Building a Multidisciplinary Bridge Across the Quality Chasm in Thoracic Oncology

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PCORI SPECIFIC AIM #3 (with process engineering sub-aim) RESEARCH PROTOCOL

Objective(s) of the study

The objective of this study is to provide rigorous evidence of the impact of multidisciplinary care on lung cancer patient outcomes. Multidisciplinary care is a model of care in which patients, their caregivers, and key specialists concurrently and directly evaluate the same patients in the presence of the patients and their informal caregivers, in order to develop evidence-based consensus care plans. Within the Baptist Memorial Health Care system, the Multidisciplinary Thoracic Oncology Program has two components: Primarily, the program is centered in a multidisciplinary clinic, wherein patients and their informal caregivers are seen by multiple specialists at a single appointment time; secondarily, the program includes a multidisciplinary conference, wherein all of the specialists potentially involved in lung cancer care discuss patients referred for presentation and make consensus recommendations for care. This study focuses primarily on the experience and outcomes of care delivered to patients evaluated in the multidisciplinary clinic. However, data from the conference may also be included in some aspects of the study. The goal is to improve the access and quality of thoracic oncologic care delivery within the Baptist Healthcare System.

The project is broken into three specific aims. The first specific aim has already been submitted separately and approved by the Baptist and University of Memphis IRBs. The second specific aim has been deemed exempt from IRB review as a quality improvement measure. The final specific aim is as follows:

> ***Specific Aim #3*** - Perform a prospective, matched cohort comparative effectiveness study of patients receiving serial vs. multidisciplinary care, with key patient-centered endpoints (survival, stakeholder satisfaction with the care experience, quality of life, timeliness and stage-appropriateness of care, quality of staging). Serial care is defined as the current system of linear, sequential, referral-based care delivery.
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> In an exploratory sub-aim, we will use computer simulation modeling provided by a process engineer to retrospectively and prospectively measure and optimize the efficiency of patient flow through the healthcare system.

Background

Lung cancer kills 160,000 patients annually; this represents 28% of all US cancer deaths. The overall annual survival rate has only improved from 12% to 17% in 33 years. This failure reflects the innate lethality of lung cancer, but also reflects defects in patient care delivery. Care for the lung cancer patient starts with an abnormal radiologic scan, proceeds through a diagnostic biopsy, tests to determine the extent of spread of the disease (stage), selection of appropriate treatment, and finally ends with patient outcomes. At each step are multiple options and independent specialists, each one engaged by a process of sequential referrals in the serial care model. This process is often not user-friendly, is riddled with inefficiency, delays, and outcome variances.

The coordinated multidisciplinary model, in which patients and their doctors collaborate to provide evidence-based care, is believed by experts to be superior, but has few examples of successful implementation. The implementation gap exists because of the paucity of good quality data, and lack of implementation know-how.

Embedded in the highest US lung cancer mortality zone, the greater Memphis area has a racially, culturally, economically, and geographically diverse population. Our research group has shown how poor quality care impairs patient survival in this region and in the greater US. We have linked patient survival to compliance with multidisciplinary care plans. In this project, we propose to rigorously test the impact of the multidisciplinary care model on patient outcomes in a community-based, private practice environment, similar to where 70% of lung cancer care is delivered in the US.

Study design

Specific Aim #3 – In this aim, we seek to conduct a prospective comparative effectiveness study, using outcomes meaningful to all key stakeholders, and covering all six Institute of Medicine (IOM) dimensions of quality improvement (safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity). Specifically, we will perform a prospective matched cohort comparative effectiveness study of the two models of care available to lung cancer patients in the Baptist Memorial Health Care system (multidisciplinary and serial). The study will focus on end-points derived from direct feedback from patients and other stakeholders in Specific Aim #1, supplemented by our prior experience, and the existing literature. These endpoints are:

1. Completeness of staging;
2. Stage-appropriate treatment rate;
3. Patient, caregiver, and provider satisfaction with the care provided;
4. Patient and caregiver quality of life;
5. Patient and caregiver perception of their inclusion in the decision-making process;
6. Survival

In an exploratory sub-aim, we will use the retrospective and prospective data generated from the routine delivery of care to lung cancer patients within the Baptist Healthcare System to develop computer simulation models of the flow of care (process engineering) to examine the most efficient pathways of care. By these means, we will critically evaluate the pattern, quality and efficiency of care within our healthcare system, using patient-centered and other stakeholder-relevant endpoints.

Research setting

Clinical care will take place within the Baptist Memorial Health Care system (Memphis metro, DeSoto County, MS, NEA Jonesboro, Oxford, MS and Golden Triangle) and data abstraction will take place at the Baptist Cancer Center in Memphis, TN. Patient, caregiver, and physician surveys for feedback will be administered by trained personnel within the research group, supplemented (as necessary) by a HIPAA-compliant professional survey company pre-approved by the administration of the Baptist Memorial Healthcare Corporation. All data analyses will be performed by statisticians at the University of Memphis, School of Public Health, using coded, de-identified, anonymized patient, caregiver, and provider data. The process engineering sub-aim will be performed by Dr. Jingshan Li at the University of Wisconsin - Madison using anonymized, coded, de-identified patient data.

Main outcomes to be measured

The main outcomes to be measured are measures of implementation success, quality of care and outcomes of care. Specifically, the outcomes are patient, caregiver, and clinical provider satisfaction

scores, patient and caregiver quality of life, timeliness of care, completeness of staging, surgical resection rate, stage-appropriate treatment rate, and survival.

Methods or procedures

This study will evaluate the quality of care received within the healthcare system by using the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework. We will use a combination of quantitative data analysis, computer simulation modeling, and analysis of survey responses to address the different components of the RE-AIM framework.

We will begin Specific Aim #3 after a 3-month lead in phase, during which we ensure that all performance targets from Specific Aim #2 are being reliably measured. This aim will include administration of a series of patient, caregiver, and provider surveys as well as analysis of the quality benchmarks mentioned above. Specifically, we propose to perform a prospective, matched cohort comparative effectiveness study of eligible patients receiving care within the multidisciplinary environment versus matched controls concurrently receiving usual, serial care in the same healthcare system.

Eligibility criteria:

Multidisciplinary cases will have an untreated but biopsy-confirmed lung cancer diagnosed, preferably within 8 weeks of screening for study eligibility. Therefore, patients will still need either a staging evaluation or selection of first line therapy, the types of decision-making most often required in lung cancer care.

Controls will be selected from the pool of patients receiving usual ('serial') care within the same institution. Two serial care controls will be matched to each multidisciplinary care case. To be eligible for inclusion, a serial care patient must have an untreated biopsy-confirmed lung cancer, diagnosed preferably within an 8 week window surrounding the diagnosis of the case to whom he/she will be matched (4 weeks prior through 4 weeks after the case's diagnosis), and will be matched hierarchically based on several matching criteria: clinical stage, performance status, insurance status, race, and age range.

All multidisciplinary clinic patients will be screened for eligibility before their initial clinic visit. If a patient is determined to be eligible to participate in Specific Aim #3, they will be approached for consent to the study by the clinical research professionals during their initial visit.

Potential serial care patients will be pre-screened for matching eligibility by the above criteria before a multidisciplinary patient has consented to participate in the study. However, potential serial care patients will not be approached for consent until after a matching multidisciplinary patient has consented to participate in this study. Each week, a list of potential matching serial care patients will be provided to the thoracic oncology research group by Baptist Health Information Management (HIM). Patients are included on this list based on an algorithm of specific ICD-9 diagnosis and CPT procedure codes that are potential identifiers of lung cancer patients who fit the matching criteria of this specific aim. Multidisciplinary clinic staff will pre-screen from the list provided by HIM on a regular basis to identify potential serial care matches. Once a multidisciplinary patient has consented to the study, these potential serial care matches will be prioritized by closest adherence to the matching criteria of the corresponding multidisciplinary patient. This list of potential serial care matches will be supplemented by lists of new lung cancer patients provided by the treating groups (medical oncology,

radiation oncology, surgery) within the Baptist healthcare system. Any potentially eligible serial care patient will then be communicated to the clinical research professionals. The clinical research professionals will then work through the list to find and consent up to two serial care patients, along with their caregivers, to the prospective comparative study.

For clinical provider feedback, we will survey clinical providers referring patients into the multidisciplinary thoracic oncology clinic and providers actively participating in the multidisciplinary thoracic oncology clinic.

REACH – To evaluate the reach of the multidisciplinary clinic, we will collect extensive data on all patients participating in Specific Aim #3. These data will cover the full timeline of a patient's care for lung cancer, including details of their history of lung-cancer-related care prompting their entry into the healthcare system, of their experience within the system, of their expected treatment and their actual received treatment, and finally the outcome of their treatment. These data will be analyzed to define the characteristics of multidisciplinary patients versus serial care patients, which will in turn address questions about the reach of the multidisciplinary clinic (i.e., what kinds of patients are likely to come into contact with multidisciplinary care and what kinds of patients do not?).

EFFECTIVENESS – In order to evaluate the effectiveness of the two models of care, we will analyze the data referenced in the Reach component. We will also administer surveys to all participating patients, their caregivers and their clinical providers. We will test our ability to obtain patient, caregiver, and clinical provider feedback using several instruments (specific questions will be drawn from the attached self-report patient, caregiver, and clinical provider measures and tailored to each stakeholder group as appropriate).

Patient feedback will be obtained on (a) satisfaction with care, and (b) quality of life (QOL), including both health-related QOL and depression/anxiety. Patient satisfaction will be measured using existing measures and measures created specifically for this study. The existing measure was originally developed for the Consumer Assessment of Healthcare Providers and Systems (Hays et al., 1999) and used in the Cancer Care Outcomes Research and Surveillance (CanCORS) Consortium (Ayanian et al, 2004; 2010), and assesses the interpersonal aspects of cancer care. Its 13 items load on three factors, including physician communication (e.g., "How often did your doctors listen carefully to you?"), nursing care (e.g., "How often were your nurses as helpful as you thought they should be?"), and coordination and responsiveness of care (e.g., "How often did the doctors, nurses, and other medical staff providing your care seem to work well together as a team?"). The three factors have been shown to have good internal consistency (Cronbach's alphas ranging from 0.84-0.86 for the three factors for both lung cancer patients and surrogate respondents (family members) (Ayanian et al., 2010). We also will use single items from CanCORS to assess overall rating of care ("Overall, how would you rate the quality of your health care since your diagnosis of cancer?") and perceived relative quality of care ("Would you say that you received medical care that was better than, about the same as, or worse than other patients with lung cancer?"). In addition, we developed items to tap aspects of satisfaction related to specific outcomes of this project, including satisfaction with the timeliness of care (e.g., "How satisfied are you with the length of time between learning that you might have cancer to being diagnosed?"), perceived obstacles to completing treatment, and perceived quality of care from specific care team members (e.g., oncologist, nurse navigator).

Patient QOL will be measured using two validated instruments. Health-related QOL will be measured with the Functional Assessment of Cancer Therapy – Lung Cancer (FACT-L) scale. The FACT-L is a widely

used, psychometrically sound, 37-item, multidimensional instrument that includes five sub-scales. Sub-scales assess physical, functional, social, and emotional domains of QOL plus lung cancer-specific symptomatology. The FACT-L has demonstrated reliability, validity, and sensitivity to within-person change (Browning et al., 2009; Cella et al., 1993, 1995, 2002; Paull et al., 2006). It is written at the 4th grade reading level, has been validated for use with special populations such as older adults and those living in rural areas, and has demonstrated equivalence in mode of administration (interview vs. self-administration).

Patient depression and anxiety will be measured with the Hospital Anxiety and Depression scale (HADS; Zigmond and Snaith, 1983), a widely used 14-item instrument to evaluate depression and anxiety in clinical populations. It was created specifically to avoid reliance on aspects of depression and anxiety that are also common somatic symptoms of illness, such as fatigue and sleep difficulties. The HADS has been extensively validated in both clinical and non-clinical populations (Bjellanda et al., 2002; Trask et al., 2004).

We also will collect data on satisfaction with care and quality of life for the main informal caregiver (defined as the person who gives the patient the greatest amount of assistance and care on a day-to-day basis) for each patient who is enrolled in the study. Satisfaction measures will parallel the measures used with patients (described above). Caregiver health-related QOL will be assessed using the Short Form (36) Health Survey (SF-36; McHorney et al., 1994). The SF-36 is a widely used and validated measure of health-related QOL. It contains 36 questions and yields a psychometrically-based profile of physical and mental health in eight areas, including vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health. The SF-36 has been validated in a number of populations, including caregivers (Bell et al., 2001, Machnicki et al., 2009) and is sensitive to change among clinical groups over time (Hemingway et al., 1997). Depression and anxiety will be assessed with the HADS, which also will be administered to patients (described above). Lastly, caregiver burden will be assessed using the Brief Assessment Scale for Caregivers of the Medically Ill (Glajchen et al., 2005), a validated 14 item scale that taps both negative (e.g., distress, lack of time) and positive (e.g., making the relationship with patient closer) aspects of caregiving.

For clinical provider feedback, we will use 2 instruments. The first instrument assesses provider satisfaction, focusing on the stated benchmarks of this study. It was developed specifically for this study, based on published surveys of provider experiences delivering cancer care (Taylor et al., 2012a, 2012b, Patkar et al., 2011; Shulman et al., 2013). The second survey is a multidisciplinary care workforce and workflow survey that seeks to identify obstacles to institutional multidisciplinary care.

The specified program benchmarks for survey administration and responses are as follows:

1. Ability to get satisfaction score responses from 60% of patients, caregivers and providers after interaction with the multidisciplinary care program;

2. Patient satisfaction scores corresponding to a 5 or 6 on a 6-point Likert-type scale (very satisfied or satisfied, respectively) in >80% of patients in surveys administered after initial clinic evaluation;

3. Provider satisfaction scores corresponding to a 5 or 6 on a 6-point Likert-type scale (very satisfied or satisfied, respectively) in >70% of providers in surveys administered after each provider's active

interaction with the clinical program, either by direct participation (for participating providers) or after referring 5 patients into the program (for non-participating providers).

Certain multidisciplinary clinic staff (clinical research professionals) will be assigned with administering these surveys. These clinical research professionals will meet with patients during their initial visit to the Multidisciplinary clinic for the purpose of consenting patients to participate in the survey administration arm of the study and possibly to participate in the prospective comparative effectiveness study (Specific Aim #3). Once a patient/caregiver dyad gives consent to participate, surveys will be administered up to three times – once near the beginning of contact with the multidisciplinary clinic, a second time after a c. 3 month interval, and a third time after another c. 3 month interval (c. 6 months from the initial baselines survey). For clinical providers, surveys will be administered three times – once near the beginning of contact with the multidisciplinary clinic, and then two more times at 6 month intervals (after 6 and 12 months). Every attempt will be made to administer surveys to patients, caregivers, and clinical providers in person. If that is not possible, surveys may be taken over the phone, or by mail, but only if necessary. Patient dyads will be compensated with a $10 Kroger gift card upon successful completion of the last round of surveys. Caregivers and clinical providers will not receive any financial compensation.

As noted above, extensive data will be compiled that encompasses the full scope of patients' experience of care for lung cancer, from initial discovery to the conclusion of treatment. To evaluate the effectiveness of patient care, extensive analysis will be performed by researchers at the University of Memphis, School of Public Health, (co-investigators on the grant, signed to a Baptist-approved subcontract) with specific attention given to timeliness of care, completeness of staging, surgical resection rate, and stage-appropriate treatment rate. The de-identified, aggregate results of this analysis will be shared with process engineers at the University of Wisconsin-Madison (co-investigators, signed to a Baptist-approved subcontract) who will use computer simulation modeling to map, measure and optimize the efficiency of patient flow through the healthcare system. Finally, the effectiveness of the clinic will be evaluated using survival time as an outcome, using data from institutional records, supplemented by the Social Security Death Index.

ADOPTION – The adoption domain of the RE-AIM framework will focus on the characteristics of physicians who participate (by referring patients into the clinic or directly providing care within the multidisciplinary environment) versus those who do not participate. This information will be collected by comparing multidisciplinary thoracic program referral records to the list of relevant specialty physicians credentialed within the BMHCC catchment area of the multidisciplinary program. Physician characteristics to be compared include demographics (age, gender) and training/practice (specialty area, years of practice, practice setting).

IMPLEMENTATION/MAINTENANCE – will be measured for the multidisciplinary program as a function of Specific Aim #2.

Data or samples to be collected

All patients will be provided a unique database identifier to anonymize research data.

Patient demographics

- sex
- race
- date of birth

- zip code of residence
- health insurance coverage
- clinical assessment
  - performance status
  - family history of cancer
- comorbidities
- smoking history
- additional risk factors

Pre-treatment care experience
- method of detection
- disease related procedures
  - radiographic scans
  - biopsy procedures
  - provider office visits
  - evaluation for chosen treatment modality

Multidisciplinary conference experience
- date of presentation
- details of patient history at time of presentation
- consensus management recommendations

Multidisciplinary clinic experience
- date of clinic visit
- details of patient experience in clinic
- treatment decisions made

Tumor characteristics (pre and post-op)
- details of T-category
  1) tumor size
  2) tumor laterality
  3) site of tumor invasion (if any)
- details of N-category
  1) number and details of suspected lymph nodes
  2) number and details of pathologically examined lymph nodes
- details of M-category: location and details of metastatic disease (if any)
- histology
- grade
- cumulative AJCC staging (clinical and pathologic)

Details of treatment
- surgery
- chemotherapy
- radiation therapy
- palliative/hospice care only
- timeline and outcomes of therapy

Benchmarks/Endpoints

Patient survival – as measured from the time from cancer diagnosis to death or data censor.

Timeliness of care – aggregate time from enrollment to specific care delivery endpoint; compared to British Thoracic Society recommendations.

Thoroughness of staging – proportion of patients with histologically confirmed (i.e.. biopsied) stage-defining lesion

Appropriateness of treatment selection – Stage I or II: surgery (or radiation therapy with documented contraindication to surgery or patient refusal) Stage III: chemotherapy and radiation therapy with or without surgery Stage IV: systemic therapy (or palliative care with documented patient refusal or contraindication to systemic therapy)
Timeliness of communication – official, verifiable communication of management decisions with providers inside and outside the multidisciplinary program and official, verifiable communication of management plans with patients and their care-givers.
Survey response rate – for patients, for caregivers, for clinical providers; number of responses versus number administered
Survey responses –measured by qualitative analysis of completed surveys

Inclusion criteria

All patients who undergo care for lung cancer or an undiagnosed lung mass within the Baptist Memorial Health Care Corporation's hospitals from January 1, 2009 until the end of the defined study period will be eligible for inclusion in the data collection for this study. In addition, caregivers of patients within the same institution and within the study window, clinical care providers (doctors and nurses) who have taken care of patients within the eligible institutions during the study window.

Exclusion criteria

Patients who do not have a biopsy-confirmed lung cancer are excluded from this study.

Vulnerable populations

No vulnerable populations will be included in this study.

Length of study

Generally, this project is funded by a 3-year grant, which starts on February 3, 2014 and ends on February 2, 2017, with the possibility of extension by up to 1 year (February 2, 2018). However, because of the need to demonstrate program sustainability, we will continue to measure the quality benchmarks that constitute specific aim 2, as a key ongoing quality improvement exercise for the clinical multidisciplinary program. In addition, because of the primary endpoint, overall survival, it may be necessary to continue long-term follow up of patients for up to 5 years after enrollment of the final patient in specific aim 3, the comparative effectiveness study.

Number of study sites

Specific Aim #3 involves the Baptist Memorial Health Care Corporation system.

Number of subjects

Specific Aim #3 will match 150 patients undergoing care in the multidisciplinary clinic with up to 300 similar patients concurrently undergoing serial care for a total of 450 patients.

However, for the process engineering sub-aim, and to examine the domains of Reach and Adoption, all patients who receive lung cancer care from January 1, 2009, onward, and the clinical providers of lung cancer care, will need to be accessible for limited data abstraction.

Sample size calculation

150 multidisciplinary clinic patients matched 1:2 with 300 serial care patients = 450 patients for Specific Aim #3. The 150 multidisciplinary clinic patients will all be selected from the estimated 960 patients examined in Specific Aim #2. We powered the prospective comparative cohort study in Specific Aim #3 based on the survival analysis. Assuming power = 80%, alpha= 0.05, two sided test, mortality rate 40%, and hazard ratio 1.25, we estimate the total sample size 427 using Cox regression procedure in PASS 11. Since Baptist Health Care System manages >800 new cases each year, 300 of which are expected to be seen in multidisciplinary clinic, in practice, we conservatively expect to be able to recruit 150 cases from multidisciplinary clinic and 300 matched serial care controls (1:2 match) in 18 months.

The above sample size estimate is based on our preliminary data. Among eligible patients, about 30% of cases are stage I/II, 30% stage III, and 40% stage IV. The corresponding one year mortality rates are 15%, 30% and 50%, respectively, and two year mortality rate is 30%, 50% and 70% respectively. Thus we estimated the range of the mortality rates from 30% to 50% in our mixed sample with a median follow up of 1.5 years. Furthermore, we estimate the relative difference in survival 20%-30% (i.e., hazard ratio between 1.2-1.3) between multidisciplinary program and controls, based on the hazard ratio reported in a study of early palliative care for stage IV lung cancer patients. Based on the above ranges, additional power analysis with a sample of 450 showed that, to reach the power 80% or above, hazard ratio is 1.3 for mortality rate of 30%; hazard ratio of 1.25 for mortality rate of 40%, and hazard ratio of 1.22 for mortality rate of 50%. A higher hazard ratio or higher mortality rate will yield larger statistical power. The sample size is adequate (power >90%) for detecting differences in rates of histologic confirmation of stage and selection of stage-appropriate treatment (20% absolute rate difference).

Statistical analysis

Specific Aim #3 will require descriptive analysis. The percent of benchmark outcomes (Table 1) will be presented. We will use Chi-square test for categorical variables such as thoroughness of staging and treatment selection. T-tests will be used for continuous variables such as timeliness of care (days, logarithm transformed). All analyses may be stratified by race, gender, socio-economic status, and insurance status. Since we will measure the quality of care outcomes regularly during the whole study period, trend analysis will be conducted to monitor the change of these outcome measures. Computer simulation models will be used for pathway optimization analysis. In addition to descriptive analysis, statistical modeling will be the main tool to compare the quality of care and survival between multidisciplinary program and controls, adjusting for measured confounders. As noted, there are three types of outcomes: categorical outcomes such as thoroughness of staging, and receipt of stage-appropriate treatment; continuous outcomes such as timeliness of care, and survival events. In addition, since we will implement matching in the prospective cohort study by entry criterion, clinical staging, performance status, insurance status, race, and age range, matching analysis will be used. Specifically, in the multivariate models, we will use the conditional fixed effects logistic regression for binary categorical outcomes; fixed effects generalized linear model with Gamma distribution and logarithm link for timeliness of care; and fixed effects proportional hazard model for survival analysis. The matching pair indicates the fixed effect. These can be analyzed by commands such as xtlogit with fe option, or stcox with strata option in Stata.

Furthermore, because care delivery and treatment differ between patients with stage I/II and stage III/IV, stratified analysis will be conducted by staging groups. Both descriptive analysis and analytical models will be used. However, statistical power may be insufficient for the stratified analysis.

Models for categorical outcomes: Assuming Yi represents whether the patient receives stage-appropriate care (yes/no), and Gi represents whether patient is in multidisciplinary program or matched control, and Xi represents other confounders except matching variables. The conditional fixed effect model can be expressed as $\text{Log}(p(Yi=1)/p(Yi=0))=\beta*Gi+\gamma Xi$. Note that intercept and matching variables are not estimated. The exponent of β is the odds ratio of receiving stage-appropriate care between multidisciplinary v. control. For other categorical outcomes, models and interpretations are similar.

Models for timeliness of care: The timeliness of care is measured in days: for example, days from the first diagnostic imaging test (earliest date of chest X-ray or CT scan) to receiving the actual treatment (surgery, chemotherapy, radiation, or hospice care); days from the first diagnostic imaging test to multidisciplinary clinic visit, and days from multidisciplinary clinic visit to treatment commencement. These variables are inherently right skewed and can be fit with Gamma distribution. In the fixed effects generalized linear model, $\text{Log}(daysi)= \beta*Gi+\gamma Xi$, the shape and scale parameters of the gamma distribution will be empirically determined based on all observations in each group. The exponent of β is the geometric mean difference of days (similar to median difference) between multidisciplinary program and controls.

Models for survival events: All patients will be followed up for at least one year from the beginning of the study (with a median of 1.5 year). The follow up time will be longer if the starting time is retrospectively tracked back to the date of first imaging diagnosis. Assuming ti represents the time (days) from the first imaging diagnosis to death, h(ti) is the corresponding hazard function, the proportional hazard model is $\log(h(ti)) = \beta*Gi+\gamma Xi$. The exponent of β is the hazard ratio of survival between multidisciplinary program and controls. In addition, the proportional hazard assumption in the model will be examined visually by plotting - log(log(survival)) and time, and also by statistically testing by adding time interaction in the model. We will also visually compare the survival curve difference using Kaplan-Meier estimate and log rank test for curve difference between two groups. Finally, the Fine-Gray competing risk model will be used to compare lung cancer specific death.

Analyses for self-reported satisfaction with care and quality of life: patient, caregiver, and provider satisfaction scores are measured using survey methods. Surveys also are used to measure quality of life, including health related quality of life and depression/anxiety (in patients and caregivers) and caregiver burden (in caregivers only). For each measure, summary scores will be calculated according to the instructions in each survey instrument. Although the scores based on Likert scales can be treated as continuous variables, we will dichotomize the satisfaction scores as satisfactory (scores 5-6 on a 6-point scale) and unsatisfactory (scores 1-4), to correspond to our benchmark criteria. Descriptive analysis and logistic model similar to the previous analyses will be used.

Potential benefits to subjects/others.

There may be no direct benefits to participants in this study. However, improvement in quality of lung cancer care is a potential direct and indirect benefit to study subjects of participation in this study. Findings of this study will be made readily available to local institutional administrators, to give them ongoing feedback on the performance of the multidisciplinary program, in order to reinforce the lung cancer quality improvement process within the whole institution. The long term benefit of this study to the lung cancer community at large is the potential overall enhancement of knowledge about ways to improve the clinical care for lung cancer patients and thereby improve the outcomes of care. In addition, the knowledge gained from this study will inform the delivery of care to all patients with complicated health problems requiring the involvement of multiple different experts in the delivery of care, in the full spectrum of the healthcare system.

Risks to subjects

The primary potential risk to study subjects is a potential breach of confidentiality causing leakage of personally identifying information. However, in 18 years of conducting clinical research, including 8 years of conducting population-based lung cancer research in the region, including the National Institutes of Health-funded Memphis Metropolitan Area Quality of Surgical Resection project, with a database similar to what is proposed for this study, we have not experienced any such breaches of confidentiality.

Data and safety monitoring plan

All study data will be stored in a protected location with access limited to approved research personnel. We will provide additional safeguards to minimize the risk of loss of patient confidentiality and any other plausible risk. All research personnel will comply with all applicable IRB and DHHS regulations, including mandated educational programs and guidelines. Subject information will be coded for anonymity. Only personnel with a need to know will have access to study information. Only coded, anonymized data will be electronically transmitted. All electronic databases will be password-protected. Hard copies of subject data will be locked in file cabinets in designated secure research locations with access limited to pre-specified research staff. All research staff will have undergone mandatory training on the performance of research on human subjects, prior to participating in this project.

The VICTR Informatics Core will be used as a central location for data processing and management. Vanderbilt University, with collaboration from a consortium of institutional partners, has developed a software toolset and workflow methodology for electronic collection and management of research data. REDCap (Research Electronic Data Capture) data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from the VICTR Informatics Core. The iterative development and testing process results in a well-planned data collection strategy for individual studies. REDCap servers are housed in a local data center at Baptist Memorial Hospital in Memphis, TN, and the University of Memphis, School of Public Health, and all web-based information transmission is encrypted. REDCap was developed specifically around HIPAA-Security guidelines and is recommended to researchers by both Vanderbilt's Privacy Office and Institutional Review Board. REDCap has been disseminated for use locally at other institutions and currently supports 240+ academic/non-profit consortium partners on six continents and over 26,000 research end-users.