PROTOCOL: Legal Evaluation for Greater Access to Cancer Care (LEGAL-CARE): A Randomized Pilot Feasibility Trial of a Legal Navigation Program
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1. Study Overview

Background and Rationale:
Despite an adept navigation workforce, the regulatory and legal landscape for patients with cancer has become increasingly difficult to navigate. Many barriers faced by patients are entrenched in local, state, and federal policies that require expertise in both social needs and the law. Our group led the first nationwide study investigating the extent to which patients with cancer encounter unmet legal needs related to disability, employment, health insurance, and financial assistance. The Legal Evaluation for Greater Access to Cancer Care (LEGAL-CARE) is a randomized pilot trial to test the feasibility of a legal navigation program. The goal is to address a critical gap in cancer care where patients carry high unmet legal need.

Study Design:
This is a single arm, pilot feasibility trial where 50 recruited patients will receive monthly outreach from a legal navigator over a 6-month period to address legal hardships during their treatment. This study will take place in UAB's medical oncology clinics and include patients aged 18 or older with newly diagnosed advanced stage cancer (stages III or IV) requiring systemic therapy. We hypothesize the legal intervention will be feasible, acceptable and improve patient outcomes.

2. Objectives

Primary Objective:

- **Assess the feasibility of implementing a legal navigation intervention**: Defined as a 70% retention rate and 75% completion of survey completion (at 3 and 6 months) during the 6-month intervention period. Retention and completion rates will be summarized with 95% confidence intervals.

Secondary Objectives:

- Assess the acceptability and appropriateness of implementing a legal navigation intervention
- Collect patient feedback through semi-structured interviews to inform future large-scale trials.
- Explore the impact of the legal navigation program on financial toxicity, quality of life, treatment delays, and healthcare utilization.

3. Study Population

Inclusion Criteria:

- Adult patients aged ≥18 years.
- Newly diagnosed with advanced-stage cancer (Stage III or IV).
- Requiring systemic therapy.
- Capable of providing informed consent.

Exclusion Criteria:

- Non-melanoma skin cancer or in-situ tumors.
- Patients with prior hospice encounters within the past year.
- Patients who are unable to participate in study procedures.

4. Study Procedures

Sample size:

As a pilot study, no hypotheses are being tested [1] (https://www.nccih.nih.gov/grants/pilot-studies-common-uses-and-misuses) therefore the study sample size is based on budgetary and logistic considerations to evaluate feasibility goals.

Screening and Enrollment:
Eligible participants will be identified during their oncology clinic visits and provided with information about the trial (**please see Appendix A for patient education materials**). After informed consent is obtained (**please see Appendix B for informed consent**), baseline assessments (noted below) will be conducted, before the legal intervention commences.

Data Collection:

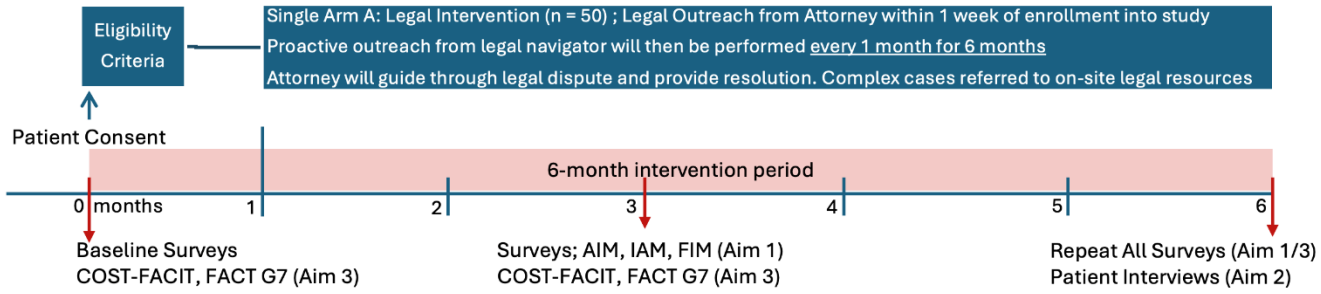
- **Baseline**: Demographics, medical history, and baseline survey of legal barriers and financial toxicity (COST-FACIT) and quality of life (FACT-G7) (**Appendices C-D**). You need to describe all the surveys, number of questions, and scoring here.
- **Follow-Up**: Surveys at 3 months and 6 months will assess changes in financial toxicity (COST-FACIT) and quality of life (FACT-G7). Additional surveys at these time points will include Assessing the Feasibility of Intervention (AIM), Intervention Acceptability Measure (IAM), and Feasibility of Intervention Measure (FIM) surveys (**Appendix E**). Information on delays in care (measured in days from first appt in our clinic to first visit for systemic treatment) and healthcare utilization (ER visits, urgent care visits, hospitalizations, ICU-level admissions, and palliative care uptake) will be obtained from the EMR at UAB (**please see Appendix F for EMR collection elements**).
- **Qualitative Interviews**: Conducted at the end of the 6-month intervention period to explore patient experiences and perceptions of legal intervention (**please see Appendix G for interview guide outline**)

Participant Incentives:
Participants will receive $30 at the end of completion of all surveys, and $50 for interviews. These incentives may be increased during the study period to maintain participation.

5. Study Intervention

Please see study schema below following details on

Fig – Study Schema



Intervention Overview:

- Participants will receive monthly outreach from a trained legal navigator over a 6-month period. The legal navigator is a lawyer (Juris Doctor, or JD) who will proactively address specific legal barriers the patient may encounter during treatment. Communication will include phone calls (and if requested, virtual consultations) tailored to patient needs. In between legal outreach periods, patients may call the legal navigator team themselves for legal needs that may arise. Legal navigator team will be from Triage Cancer, a

nationwide non-profit organization with a track record of assisting patients with legal barriers following a cancer diagnosis.

- While some of the challenges patients face-such as disability benefits, employment discrimination, health insurance denials, and financial assistance-may also be encountered by social workers, the role of legal navigators is distinct to that of social workers. Legal navigators specialize in interpreting and applying legal frameworks, understanding state and federal regulations, and providing direct legal guidance in areas where legal expertise is critical. For e.g., while a social worker may be able to re-direct a patient at risk of losing housing or financial assistance to additional community resources, a lawyer is able to help the patient interpret legal rights, assist with required paperwork, and provide guidance on navigating legal systems to remove barriers. Similarly, when a patient loses their job, experiences discrimination, or cannot be hired due to a cancer diagnosis and is losing their disability and/or employment benefits, it is the lawyer that is able to help the patient understand their legal rights. You require two completely different skillsets to assist with these, one that a social worker does not carry – that a legal navigator is trained to assist with
- This legal navigation approach ensures that patients receive specialized legal expertise in addressing complex, systemic barriers while complementing, rather than overlapping, social work services.

Intervention Details:

1. Monthly Outreach by Legal Navigator:

- **Frequency and Mode of Communication:**
  - Participants will receive **one scheduled outreach per month** for six months.
  - Communication will be conducted via phone calls, with an option for virtual consultations based on participant preference.
  - Each session will last approximately 30–60 minutes, depending on the complexity of the participant's needs.
- **Discussion Topics:**
  During each outreach session, the legal navigator will:
  - Identify new or ongoing legal barriers (e.g., insurance denials, employment disputes, housing issues etc).
  - Review progress on previously identified issues and any actions taken.
  - Provide tailored guidance and resources for addressing specific legal concerns.
  - Offer general legal education on topics such as:
    - **Health Insurance Navigation:** Medicaid/Medicare issues, private insurance appeals, COBRA, and coverage gaps.
    - **Employment Rights:** Understanding FMLA, ADA protections, and wrongful termination.
    - **Disability Benefits:** Applying for Social Security Disability Insurance (SSDI), Supplemental Security Income (SSI), or appealing denied claims.
    - **Financial Assistance:** Locating and applying for programs that provide assistance with medical bills, rent, or utilities.
    - **Estate Planning and Directives:** Creating or updating wills, advance directives, or power of attorney documents.

2. Tailored Legal Support:

- Legal navigators will assess each participant's unique situation and provide step-by-step instructions or direct assistance in resolving legal issues.
- For cases requiring specialized legal expertise or representation, participants will be referred to local resources, including Legal Services Alabama or other partner organizations.

3. Proactive Follow-Up:

- Navigators will follow up with participants regarding unresolved legal issues or new developments. Follow-ups will occur between monthly sessions if required.

4. Between-Session Support:

- Participants may initiate contact with the legal navigator team between monthly sessions for new or urgent legal concerns.
- Legal navigators will respond to patient inquiries within 2–3 business days and prioritize urgent issues such as impending housing eviction or denial of time-sensitive treatments.

5. Documentation:

- All interactions, including participant concerns, recommendations, and resolutions, will be documented in a secure system. This documentation will track intervention fidelity and outcomes.

6. Participant Resources:

- Participants will receive educational materials (print or electronic) summarizing key legal rights and resources discussed during the outreach sessions.

6. Data Management

Data Collection Methods:

- All survey will be collected through REDCap, a secure, web-based application for managing research data.
- All interview data will be managed and analyzed using NVivo, a secure software designed for qualitative data management and analysis
- Information on delays in care (measured in days from first appt in our clinic to first visit for systemic treatment) and healthcare utilization (ER visits, urgent care visits, hospitalizations, ICU-level admissions, and palliative care uptake) will be obtained from the EMR at UAB (**please see Appendix F**)

Data Monitoring:

The principal investigator (Dr. Qasim Hussaini), and clinical research coordinators (Ms. Indya Starks and Ms. Tanvi Padalkar) will regularly monitor data quality and completeness. An independent data monitoring committee (DMC) will be established to oversee the integrity of the data and patient safety.

7. Statistical Analysis Plan

Primary Outcome:

- **Feasibility**: Defined as a 70% retention rate and 75% completion of surveys (at 3 and 6 months) during the 6-month intervention period. Retention and completion rates will be summarized with 95% confidence intervals.

Sample size: We will recruit 50 patients to assess intervention feasibility, with no power calculation needed as efficacy is not the primary objective [1]. As a pilot study and consistent with NIH guidance, the sample size is not powered for formal statistical inference but was considered based on examining the feasibility and acceptability of the approach and on refining the intervention design and procedures in preparation for a future larger proposal [2].

Analytical approach: Led by the Dr. Hussaini (PI) with input from Dr. Andres Azuero (co-mentor biostatistician) and implemented by staff analyst, Dr. Luqin Deng (research analyst/statistician).

Assess feasibility of the intervention: Proportions of: a) eligible approached patients that accept to trial participation; b) proportion of participating patients retained at follow-up; and c) proportion of participating patients completing at least 75% of surveys, will be estimated and

confidence intervals will be computed with simple logistic or probit regression models and inverse link transformations. Descriptive statistics and measures of effect size (e.g., Cohen's d, Cramer's V) will be used to explore association between the proportions of interest and participant sociodemographic characteristics and reported legal barrier types.

Secondary Outcomes:

Explore patient perceptions of legal intervention impact: We will use qualitative methodology therefore biostatical approaches are not applicable. Sampling for qualitative inquires is sequential and targeted to individuals who can provide insights on the processes under study. Typically, pilot qualitative approaches involve ~20 participants and expect to have a sufficient participant pool to carry out the qualitative inquiry [3,4]. This sample size follows qualitative research best practices, ensuring thematic saturation while maintaining feasibility within the study timeline. If thematic saturation is not reached, we will increase this number.

Evaluate trajectory of financial hardship, health-related quality of life, delays in care, and health care utilization: Brief description followed by detailed statistical plan

- **Financial Toxicity**: Changes in COST-FACIT scores will be analyzed using linear mixed-effect models.
- **Quality of Life**: FACT-G7 scores will be analyzed at baseline, 3 months, and 6 months, with adjustments for baseline values.
- **Delays in Care**: Time-to-event analysis will be conducted using Cox proportional hazards models, comparing the time from diagnosis to treatment initiation between the two groups.
- **Healthcare Utilization**: Emergency department visits and hospitalizations will be analyzed using generalized linear mixed models. Results will be presented as mean ratios or odds ratios.

Here we will use repeated measures (baseline, 3 month, and 6 months post-intervention) of survey measures (collected directly) and utilization rates (extracted from EHR). Baseline characteristics and outcomes will be examined with descriptive statistics and measures of effect size. For survey outcome scales (COST-FACIT and FACT-G7), linear mixed-effect models will be fitted with all available data to estimate mean outcomes at each time-point by group. Linear contrasts will be used to estimate mean differences between groups at the follow-up times, adjusted for baseline and 95% confidence intervals will be computed. The models will be of the form $\widehat{Y_{ij}} = \beta_0 + \beta_1 Y_0 + \beta_2\, T1 + \beta_3 T6 + \beta_4\, LEGAL + \beta_5 T1 \times LEGAL + \beta_6 T6 \times LEGAL + \gamma_i$, where $\widehat{Y_{ij}}$ is the value of an outcome for subject *i* at time *j*, β_1 is the coefficient for the baseline outcome value (Y_0), β_0, β_2, β_3 are coefficients specific to the reference group (enhanced usual care), β_4, β_5, β_6 are coefficients specific to the legal intervention group, $LEGAL$ is a binary indicator of group, $T1$ is a binary indicator for time at 1-month post-intervention, and $T6$ is a binary indicator for 6 months. Linear combinations of model coefficients allow estimation of means by group as well as mean differences. The between-group contrast at 1-month post-intervention (adjusted for baseline) is estimated by $\beta_4 + \beta_5$, and the between-group contrast at 6-months (adjusted for baseline) is estimated by $\beta_4 + \beta_6$. Baseline SDs will be used to rescale the contrasts into standardized measures of effect (Cohen's d). For delays in care, we will use time-to-event analysis methods, such as Cox proportional hazards models, to compare the time from new diagnosis to treatment initiation between enhanced usual care and legal intervention groups. Hazard ratios will be estimated with 95% confidence intervals. For health care utilization measures, generalized linear mixed-effect models will be used. Here, a link-transformation of the expected outcome value is modeled. For discrete count outcomes (e.g. urgent care visits) a default link-transformation is the natural logarithm of the mean, and for binary outcomes (e.g. whether a hospitalization occurred) a default link-transformation is the natural logarithm of the

odds ($odds = p/[1-p]$). Inverse-link transformations will be used to estimate estimated expected values of the outcomes by group at each time-point. For count outcomes, contrasts are estimated as mean ratios, and for binary outcomes contrasts can be estimated as odds ratios (default) or as relative risks (if the model is fitted with a log-link and a robust standard error). 95% confidence intervals will be computed. We will use SAS (version 9.4M8) and R (version 4.4.2) for the statistical analysis of quantitative data.

8. Safety and Adverse Events

Safety Monitoring:
Any adverse events related to the legal intervention will be recorded and reported to the IRB. Although legal navigation is a low-risk intervention, any significant issues related to stress, patient dissatisfaction, or legal complications will be addressed by the study team.

9. Ethical Considerations

This study will be conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines. Informed consent will be obtained from all participants, and confidentiality will be maintained. Study approval is on track to be obtained from the UAB Institutional Review Board (IRB).

10. Dissemination of Results

The results of this trial will be published in peer-reviewed journals and presented at major oncology conferences, including ASCO and/or ASCO Quality Care Symposium. Patient-friendly summaries will also be disseminated through advocacy organizations and local clinics. Collaboration with Legal Services Alabama and Triage Cancer will help ensure broader dissemination to policy-makers and healthcare providers.

11. Timeline

Milestone	Timeline
IRB Approval and Protocol Finalization	Pre Grant
Training Phase	Months 1-3
Recruitment Initiation	Month 4
Completion of Enrollment	Month 16
Primary Data Collection (Baseline, 3-month, 6-month)	Months 4-24
Data Analysis	Months 14-26
Manuscript Preparation	Months 24-30
Dissemination	Months 28-36

12. Conclusion:

The LEGAL-CARE study addresses a critical gap in cancer care where patients carry high unmet legal need, and existing support structures—both at home and within medical teams—are inadequate to manage these unmet legal needs. It will be the first oncology study to evaluate the feasibility of proactive legal navigation intervention and assess its impact on patient outcomes. It will create a unique partnership between a cancer center and its providers and social workers, local legal aid groups in Alabama, and national non-profit legal groups in the US. Finally, the LEGAL-CARE study will provide key implementation insights in preparation for a larger multi-site trial that may support the scalability and long-term sustainability of legal interventions in cancer care in diverse geographic and clinical settings.

14. Appendices

- **Appendix A –** Patient Education Materials
- **Appendix B –** Patient Consent Form
- **Appendix C** – Survey Instruments (COST-FACIT)
- **Appendix D** – Survey Instruments (FACT-G7)
- **Appendix E** – Survey Instruments (AIM, IAM, FIM)
- **Appendix F** – EMR Collection Elements
- **Appendix G** – Interview Guides

References:

1. Pilot studies: Common uses and misuses. NCCIH. Accessed March 30, 2024. https://www.nccih.nih.gov/grants/pilot-studies-common-uses-and-misuses

2. Teresi JA, Yu X, Stewart AL, Hays RD. Guidelines for Designing and Evaluating Feasibility Pilot Studies. *Med Care*. 2022;60(1):95-103.

3. Polit, D.f. and beck, C.t. (2017) Nursing Research Generating and Assessing Evidence for Nursing Practice. 10th Edition, Wolters Kluwer Health, Philadelphia, 784 p. - references - scientific research publishing. Accessed October 3, 2024. https://www.scirp.org/reference/referencespapers?referenceid=2325091

4. Hennink M, Kaiser BN. Sample sizes for saturation in qualitative research: A systematic review of empirical tests. *Soc Sci Med*. 2022;292(114523):114523.