68,71
73	45 or 54 or 60 or 65
74	73 not 72
75	and/10,74 This row general cancer patient navigation systematic reviews/meta-analyses
76	and/11,74 This row lung cancer patient navigation systematic reviews/meta-analyses

CINAHL(EBSCOhost)

Date searched: July 27, 2018

Searched by: Information Specialist

Concept	Controlled Vocabulary Terms	Free Search Terms
Search for Trials of Patient Navigation for Lung Cancer		
Patient Navigation	(MH "Patient Navigation") OR	(TI (navigation OR navigator OR navigators) OR AB (navigation OR navigator OR navigators) AND TI (lay or layperson or nurse* or patient* or peer* or "social work*" or volunteer*) OR AB (lay or layperson or nurse* or patient* or peer* or "social work*" or volunteer*)) NOT electromagnetic OR tomography OR bronchoscopic
	AND	
Lung Cancer	(MH "Lung Neoplasms+") OR (MH "Carcinoma, Non-Small- Cell Lung") OR	(TI (cancer OR carcinoma OR neoplasm) OR AB (cancer OR carcinoma OR neoplasm) AND (lung OR pulmonary OR bronchial) OR AB (lung OR pulmonary OR bronchial))
Limits:		Published Date: 20140101-20181231 [2014 to present] AND Source Type = "Academic Journals"
Search for General Models for Patient Navigation in Cancer.		

Concept	Controlled Vocabulary Terms	Free Search Terms
Patient Navigation	(MH "Patient Navigation") OR	(TI (navigation OR navigator OR navigators) OR AB (navigation OR navigator OR navigators) AND TI (lay or layperson or nurse* or patient* or peer* or "social work*" or volunteer*) OR AB (lay or layperson or nurse* or patient* or peer* or "social work*" or volunteer*)) NOT electromagnetic OR tomography OR bronchoscopic
	AND	
Cancer in General	((MH "Carcinoma") OR (MH "Neoplasms+") OR (MH "Cancer Survivors") OR (MH "Cancer Screening") OR (MH "Cancer Care Facilities")) OR	((carcinoma OR neoplasm OR cancer) OR AB (carcinoma OR neoplasm OR cancer))
	AND	
Models	((MH "Classification") OR (MH "Conceptual Framework") OR (MH "Theory+")) OR	(TI (taxonomy OR classification OR theory OR model OR conceptualization OR framework) OR AB (taxonomy OR classification OR theory OR model OR conceptualization OR framework))
Limits	Published Date: 20140101-20181231 [2014 to present] AND Source Type = "Academic Journals"	