Project SUPPORT:

(Socio-legal Services for Underserved Populations Thru Patient Navigation to Optimize Resources During Treatment)

Protocol: 9/1/2017
Clinicaltrials.gov identifying number: NCT02232074
IRB: H-32599

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This study has been approved by the Boston University Medical Center Institutional Review Board. IRB #: H-32599

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5. Roles and responsibilities

Name	Organization	Role	Responsibility
Tracy Battaglia MD, MPH	BMC	PI	Provide complete oversight of the program including its design, implementation, analysis and dissemination activities.
Naomi Ko, MD	BMC	Co-PI	Provide leadership in coordinating intervention with oncology and lead clinical adjudication team.
Kerrie Nelson, PhD	BUSPH	Statistician	Responsible for providing the research team with randomization, input on the preparation of analyses for dissemination and preparation of scientific manuscripts.
Na Wang,	BUSPH	Statistical Analyst	Create data dictionaries, clean datasets, develop statistical programs and work with statistician to conduct analyses.
Sharon Bak, MPH	BMC	Data Manager	Responsible for implementing data management and chart abstraction procedures and quality control of data.
Penny Price Johnson, MC	BMC	Study Research Coordinator	Provide oversight of day-to-day study management and oversight of RAs
Jennifer Pamphile	BMC	RA	Screen, recruit and enroll eligible patients. Complete study surveys.
Samantha Morton, JD	MLPB	Executive Director MLPB	Oversee all aspects of integration of MLPB support and capacity-building in the Intervention Navigator and responsible for data collection relating to legal needs.
JoHanna Flacks, JD	MLPB	Legal Director MLPB	Manage all aspects of legal service delivery to participants during the intervention period.
Katie Finn	BMC	Patient Navigator Supervisor , Hematology/Oncology	Provide clinical supervision in oncology for both the intervention and the control navigators.
Laura Ochoa	BMC	Intervention PN	Navigate all patients enrolled in the intervention arm for the duration of the intervention period.
Sabrina Morton	BMC	Intervention PN	
Amy Proctor	BMC	Control PN	Navigate all patients enrolled in the control arm for the duration of the intervention period.

Name	Organization	Role	Responsibility
Deb Bowen, PhD	BUSPH	Scientific Steering Committee Advisor	Guide the methodology, data collection, analyses and dissemination activities
Victoria Parker, DBA	BUSPH	Scientific Steering Committee Advisor	
Roy Davis	Community	Patient Advisory Group	Provide patient perspectives and guidance on the conduct of research project
Elizabeth Rhodes	Community	Patient Advisory Group	
Marilyn Simmons	Community	Patient Advisory Group	
Carolyn Barnes	Community	Patient Advisory Group	
Joyce Gandy	Community	Patient Advisory Group	

PI: Principal Investigator, **RA:** Research Assistant, **MLPB:** formerly known as Medical Legal Partnership | Boston **PN**: Patient Navigator, **BMC**: Boston Medical Center, **BUSPH**: Boston University School of Public Health

Scientific Steering Committee:

a. Comprised of the study key personnel and 2 additional investigators at Boston Medical Center with expertise in cancer and community health interventions:

b. This committee consults with the research team guide the methodology, data collection, analyses, and dissemination activities throughout the course of the study.

c. Scientific Steering Committee meetings are held a minimum of four (quarterly) and a maximum of six (bimonthly) times per year.

Patient Advisory Group:

This committee serves as a formal communication vehicle for patients to take an active role in decisions related to the research design, study implementation, and dissemination activities.

a. Each member of the Patient Advisory Group brings an individual experience of cancer treatment, survivorship, and talents. As the project evolves, division into separate working groups such as dissemination and outreach will provide an opportunity for these talents to be best represented.

b. Each advisory group meeting will include a discussion of current and future dissemination activities that will be designed by the patients but supported and executed by program staff.

c. Patient Advisory Group meetings are held a minimum of four (quarterly) and a maximum of six (bimonthly) times per year. The Patient Advisory Group is also invited to participate in the quarterly (4 times per year) Community Advisory Board meetings.

Introduction

6. Background and Rationale

Cancer inflicts a substantial toll on society with a disproportionate burden borne by minority and low income populations. Prevalence of cancer in the US was estimated at 15,112,198 cases in 2015 with 1,735,350 new cases in 2018 (1, 2). Cancer remains the second leading cause of death in the US, accounting for over 598,030 deaths in 2016 (3) Since the year 2000, cancer mortality surpassed heart disease as the leading cause of death in women aged 40–79 and men aged 60–79 (4). Breast, lung and bronchus, and prostate cancer account for the highest mortality rates nationwide (1, 5). It has long been recognized that the burden of cancer falls disproportionately on people of color (6). Both incidence and mortality are elevated among minorities, especially Blacks, who are more likely to be diagnosed with certain cancers, to be diagnosed at advanced stage, and to die from the disease (7). Evidence is clear, though, that race and ethnicity are closely related to socioeconomic status (SES), so many racial/ethnic disparities are associated with differences in income, education and health insurance coverage (8). Studies consistently show that the cancer burden increases as income, insurance status and educational attainment decline,(1, 9-11) regardless of race/ethnicity.

Cancer health disparities are growing despite ongoing advances in scientific discovery. While overall cancer mortality rates continue to decline, not all segments of the US population benefit equally from this progress (12). Death rates in those with lower SES, as defined by education, occupation, or residence, have shown little or no decrease, and even increased in some instances (7, 13, 14). Any decrease in cancer death rates among minorities has occurred later and has been slower compared to Whites. As a result, the gap in mortality rates between advantaged and disadvantaged segments of the US population has continued to widen (7, 13, 14). For instance, cancer death rates for men in 1993 were two times higher in the least educated compared to the most educated groups, but by 2007 this mortality difference had increased to nearly three-fold (7). Despite continued advancement in early detection and targeted treatments for women with breast cancer, Black women continue to die from breast cancer at a higher rate than their White counterparts (7).

Social determinants of health create obstacles in obtaining timely, quality care and are one of the underlying causes for existing cancer disparities. While the interplay of race, poverty and other socioeconomic indicators on cancer outcomes is complex, research has clearly documented the impact that barriers to accessing cancer care have on patient outcomes, regardless of race/ethnicity (13-16). One primary cause of cancer disparities among lower SES populations is the presence of financial, structural, and personal barriers to health care, including inadequate health insurance, lower literacy, and reduced access to recommended preventive care and treatment service (1). These obstacles to cancer services create documented delays in care and are increasingly scrutinized as a source of poor survival for many vulnerable populations,(17-26) while large population-based studies find that equal high quality treatment can significantly reduce disparities in mortality (27). **Thus, evidence-based interventions to reduce delays in care resulting from social barriers or obstacles are needed to reduce disparities in cancer outcomes.**

Patient navigation represents a promising remedy to reduce cancer disparities by intervening to address barriers to timely care. Navigation is a patient-centered care coordination model that uses lay health workers who are integrated into the healthcare team to support disadvantaged patients for a

defined episode of cancer-related care (28-30). The specific goal of navigation is to reduce delays in care by identifying and addressing patient barriers to care. Our research team at Boston Medical Center (BMC) pioneered the development of a lay patient navigation model supporting low income minority patients that demonstrated significant impact on timely care (31-36) and contributed to widespread dissemination of navigation as a current standard in cancer care (6, 37). Patient navigators are trained to work closely with patients and providers to identify individual patient obstacles to care (38, 39) and then link patients to existing loco-regional resources to overcome them. Barriers documented most frequently include: communication issues, scheduling issues and socio-cultural issues such as fear or mistrust. Patient navigators helped reduce missed appointments by 50% and also decreased time to screening and diagnosis (31, 33, 34).

To facilitate discussion on how to improve navigation services for patients with cancer, the National Cancer Policy Forum of the National Academies of Sciences, Engineering, and Medicine held a workshop on Establishing Effective Patient Navigation Programs in Oncology in Washington, DC, on November 13 and 14, 2017. At this workshop, a broad range of experts, including clinicians, navigators, researchers, and patients, provided an overview of patient navigation, explored current models of patient navigation programs, identified lessons learned from implementation of patient navigation programs as well as gaps in the evidence base, including the need for comparative effectiveness studies to inform best practices (40).

In the years leading up to our study design process and proposal submission, preliminary studies by our research team suggested that the presence of barriers, particularly certain **socio-legal barriers**, contribute to persistent delays in care despite navigation. We defined **socio-legal barriers** as social problems related to meeting life's most basic needs that are addressed by existing public policy, law, regulation and programming and are thus potentially remedied through legal advocacy/action (41). (Over time, socio-legal barriers may become understood as part of (or even subsumed) by the broader category of Social Determinants of Health (SDOH), a concept whose taxonomy is still young in the domain of academic medicine.

Indeed, while Project SUPPORT was conceptualized in 2011-13, it was not until May 2017 that CMS published for the first time on the topic of "health-related social needs": https://nam.edu/wp-content/uploads/2017/05/Standardized-Screening-for-Health-Related-Social-Needs-in-Clinical-Settings.pdf.) Project SUPPORT was grounded in MLPB's experience that social needs have a legal dimension (a) to the extent that a patient has sought resources or assistance from an agency/authority (perhaps with the encouragement and help of a patient navigator) and has been denied that support, possibly in violation of the patient's legal rights, or (b) the patient and navigator are aware of the unmet social need but not aware that they have legal rights, or if they are aware -- how to exercise them effectively.

Unmet essential needs that often involve socio-legal barriers are reflected in the acronym **I-HELP** initially published in *Pediatrics* in October 2007: **I**ncome supports & **I**nsurance; **H**ousing & Utilities; **E**mployment & **E**ducation; **L**egal Status; **P**ersonal & Family Stability/Safety (42). Each category reflects basic life needs that, if not met, may affect health and may be amenable to direct legal advocacy or service intervention should initial efforts by patients/families to satisfy these needs be unsuccessful.
Data from the National Patient Navigation Research Program (PNRP), the largest multi-site study of navigation in cancer care to date, documents the impact socio-legal barriers have on equitable cancer

care. Using a list of 20 discrete barriers to care (43), PNRP navigators were also trained to document reported patient barriers to care during each patient encounter.

Analyses found that navigated patients with documented barriers to care experience less timely resolution of their screening abnormalities; the more barriers present, the less timely their care (44). In a secondary analysis, we categorized barriers into two groups: 1) socio-legal barriers and 2) other barriers. Among 1,493 patients receiving navigation, only 6% had socio-legal barriers to care documented by the navigator. The top 3 barriers documented by navigators were: language issues (25%), scheduling issues (14%), and fear (12%). Yet, those with socio-legal barriers to care were less likely to have timely resolution of diagnostic care (aHR: 0.51, 95% CI: 0.39, 0.66) compared to those with other barriers, even when accounting for the presence of multiple barriers. This is one of the most robust findings in the Boston PNRP dataset, and a stronger predictor of delay in treatment than insurance status or race and ethnicity (45).

These findings are supported by other navigation studies that report outcomes are limited by housing, insurance and financial needs (46-48). **Therefore, it makes sense that navigation had only a modest effect in our low-income population in prior navigation studies, as navigators were not trained to identify or address these complex socio-legal barriers to care with remedies external to the healthcare system.**

Research demonstrating the impacts of integrating legal support into patient care – exemplified by the medical-legal partnership approach -- is only beginning to emerge, but much more needs to be known regarding the size of effects (15, 41, 49, 50). Current legal reports document improvements in self-reported health, including feeling more empowered after receiving MLPB services (50), having reduced stress (49), and improvement in one's general health (15).

A retrospective study of patients in palliative care found that 297 referrals made to an MLPB program from 2004 through 2007 addressed patients' legal needs, from reinstating food stamp benefits, to executing last wills and testaments (51). A pilot study of an MLPB tailored for pediatric patients found the proportion of families who accessed food and income supports significantly increased, while the proportion of families who avoided medical care due to perceived cost and insurance barriers significantly decreased (15). In a pilot study of 20 cancer patients who received legal services, 75% said the legal services reduced stress and 45% reported a positive impact on their financial situation, 30% said the services helped them maintain their treatment regimen, and 25% said legal services helped them keep medical appointments (52). **However, rigorous research demonstrating the impact of legal support for disadvantaged populations on timeliness of care in general, and of cancer care in particular, are lacking, representing a critical gap in the science of cancer disparities.**

Project SUPPORT (**S**ocio-legal services for **U**nderserved **P**opulations through **P**atient Navigation to **O**ptimize **R**esources during **T**reatment) is an innovative, patient-centered intervention that was designed in partnership with a diverse group of community stakeholders to address persistent cancer care disparities for vulnerable cancer patients seeking services at an inner-city safety net hospital. We utilize Community-Engaged Research methods to design, implement and evaluate a comparative effectiveness care delivery randomized controlled trial for a racially/ethnically diverse, low income population with newly diagnosed cancer.

We hypothesize that compared to standard navigation, a navigation intervention supported by legal advocacy will address patient-reported socio-legal barriers and lead to delivery of equitable cancer care. Our specific aims are to measure the impact of a **legal support-enhanced patient navigation** intervention on:

1) Clinically relevant outcomes: receipt of timely and quality cancer care.

2) Patient-reported outcomes: distress, needs and satisfaction.

3) Intermediate outcomes: *socio-legal barriers to cancer care*.

7. Objectives

Research Question: Compared to standard patient navigation, will a more patient-centered navigation intervention in partnership with the MLPB (formerly known as Medical Legal Partnership | Boston) that identifies and addresses socio-legal barriers to care in newly diagnosed cancer patients seeking care in an urban safety-net result in: 1) improvements in patient-reported distress, perceived needs, self-efficacy and satisfaction with the navigator, 2) more timely and better quality care, and 3) elimination of patient-reported socio-legal barriers to care?

Hypothesis: compared to standard navigation a navigation intervention supported by legal advocacy will address patient-reported socio-legal barriers and lead to delivery of equitable cancer care

8. Trial Design

Randomized controlled trial

- N= 374 newly diagnosed breast & lung cancer patients
- 187= Control (standard navigation)
- 187= Intervention (MLPB enhanced navigation)

Methods

9. Study Setting

Boston Medical Center

Study participants will be identified by screening recently diagnosed breast and lung cancer patients presenting for care Boston Medical Center. Eligible patients will be identified using 3 sources (pathology reports, referrals and weekly multidisciplinary tumor board conference

10. Eligibility

All patients must meet the following criteria in order to participate in project SUPPORT:

Eligibility criteria:

- Newly diagnosed lung or female breast cancer
- 18 years or older
- Receiving cancer treatment at Boston Medical Center
- English, Spanish or Haitian Creole speaking
- Patient is eligible within one month (30 days or less) of being notified of her/his cancer diagnosis.

Exclusion criteria include:

- Patient informed of cancer diagnosis >30 days
- Patient under 18 yrs. of age
- Primary language something other than English, Spanish or Haitian Creole
- Undergoing treatment for concurrent cancer
- Male breast cancer patients
- Patient has history of cancer or has received cancer treatment within the last 5 years
- Institutionalized/cognitive impairment such as: dementia or metabolic, medication or drug induced, psychosis (given the unique challenges to their treatment decision making/adherence and the fact that the intervention would not include the patient directly, but rather the family).
- Small Cell Lung Cancer type

11. Intervention

Control arm: Standard Patient Navigation

a. Current standard of care for cancer patients at BMC
b. Patient Navigators (PN) complete navigation training through the Oncology Department
c. PN follows the Care Management Model
    i. Case identification
    ii. Barrier identification
    iii. Care plans to address identified barriers
    iv. Long term tracking

Intervention arm: MLPB-enhanced patient navigation

a. Intervention Patient Navigator (IPN) has had standard of care patient navigation training through the Oncology Department
b. IPN interactions with patients are documented by the IPN in the Oncology Navigator template in the EMR
c. Navigator has also completed MLPB orientation and training
    i. Focusing on 3 areas:
        1. Housing
        2. Employment
        3. Disability
    ii. Additional trainings will cover study specific protocol and procedures:
        1. protocol implementation & documentation
        2. administering detailed legal screen/facilitation questions
        3. present information/consult to MLPB
    iii. MLPB training curriculum includes: social determinants of health, range of available legal remedies, needs assessment through comprehensive screening, developing and implementing care plan through legal triage consultation
    iv. The Intervention PN (IPN) will administer a **Detailed Legal Screen** to all study participants randomized to the intervention group within the first week of study enrollment and again at 3 months post-enrollment
    v. Once an initial **Detailed Legal Screen** is completed with the participant, IPN will contact MLPB to discuss the participant's responses to the screen
    vi. MLPB documents decisions on **Level of Legal Need** form.

Level of Legal Need Coding

Outcome	Level of need	Action
Non-legal issue	0	Facts conveyed by patient to PN, and PN to MLPB, do not reflect that patient has a legal risk/need (as opposed to some other type of need).
Basic legal issue	1	Facts conveyed by patient to PN, and PN to MLPB, reflect that patient has a legal risk/need, but one that can be addressed through MLPB sharing referral recommendations and/or simple information via a single interaction between MLPB and PN (for transmittal to the patient by PN, as appropriate). No follow-up consultation between MLPB and PN is expected or planned.
Intermediate legal issue	2	Facts conveyed by patient to PN, and PN to MLPB, reflect that patient has a legal risk/need, addressing of which will involve multiple consultations between PN and MLPB re: available strategies - contemplates an ongoing advocacy coaching interaction.
Complex legal issue	3	Facts conveyed by patient to PN, and PN to MLPB, reflect that patient has a more complex legal risk/need, so, depending on the nature of the issue and the timing, MLPB either will: (a) provide pro se advice and counsel to patient; (b) refer patient to a specialized resource for free legal assistance; or (c) schedule patient for an MLPB legal intake interview.
Out of MLPB scope issue	9	Facts conveyed by patient to PN, and PN to MLPB reflect that patient has a legal risk/need that is outside the scope of MLPB coverage for this study (such as a criminal law, immigration law, or personal and family safety & stability law issue); MLPB provides readily available referral information only.

11.1 Participant Withdrawal

When a participant expresses interest in withdrawing from Project SUPPORT, the RA should try to ascertain and document the reasons why the participant has chosen to withdraw and what study components, if any, the participant is willing to continue participating in.

<u>Information needed to document withdrawal in REDCap project</u>
Whether withdrawal was a result of decision made by participant or investigator

1) Reason(s) for withdrawal, if known
2) Whether withdrawal was from all components of research study or just the primary interventional component
3) Date of withdrawal
4) Did confirmation of withdrawal occur over the phone or in person

12. Outcomes

12.1 Primary Outcomes

Time to first treatment

1) **Timely initiation of care:** The receipt of timely care will be defined as initiation of care within 90 days, as this the shortest delay that has been shown to consistently affect mortality and categorized as a dichotomous variable (yes/no). The time element will be calculated from date of diagnosis (Time 0) to date of treatment initiation (Time 1). The date chosen for the Time 1 variable will depend on the recommend care plan for each patient, as derived from the chart abstraction and based on patient presentation, including but not limited to stage at diagnosis and co-morbid medical conditions. In all cases Time 1 will be defined as the date of the first treatment **after** patient has received a definitive cancer diagnosis.
2) **Time to initiation of care**: continuous outcome defined as the number days from diagnosis (Time 0) to treatment initiation (Time 1).
3) **Rate of missed appointments:** percent of scheduled appointments that are missed over 12 month period.
4) **Quality of care**: Dichotomous variable (Y/N) based on select measures of quality care, as developed jointly by the Commission on Cancer, NCCN and American Society of Clinical Oncology
    a. Measured using data abstracted from medical chart

12.2 Secondary Outcomes

Patient-Centered Outcomes (PCOs)

1) ***Distress***: Oncology regulatory bodies recommend routine use of screening for *distress,* often referred to as the sixth vital sign in cancer care, as an integral part of comprehensive care (53). Distress is defined as “a multifactorial unpleasant emotional experience of a psychological, social and/or spiritual nature that may interfere with the ability to cope with cancer, its physical symptoms and treatment”(53). Elevated levels of distress are linked to reduced quality of life, poor adherence to treatment and even reduced survival (54-58). We selected the ***Distress Thermometer (DT)***(59) as a simple and validated measure of *global distress* which is widely used in cancer studies. This one item instrument utilizes a figure and asks individuals to rate distress levels during the past week. Scores range on an 11-point scale from 0 (none) to 10 (extreme distress).

2) ***Psychosocial needs assessment:*** Standardized distress screening tools such as the DT are insufficient to pinpoint the specific problems contributing to stress (60). *Needs assessment* is a recommended strategy that focuses on identifying unresolved patient concerns contributing to distress (61) and lie at the core of our conceptual model for this proposed intervention. Assessment of needs is indicative of the gap between patient experiences and expectations. Our hypothesis was that a navigation intervention that detects and addresses socio-legal barriers will result in a reduction in perceived needs over time. While many validated needs assessment tools exist (62), the ***Cancer Needs Inventory (CaNDI)*** (63) was selected for several reasons: a) the 7 domains capture needs reported most commonly by our patient partners, b) the instrument has a 5th grade reading level, c) it had rigorous psychometric testing in diverse populations and d) it takes less than 8 minutes to complete (63). Patients rate the extent of their concern in the past two weeks with 39 items across the 7 domains (anxiety, depression, emotional, social, healthcare, practical and physical) on a scale from 1 (not a problem) to 5 (very severe problem). Items are

summed to create a total distress score (63). Based on feedback from both the Intervention and Control Navigator along with the Oncology Social Worker, we modified the CaNDI by deleting one question related to suicidality. During the early part of recruitment it was determined that the question was disruptive to patient care and thus our provider stakeholders recommended we drop the question. As a result the CaNDI instrument only included 38 questions.

3) ***Patient satisfaction*** reflects a core dimension of healthcare quality and patient-centered care (64-66). Patient satisfaction indicates the extent to which patients' healthcare experiences match their expectations (67, 68). The construct of patient satisfaction has been linked to health status, quality of life, and adherence to recommended treatment (69-71). The ***Patient Satisfaction with Interpersonal Relationship with Navigator (PSN-I),*** a 9-item navigation-focused measure that produces a composite score to assess satisfaction with aspects of care in which navigation and has been validated in both English-speaking and Spanish-speaking populations (72). This survey instrument was administered at the 6 and 12 month follow ups interview.

4) ***Case Cancer*** Self-efficacy; measure of patient's confidence in understanding and participating, maintaining a positive attitude and seeking and obtaining information surrounding their cancer care. It is a 12 item survey (scale 1-4) with 3 domains: seeking and obtaining information, understanding and participating in care, and maintaining a positive attitude. Add responses to create score for each subscale & total scale; higher score=higher self-efficacy

13. Participant timeline

Data collection forms

Study forms will be administered by a Research Assistant (RA) at the following study time points: Baseline, 3, 6 and 12 months follow-up. RAs will work with the patient to schedule study visits to coincide with patient's clinic visits.

Form	Study Time period			
	Baseline	**3 month**	**6 months**	**12 months**
General legal screen (I-HELP)	X	X	X	X
Cancer Needs Distress Inventory (CaNDI)	X		X	X
4-item Brief health literacy Screening Tool (BRIEF)	X			
Distress Thermometer (DT)	X	X	X	X
Communication and Attitudinal Self-Efficacy (CASE)- Cancer	X		X	X
Employment Baseline Questions	X			
Berkman-Syme Social Support Survey (added to protocol January 2015)	X	X		
MOS (added to protocol January 2015)	X	X		
Detailed Legal Screen*	X	X		
Level of Legal Need*	X	X		
Patient Satisfaction with Navigation			X	X

*Intervention arm only

14. Sample Size

Sample size estimates for the clinically relevant outcomes are based on the primary metric: **timely initiation of primary treatment**, a dichotomous outcome (yes/no) calculated for each subject. Since clinical outcomes will be derived from the medical record, we do not anticipate any loss to follow up on these outcomes. We anticipate our study will have 80% power of detecting an advantage to navigation enhanced by a medical-legal partnership, if the enhanced intervention raises the percent in each group receiving timely initiation of care from 76% to 90.5% (testing at the two-tailed .05 level) from patient navigation alone to legal navigation. Comparison of the two study groups on our secondary outcome of time to initiation of cancer treatment, or the number of days to the start of treatment, through survival analysis, takes advantage of more information and should provide somewhat greater power. For example, given the above scenario, (76% vs. 90.5% initiation of care by 90 days) and assuming a constant hazard, (i.e., exponential survival), a log rank test gives 86% power of detecting a difference between the two study groups.

Second, we will conducted separate analyses for the breast and lung cancer participants.

15. Recruitment

Working with oncology providers, Project SUPPORT research assistants approached individuals meeting the eligibility requirements on the day they received their cancer diagnosis or shortly thereafter. Once the physician had met and discussed the diagnosis with the patient, a research assistant who spoke the patient's language (English, Spanish, or Haitian Creole) introduced the study using the informed consent as a guide. The patient was presented with a brief description of the study, a copy of the informed consent and would decide whether they would like to discuss the study further or have the research assistant contact them at another time. Research assistants followed up with those patients that were eligible and interested in participating until they made a decision about enrollment or exceeded the 30 day period from diagnosis to be enrolled. The research team maintained a presence in clinic and engaged both the new and existing providers at tumor board conference and through frequent email communication.

Assignment of interventions

16. Allocation

1) Comparison of study groups on demographic and clinical characteristics will be done to assess the success of randomization. With our stratified blocked randomization scheme, treatment groups will be balanced with regard to gender, insurance (public/private) and race (white/non-white) in a manner proportionate to those in the study population.
2) To ensure balanced group assignment on key demographic characteristics, randomization for Breast Cancer patient (females only) will be based on race (white/nonwhite) and insurance status (private/public) resulting in the following strata:
    a. White, Private insurance
    b. White, Public insurance
    c. Nonwhite, Private insurance
    d. Nonwhite, Public insurance

3) If differences in baseline characteristics are detected on other characteristics, these will be included as covariates in later analyses.

17. Blinding

The study statistician conducted the randomization procedure using the statistical software package R version 12.0 [ref]. For each group (a through d above), study participants will be randomized into one of the two treatment groups: patient navigation with legal aid, or standard patient navigation, using a block randomization design to ensure that some balance between treatment groups is achieved as the study progresses. Random block sizes of 2 and 4 will be employed in a random order. Within blocks of size 2, one patient will be randomly assigned to receive patient navigation with legal aid (Intervention) while the other patient will receive patient navigation only (Control). In block sizes of 4, two of the four patients will randomly be assigned to receive patient navigation with legal aid while the other two patients will receive patient navigation only.

The investigator and clinicians assessing the outcomes of the study will remain blinded to each participant's treatment group assignment until the study is completed.

The randomization scheme developed by the Biostatistician will be incorporated into the RedCap data management system. When Screening forms are entered into Redcap, those patients that enroll will be randomized based on their strata and linked to study Ids in RedCap.

Ref: *R Core Team (2012). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. ISBN 3-900051-07-0, URL http://www.R-project.org/*

Assignment of Study ID- each patient that is eligible and has signed a consent form, will be entered into the RedCAP project for the study, confirming eligibility before the system randomizes participant into the intervention or control group. The patient will be assigned a unique 4 digit study id. The first digit will identify which cancer type the patient has been diagnosed with (1 for Breast, 2 for Lung) and then numbers will be assigned in sequential order.

- Ex: The 5th Breast cancer participant will have Study ID 1005
- Ex: The 29th Lung cancer participant will have Study ID 2029

Data collection, management, and analysis

18. Data Collection

General Instructions for Completing Forms

- Forms completed by the participant:
    - Surveys will be administered by the study RA
    - RA will speak with patient preferably in person but possibly over the phone to administer surveys.
    - The RA will verbally ask the patient each question on the surveys, to ensure consistency in understanding and account for differences in literacy levels of study participants.
    - Responses will be marked on survey instrument and returned to office for data entry and proper storage.
    - Before completing the interview session the RA will review the surveys to ensure there are no missing items or data, and if any items were left blank the RA will follow-up with the participant before the end of their meeting to collect any missing data

- Forms completed by research personnel:
    - Screening information, clinical abstractions will be completed by trained research personnel
    - Training- study team members will be trained on abstracting relevant data from the Electronic Medical Record. Training will cover basic cancer care and treatment as well as how to review an electronic medical chart and identify key clinical data elements for data collection
    - Adjudication/quality review- to ensure quality data a clinical adjudication team will review and confirm key clinical data elements. Key variables will be abstracted by a second abstractor, results compared and discrepancies flagged for resolution by Data Manager

19. Data Management

Missing data/integrity of data
Every six months data will be reviewed by the Data Manager, the Biostatistician and the Analyst to determine if any patterns for missing data are present. If issues are found, adjustments will be made to the training and data collection protocol.

Retention

To minimize attrition research assistants worked with each patient's schedule to identify a convenient meeting time for the patient to complete his/her surveys. Patients had the option of completing follow ups in person or over the phone. The flexibility of the research assistants coupled with their language concordance with the patients and incentives provided after each follow-up, contributed to study retention and high follow up rates.

REDCap Data management system

REDCap is a password protected, HIPAA compliant, web-based application for building and managing online surveys and databases. It also has the ability to track and report on study progress at the participant level as well as the study level. Data Collection forms will be entered onsite through REDCap by a trained member of the research staff. For quality assurance purposes, 10% will be verified by a second staff member.

Data Storage
All paper data collection tools will return to the WHU office after completion. They will be stored in a secure, locked cabinet within the office, only accessible to study staff with ID access and will be retained for 7 years after the last participant has completed the project.

20. Statistical methods

Population under study: Patients newly diagnosed with breast or lung cancer at BMC who volunteer to participate in the study and complete the I-HELP general legal screen at baseline to indicate the presence of legal need.

Analysis

Primary Clinical Outcomes: To measure the impact of patient navigation enhanced by MLPB intervention on *receipt of timely and quality cancer care:*

- Our primary analysis will use multiple logistic regression models to compare the proportion of patients with *timely initiation of treatment* across study groups, adjusting for the influence of race/ethnicity (white vs non-white), cancer site, insurance status (private vs public), and other covariates that may have a significant effect on the outcome and may be unbalanced across the two study groups.
- Study groups will also be compared on the secondary clinical outcome of *time to initiation of primary cancer treatment* (the number of days from diagnosis to start of treatment) through Kaplan-Meier survival curves (unadjusted analyses) and Cox proportional hazards regression models controlling for cancer site and other covariates (adjusted analysis).
- *Receipt of quality care* for each cancer type will be analyzed through logistic regression.
- For the analysis of the rate of missed appointments, patients will differ on the number of scheduled appointments over the study period. We will generate summary measures of the rate and total numbers of missed appointment for the total study cohort and by treatment group.
- The primary analysis will include only participants who have legal issues at baseline (defined by the results of their baseline I-HELP general legal screen, which will take place within one month of new diagnosis). This will be the official sample of patients which the sample size calculations are based (n=117 in each group adjusting for 10% dropout).

Secondary outcomes: To measure the impact of patient navigation enhanced by MLPB intervention on patient-reported outcomes: *distress, needs, and satisfaction*:

- Patient-reported outcomes will be measured at baseline, 3 month follow-up, 6 month follow-up, and 12 months using summation scores with established subscales.
- Multiple linear regression models controlling for baseline levels of the outcome (i.e., analysis of covariance models) will be used to compare study groups on changes in *distress* and *psychosocial needs* at follow-up. Multiple linear regression models will also examine intervention effects on *satisfaction* scores.
- Covariates in each model may include age, race/ethnicity, stage of disease, and other covariates that may have a significant effect on the outcome and may be unbalanced across the two study groups.

Monitoring

21. Interim Analyses

Due to the nature of the study interim analyses will not be performed.

22. Harms

Involvement in this study has minimal risks. The main potential risk of this study is loss of confidentiality. It is unlikely that this will occur as several safeguards in place, including, entering data into a HIPAA compliant database requiring two-step authentication with passwords, keeping forms in a locked cabinets and only conducting data analysis on a data set that is coded and does not contain any direct identifiers. There is also a risk that some of the questions may make the participants feel uncomfortable. Participants will be reminded that they can refuse to answer questions that they are uncomfortable with.

23. Auditing

An external audit was not required for this project. However, eligibility for each participant enrolled will be verified by the Study Coordinator or the Data Manager.

Ethics and Dissemination

24. Research Ethics Approval

This protocol, the informed consent forms (Appendix 32.2), and associated study documentation was reviewed by the Boston Medical Center IRB and Research Ethics Committee for scientific content and compliance with all applicable research and human participants regulations and subsequently approved on 12/04/2013.

25. Protocol Amendments

Any modifications to the protocol which is determined to impact the study will be subject to review and approval by BMC IRB. This may include but is not limited to changes of objectives, design, patient population, sample sizes, or procedures. Administrative changes to the protocol that are determined to have no effect on study conduct will be documented by the internal study team throughout the course of the study.

26. Consent

Prior to consent the all interested subjects will be informed that they may be asked sensitive questions, including questions about the medical status of the patient and their family members, income and means of support, health insurance and current housing situation, immigration status or domestic violence. The patients assigned to the navigation arm will be asked more sensitive questions than the standard navigation arm due to the questions contained in the legal intake. They will be informed that they do not have to answer any questions that make them feel uncomfortable, and that not participating or not answering any questions will not impact the medical care they receive. If the patient is unable to stay after their oncology appointment to enroll in the study but they are interested in participating, informed consent will be conducted and the patient will be given the option of coming to BMC at another time to meet with the PN in a private setting or complete the baseline and follow –up surveys over the phone. To review the informed consent procedure and associated form refer to Appendix 32.2 and 32.3 respectively.

27. Confidentiality

We have many safeguards in place, including keeping files in a locked cabinets and only conducting data analysis on a coded data set that does not contain any identifiers. Only IRB approved study staff will have access to the study data. All paper related materials for this study that contains identifiers will be stored in a locked cabinet in the PIs office and only the PI and RA will have access to it. All data will be kept on a password protected computer and only the study PI and study RA will be able to access it. The password to access the data will be changed every 60 days. It is also possible that the participants may feel uncomfortable about some of the questions being asked as they might be perceived as sensitive in nature. The participants will be informed that they don't have to answer any questions that make them feel uncomfortable and can stop the interview at any time.

28. Declaration of Interests

BMC Investigators, MLPB and research team members complete an annual Conflict of Interest form required by the Compliance department at BMC and TSNE.

29. Access to Data

All data will be stored at BUMC and analyzed by BUMC staff. Research staff may look at aggregate data during research meetings. All participants will be assigned a subject ID code during the informed consent process and will only be known by this assigned ID code during discussions with MLPB and during data analysis. The master code for subject IDs will only be seen by the patient navigator who will be doing the initial consenting of the participants and assigning the code, the research assistant and study PI listed on the study application. All data will be kept in a locked office and on a locked computer. The Principal Investigator will be given access to the cleaned data sets.

30. Ancillary and Post Trial Care

Due the low risk nature of the study, ancillary provisions were not required.

31. Dissemination Policy

The Project SUPPORT research team, Scientific Advisory Board and the Patient Advisory Group will work together to consider options for dissemination and the best way to convey the results of complex statistical analyses. The research team has generated a list of potential analyses and papers, beyond the primary outcome and who will act as a lead author for each of these potential papers.

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Appendices

32. Consent Form and Other Participant Documentation

32.1 Recruitment Materials

Research Study Opportunity

Project SUPPORT (Socio-legal Services for Underserved Populations thru Patient Navigation to Optimize Resources during Treatment)

We are doing a study on medical-legal issues that could impact cancer care and treatment. This study is trying to test what type of patient navigator training works the best for cancer patients at BMC. Participants will be randomly placed in one of two groups; one group will be assigned a standard patient navigator, one group will get a patient navigator who has special training in legal needs common to cancer patients.

Who can join the study?

- Newly diagnosed breast or lung cancer patients who get cancer care at Boston Medical Center
- Over 18 years of age
- Speak English, Spanish or Haitian Creole.

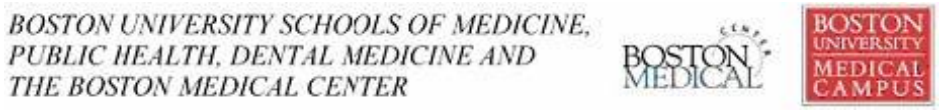
What will I have to do?

You will complete surveys within one month of your diagnosis, 3 months, 6 months and 1 year later. We will also get some medical information about your treatment from your medical record.
You will receive a $25 CVS gift card every time you take the surveys. You can make $100 in CVS gift cards for your involvement in this study.

Participating in this study will not affect your care. All information given will not be shared with anyone outside of the research team.

If you are interested in participating in PROJECT SUPPORT please contact the research assistants: at 617-XXX-XXXX

32.2 Consent Form



RESEARCH CONSENT FORM

Title of Project: Project SUPPORT (Socio-legal services for Underserved Populations thru Patient Navigation to Optimize Resources during Treatment)

IRB Number: H-32599
Sponsor: Patient Centered Outcomes Research Institute, (PCORI) and the Medical Legal Partnership, (MLP) Intervention.

Principal Investigator:
Tracy Ann Battaglia, MD, MPH
Tracy.Battaglia@bmc.org
Center of Excellence in Women's Health
801 Massachusetts Avenue
Boston, MA 02118
617-638-8036

Background
This research study is being conducted by a research team from Boston Medical Center (BMC) and the Medical Legal Partnership| Boston (MLP|Boston). MLP/ Boston is not part of BMC but is a private non profit that BMC is partnering with for this study. You have been invited to participate because you have recently been diagnosed with Breast or Lung Cancer.

Purpose
The purpose of this study is to see if assessing legal needs of newly diagnosed breast or lung cancer patients leads to better clinical outcomes.

What Happens In This Research Study
You will be one of approximately 374 subjects to be asked to participate in this study.

The research will take place at the Boston University Medical Center.

Once you have agreed to participate in the study, you will be asked to complete 8 different surveys. These surveys will ask you questions about your level of distress, housing issues, disability issues, employment issues and personal stability. These questions will help us learn more about you and any problems you might be having.

After you finish those surveys you will be put into one of two groups. One group will receive assistance from a patient navigator (PN). This Patient Navigator will remind you of your upcoming appointments and help you with any issues that may make it difficult for you to come to an appointment. The other group will have a Patient Navigator that also has special training to help patients who have legal needs. If that Patient Navigator decides you are in need of legal services she will get you access to a lawyer from MLP/Boston free of charge. You will not have a choice which group you are placed in for the study. The assignment to one group or the other is done by random placement, like the flip of a coin.

You will be asked to complete several surveys 3, 6 and 12 months later so we can see how your needs have

changed over time. In addition to the 3, 6 and 12 month surveys, we will call you at 9 months to confirm or update your contact information. These surveys can be done either in person at one of your doctor appointments or over the telephone. It will take around 60-90 minutes to complete the surveys now and when you take them again at 3, 6 and 12 months.

If you are enrolled in the group that gets access to a lawyer, and your answers to the questions asked in the study indicate that you need to speak with a lawyer, that meeting with the lawyer is estimated to take an additional 60-90 minutes. We will also collect information about your medical status from your medical record at 6 and 12 months after enrollment. We will look for data on your cancer treatment and overall health.

Risks and Discomforts

It is possible that you may be uncomfortable answering certain questions. If this happens, you may skip those questions. There is a small risk that people who are not the researchers could find out information that is collected. However, the study staff has taken steps to minimize this risk and will make sure all study materials are stored securely where only study staff can see them. Once the intake interview is completed all data will be coded in a special way and you will only be known by a coded study ID and your name and contact information will be kept in a separate location.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

Potential Benefits

There is no direct benefit for participation. If you are in the intervention part of the study, this study may help identify an unmet legal need(s) and the potential to meet with a legal representative from the MLP/Boston to help you.

Alternatives

You can contact your local legal aid services or a private lawyer for help with any legal or social service needs or concerns you may have. You do not have to be in the study. If you choose not to be in the study you may receive the usual patient navigation to assist you with your appointments if your doctor feels that it would be helpful for you.

Subject Costs and Payments

There are no costs for you to participate in this study. You will be compensated with a $25 gift card once you have completed each part of the study (Enrollment, 3 6 and 12 month surveys) for a total of $100.

Confidentiality

Information from this study and from your medical record may be reviewed and photocopied by the state and federal regulatory agencies such as the Office of Human Research Protection as applicable, and the Institutional Review Board of Boston University Medical Center. Information from this study and from your medical record may be used for research purposes and may be published; however, your name will not be used in any publications.

Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

You may obtain further information about your rights as a research subject by calling the Office of the Institutional Review Board of Boston University Medical Center at 617-638-7207.

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, Use the phone number on the first page of this form.

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect your being able to get health care at this institution or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

Protection of Subject Health Information

You have certain rights related to your health information. These include the right to know who will get your health information and why they will get it. If you choose to be in this research study, we will get information about you as explained below.

- medical information from your medical chart will be collected as part of this study

HEALTH INFORMATION ABOUT YOU THAT MIGHT BE USED OR GIVEN OUT DURING THIS RESEARCH:

Information from your hospital or office health records at BUMC/BMC or elsewhere. This information is reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside of BUMC/BMC, you will be asked to give permission for these records to be sent to the researcher.

□ New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

WHY HEALTH INFORMATION ABOUT YOU MIGHT BE USED OR GIVEN OUT TO OTHERS

The reasons we might use or share your health information are:

□ To do the research described here

□ To make sure we do the research according to certain standard set by ethics, law, and quality groups

PEOPLE AND GROUPS THAT MAY USE OR GIVE OUT YOUR HEALTH INFORMATION

□ PEOPLE OR GROUPS WITHIN BUMC/BMC

- Researchers involved in this research study
- The BUMC Institutional Review Board that oversees this research

□ PEOPLE OR GROUPS OUTSIDE BUMC/BMC

- People or groups that we hire to do certain work for us, such as data storage companies, or laboratories.
- Federal and state agencies if they are required by law or involved in research oversight. Such agencies may include the U.S. Department of Health and Human Services, the National Institutes of Health, the Massachusetts Department of Public Health.
- Organizations that make sure hospital standards are met
- The sponsor(s) of the research study, and people or groups it hires to help them do the research

- Other: MLP BOSTON

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must. We ask anyone who gets it from us to protect your privacy. However, once the information leaves BUMC, we cannot promise that it will be kept private. In most cases any health data that is being given out to others is identified by a unique study number and not with your name. So, although in some cases it is possible to link your name to the study data, this is not usually done.

TIME PERIOD FOR USING OR GIVING OUT YOUR HEALTH INFORMATION

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

YOUR PRIVACY RIGHTS

□ You have the right not to sign this form that allows us to use and give out your health information for research. If you don't sign this form, you can't be in the research. This is because we need to use the health information to do the research.

□ You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the researchers in charge of this research study.

If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.

□ You have the right to see and get a copy of your health information that is used or shared for research. However, you may only get this after the research is finished. To ask for this information, please contact the person in charge of this research study.

IF RESEARCH RESULTS ARE PUBLISHED OR USED TO TEACH OTHERS

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.)

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

_____

Subject (Signature and Printed Name) Date

_____

Person Obtaining Consent (Signature and Printed Name) Date
BUMC/BMC

_____

Witness (Signature and Printed Name) Date (To be used if applicable)