Colorectal Cancer Legal and Administrative Burden Support (COLLABS): A Pilot Clinical Trial

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ABSTRACT

PURPOSE Engagement with legal teams after a cancer diagnosis—medical-legal partnerships (MLPs)—can identify, prevent, and resolve health-harming legal needs (HHLNs). Cancer Legal Care (CLC) is a nonprofit providing free legal services to persons affected by cancer in Minnesota. We sought to conduct a pilot study of delivering proactive and free legal support through CLC.

METHODS We conducted a single-arm, mixed-methods pilot study to assess the feasibility and acceptability of delivering legal support, and preliminary efficacy in addressing HHLNs to 20 adults with advanced-stage colorectal cancer. CLC staff conducted an initial screening visit, crafted an individualized plan, and provided structured as well as personalized legal support over the 6-month study period. We collected patient-reported outcomes (assessing comfort with health-related tasks, financial toxicity, stress, coping, and self-esteem) at baseline, 3 months, and 6 months, and conducted end-of-study interviews to explore participant experiences.

RESULTS The study met predefined feasibility (90% of participants completed initial screening visit, 90% remained engaged, 80% completed the study) and acceptability (81% of participants recommended the intervention to others) benchmarks. The initial legal checkup visit lasted a median of 45 minutes, 61% self-identified HHLNs, and CLC attorneys identified additional HHLNs for 72%, with median 3 HHLNs per participant. On the basis of participant preference, 100% of visits were virtual, with attorneys spending a median 3.5 hours per participant, often also supporting individuals with administrative burdens and providing emotional support. After the 6-month study period, participants expressed greater comfort with tasks such as addressing unexplained bills, guardianship planning, and ensuring insurance coverage compared with baseline. Participants noted very high satisfaction with the interpersonal relationships with CLC staff, felt empowered and supported, and suggested including informal care partners in future work.

CONCLUSION Proactive legal care to address HHLNs through a MLP was feasible, acceptable, and valued by patients. Despite no requirement for baseline legal need, HHLNs were prevalent and addressable. This work underscores the importance of further study on how interdisciplinary teams can best deliver sociolegal care to persons with cancer.

ACCOMPANYING CONTENT

- Appendix
- Data Sharing Statement
- Protocol

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INTRODUCTION

Patients with cancer often have health-related social needs (eg, housing instability, employment concerns, medical debt, etc).[1] In one study of patients recently diagnosed with cancer, 77% reported at least one sociolegal challenge.[2] In a multicenter prospective study, more than 70% of patients with newly diagnosed metastatic colorectal cancer experienced major financial hardship despite nearly all having health insurance.[3] Patients with advanced-stage colorectal cancer may be particularly vulnerable to health-related social needs, given the availability of effective but long-term treatments; colorectal cancer also affects broad sociodemographic groups (eg, younger adults and older adults, across sexes and race/ethnicities).[3,4] These challenges present as health-harming legal needs (HHLNs) and include issues such as employment discrimination, food insecurity, housing instability, and threats to physical safety.[5]

CONTEXT

Key Objective

To assess the feasibility and acceptability of delivering proactive legal support and its preliminary efficacy in addressing health-harming legal needs (HHLNs) among 20 adults with colorectal cancer through a medical-legal partnership (MLP) in a pilot study.

Knowledge Generated

Delivering legal support virtually was feasible and acceptable. Despite no requirement for baseline sociolegal need, HHLNs were common (median 3 per participant) with attorneys spending a median 3.5 hours per participant over a 6-month period, often also supporting individuals with administrative burdens and providing emotional support. Compared with baseline, participants expressed greater comfort with tasks such as addressing unexplained bills, guardianship planning, and ensuring insurance coverage.

Relevance

These data highlight the prevalence of HHLNs among unselected individuals with cancer and the potential role of MLPs in addressing these, while underscoring the importance of further study on how interdisciplinary teams can best deliver sociolegal care to persons with cancer.

Failure to address HHLNs are associated with financial toxicity, psychosocial distress, demoralization, delayed or forgone care, reduced quality of life, and worse survival.[6-10] Well-intentioned clinical teams often lack the resources, expertise, and processes to resolve these issues, many of which are actually legal in nature.[1] For example, historical housing discrimination is associated with worse contemporary access to colon cancer care and outcomes,[11] but clinical teams may be unable to directly affect important HHLNs such as housing. Medical-legal partnerships (MLPs) represent an advanced form of collaborative patient advocacy with the potential to proactively identify and resolve patient HHLNs.[2,5,12-19]

Cancer Legal Care (CLC) is a nonprofit organization providing free legal services to persons affected by cancer (patients and care partners) across Minnesota. CLC has served over 15,000 individuals residing in 79 of 87 minnesota counties since 2007. They offer an array of legal support, covering issues such as insurance coverage, Social Security benefits, employment and disability concerns, housing issues, debt management, and estate planning, alongside other identified issues. In a survey of 120 CLC clients (receiving CLC services in the past 2 years), the most common legal concerns included wills, powers of attorney, or health care directives (41%), employment issues (32%), and Social Security disability insurance (30%).[20] Clients indicated a preference for proactive connection to CLC services through their oncology care team, to overcome barriers to legal care access such as perceived legal costs. Despite enthusiasm for MLPs, existing models are often reactive, relying on ad hoc emergency referrals through unstructured pathways.[5,15,16]

We sought to conduct a pilot study designed to assess the feasibility, acceptability, and preliminary efficacy of providing free, proactive legal care services to patients with advanced colorectal cancer facilitated through their oncology care team to screen for and proactively address HHLNs.

METHODS

This was a single-arm pilot study conducted at the University of Minnesota/M Health Fairview/Masonic Cancer Center—a National Cancer Institute–designated comprehensive cancer center—in Minneapolis, Minnesota, in partnership with CLC. Each participant received personalized legal support from CLC over a 6-month period, with the option to continue receiving legal services beyond the study period off trial. Trial participation did not affect any cancer care activities. The trial was approved by the University of Minnesota Institutional Review Board. We obtained informed consent from all participants. The trial was registered at ClinicalTrials.gov (Identifier: NCT06475664).

Participant Selection

Eligible participants were English-speaking adults (age 18 years and older) with a diagnosis of advanced stage (AJCC stage III or IV) colorectal cancer and an estimated life expectancy >6 months. Non-Minnesota residents were excluded, because CLC can only provide services to Minnesota residents. To capture a range of experiences, participants could be at any point in their cancer course after diagnosis (did not require enrollment within a certain time period from diagnosis), and there was no formal screening or requirement of baseline sociolegal or financial concerns for participation. A total of 20 patients were planned and enrolled in this pilot study. The study was conducted between September 2024 and May 2025. Potential participants were

identified by their oncology care team and referred to the research team.

Study Design

After enrollment, participants were introduced to a CLC attorney for an initial legal care checkup. The CLC team has five attorneys on staff whose sole practice focused of on cancer-related legal needs: insurance denials for coverage of care, disability rights, employment protections, debt, and estate planning. Study-related tasks were largely completed by one attorney (R.K.) with previous professional experiences as a bone marrow transplant nurse and transplant coordinator. In addition to the in-house team, CLC has an expansive group of over 75 volunteer attorneys specializing in practice areas such as estate planning, disability rights, and employment. The timing and mode of this consultation (in-person, video, or phone) were based on patient preference. Initial consultations occurred within 2 months of enrollment and were scheduled for approximately 1 hour. During this meeting, (1) participants self-reported active issues, and (2) a CLC attorney used a standard issue-spotting checklist covering potential legal issues such as employment rights, insurance coverage or claims denial, health care provider billing, eligibility for Social Security disability benefits, mortgage or housing issues, estate planning, and debt management, to screen for additional issues. On the basis of the initial assessment, CLC developed personalized legal care plans, including actions such as legal consultation, document preparation, direct legal representation, or referrals to other resources or organizations.

After this initial legal checkup, participants could identify and request legal services at any time by directly reaching out to CLC through direct phone or email. CLC attorneys remained available for ongoing support throughout the study period, continuing to provide free legal services, and engaging with the oncology team to implement any medical interventions if needed. CLC staff conducted scheduled follow-up calls at 3 months (±1 month) and 6 months (±1 month) to determine if participant circumstances changed or if any new legal issues arose. The study schema is shown in Appendix Figure A1 (online only). The CLC team did not have formal documentation privileges in the electronic medical record and communicated the study/clinical care team as needed after seeking permission from participants.

Data Collection

We collected baseline clinical and sociodemographic information on the basis of self-report and the electronic health record. Upon enrollment, participants completed a baseline survey administered via REDCap before meeting with CLC staff (defined as month 0). Participants also completed these questionnaires at 3 months (±1 month) and at 6 months (±1 month). These surveys assessed patient-reported outcomes (PROs), including stress (Perceived Stress Scale-4),[21] coping ability (Pearlin scale),[22] financial burdens (COST measure),[23,24] quality of life (Spitzer Uniscale),[25] distress (National Comprehensive Cancer Network distress thermometer),[26] self-esteem (Rosenberg scale),[27] life engagement (Life Engagement Test),[28] comfort level with accessing cancer care (Cancer Behavior Inventory-B),[29] and comfort level with legal-related tasks (adapted from the literature with input by the study team).[5,30] We included multiple efficacy PROs to assess the intervention's impact on multiple aspects of patients' lives. Additionally, we assessed a 13-item CLC Services Questionnaire, adapted from implementation science frameworks,[31] and a nine-item Patient Satisfaction with Interpersonal Relationship with Navigator (PSN-I).[32] PRO details are provided in Appendix Table A1. At the end of the 6-month study period, participants were invited to complete a semistructured interview. Qualitative interviews were audiorecorded, transcribed, and illustrative quotes were selected to reflect salient insights. Participants were offered $100 in US dollars (USD) compensation for their time.

Primary Outcomes

Feasibility was evaluated on the basis of three measures: (1) initial engagement (percentage who completed the initial legal care checkup), (2) continued engagement (percentage who remained in contact with CLC at 3 months), and (3) intervention completion (percentage who received at least one legal service). A priori feasibility was defined as ≥50% for each metric.

Acceptability was determined on the basis of participants rating their likelihood of recommending this intervention to other patients at 6 months using a Likert scale (1 = not at all likely; 5 = very likely). The intervention was considered acceptable if at least 50% selected a rating of ≥4.

Efficacy was assessed using descriptive changes in PROs. We recorded the outcomes of HHLNs and CLC interventions. We gathered participant and CLC staff feedback.

RESULTS

Enrollment and Sociodemographic Characteristics

We received referrals for and approached 23 patients and enrolled 20 patients. Reasons for nonenrollment included not being a Minnesota resident (n = 2, both Wisconsin) and feeling burdened by expected questionnaires (n = 1). We received referrals from nine different clinicians, including medical oncology and colorectal surgery physicians, advanced practice providers, and nurses. Of the 20 participants, 12 (60%) were male. Seven (35%) were age 31-45 years and six (30%) were age 61 years and older. Twelve (60%) were employed full-time or part-time, eight (40%) reported annual household annual income <$25,000 USD, and 12 (60%) were married or partnered. Baseline sociodemographic and clinical characteristics are outlined in Table 1 and Appendix Table A2. Two patients experienced intensive

TABLE 1. Select Participant Sociodemographic and Clinical Characteristics

Characteristic	No. (%) Total Number = 20
Age, years	
31-45	7 (35)
46-60	7 (35)
61-75	5 (25)
75+	1 (5.0)
Self-identified sex	
Male	12 (60)
Female	8 (40)
Self-identified race	
Black	2 (10)
White	18 (90)
Self-identified ethnicity	
Hispanic/Latino	1 (5)
Non-Hispanic/Latino	19 (95)
Household annual income, USD	
Under $15,000	6 (30)
$15,000 to $25,000	2 (10)
$25,000 to $50,000	4 (20)
$50,000 to $100,000	2 (10)
More than $100,000	6 (30)
Occupation status	
Working full time	9 (45)
Working part time	3 (15)
Retired	0 (0)
Long-term leave of absence due to cancer	8 (40)
Unemployed	0 (0)
Did patient have a designated care partner, and if yes, the relation	
Partner/spouse	13 (65)
Child/grandchild	3 (15)
Parent	2 (10)
No designated care partner	2 (10)
Colorectal cancer stage at enrollment	
III	7 (35)
IV	13 (65)

Abbreviation: USD, US dollars.

medical issues after enrollment, did not complete legal checkup visits, and were excluded from 3-month analysis (n = 18 at 3 months) and an additional two patients were withdrawn from study due to disease progression/death before 6 months (n = 16 at 6 months).

CLC Services and Follow-Up

All 18 participants who completed the legal checkup visit opted to schedule the initial checkup visit virtually (phone, 15; video, 3). The median (range) duration of initial consultations was 45 minutes (15-60). Eleven of the 18 participants came to the initial consultation with self-identified legal needs. Furthermore, 13 of the 18 participants had additional legal concerns that CLC attorneys identified with their legal screening. Overall, there were an average of three legal needs per participant (Appendix Table A3). Table 2 details illustrative examples of the range and impact of legal issues identified and addressed.

A total of 90 hours and 45 minutes of legal work was completed, median 3 hours and 30 minutes per participant (all pro bono to participants).

Feasibility and Acceptability Outcomes

All three feasibility metrics met our prespecified ≥50% threshold: 18/20 (90%) completed the initial legal care checkup meeting; 18/20 (90%) continued communications with CLC at 3 months; 11/20 (55%) continued communications with CLC at 6 months (55%); and 18/20 (90%) received at least one legal service by the end of 6 months. Participants also found the intervention acceptable—at 6 months, 13/16 (81%) indicated they were likely or very likely to recommend CLC services to other patients—meeting the predefined benchmark of ≥50%. The remaining three patients (19%) responded neutrally; no participants selected unlikely or very unlikely. The survey completion rates were 18/20 (baseline), 18/20 (3 months), and 16/20 (6 months).

Implementation Outcomes and Experience With CLC

Among the measures assessing Acceptability of Implementation, Implementation Appropriateness, and Feasibility of Intervention, the range of agree or completely agree across the four items within each construct was 69%-94% (eg, "The CLC referral and follow-up process meets my approval"; 15/16, 94%); 56%-62% (eg, "The CLC referral and follow-up process seems like a good match for my needs"; 9/16, 56%); and 69%-88% (eg, "The CLC referral and follow-up process seems easy to use"; 14/16, 88%), respectively.

Participants reported extremely high levels of satisfaction with their CLC contact (attorney) across PSN-I domains. For example, at 6 months, rates of agree or completely agree were 14/16 (88%) for "My CLC contact gives me enough time," 15/16 (94%) for "My CLC contact listens to my problems," and 14/16 (88%) for "My CLC contact is easy for me to reach."

Efficacy Outcomes

Comfort With Tasks

From baseline to 6 months, participants' comfort with accessing care and legal-related tasks largely improved (Fig 1). For example, the percentage of participants reporting increased (6-month minus baseline difference >0) comfort over time addressing unexplained bills (86%), guardianship planning and execution (77%), ensuring insurance coverage for cancer care (62%), seeking consolation/support (62%), sharing feelings of concern (56%), remaining relaxed and

TABLE 2. Select Illustrative Patient Experiences

Illustrative Scenarios of Patient Presentations to the Initial Legal Care Checkup	Actions and Outcomes
Presented with a range of issues; more uncovered during consultation	A client presented several legal issues including a $900 USD ambulance bill (equating to 25% of the household of eight's gross monthly income), housing stability concerns, and a request to receive Supplemental Security Income backpay. The CLC attorney also identified additional needs including understanding current benefits, the client's caregiver's lack of understanding of her basic rights of time off from work, and a need for additional financial resources CLC's Insurance Claims and Advocacy Resolution Program provided representation and advice to the client in navigating the $900 USD bill. The CLC team worked with the ambulance service and insurance and was able to determine the client actually held $45 USD member responsibility CLC's Social Security Application Assistance Program provided advice regarding the participant's desire to receive backpay and Social Security Disability Insurance. The program attorney was able to review documentation and advise the client in their misunderstanding of the current benefits that they were actually receiving, and how to receive additional benefits for their children CLC contacted the local Public Housing Authority on behalf of the client to advise on wait times and the effect of disability on the client's application The CLC attorney connected the family with financial resources and grants The CLC attorney advised the client's caregiver on their rights for time off from employment to care for the client
Chose to limit assistance to issues already known to them	A client was unemployed and experiencing food insecurity and significant financial need. The client had applied for Supplemental Security Income and Social Security Disability Insurance with the assistance of an outside attorney and received a denial CLC's Social Security Application Assistance Program subsequently provided representation to the participant in a formal request for reconsideration. Ultimately, the request for reconsideration was denied and the client was advised in filing an appeal and requesting a hearing. If approved, this would be a significant form of stable income for the participant The CLC attorney also informed the participant about potential public benefits including General Assistance and Supplemental Nutrition Assistance Program The attorney connected the participant with a local program offering an immediate one-time financial grant as well as other financial grants and no-cost community-based food resources
Presented with no identified legal concerns; significant issue identified during consultation	A client presented with no pressing issues Given the fact that he was employed, the CLC attorney advised the participant on their legal rights for time off from employment, concerns around disclosure of their diagnosis, and for requesting reasonable accommodations under the Americans with Disabilities Act related to their symptoms and treatment During the consultation, the CLC attorney identified that the client had a handwritten will but no legal will, health care directive, or power of attorney. The client did not realize that the handwritten will was not legally valid and that more formalized documentation would need to be put into place to effectuate his wishes. The client was represented in the preparation of these documents through CLC's Estate Planning program

Abbreviations: CLC, Cancer Legal Care, USD, US dollars.

not allowing scary thoughts to upset (me; 56%), accessing cancer care (53%), affording cancer care (53%), maintaining a good credit history (53%), and maintaining stable housing (50%).

Distress and Quality of Life

We observed minimal changes in distress and quality of life over 6 months. The proportion of participants noting minimal (−1 to +1 on a 10-point scale) changes in distress was 40% (median 5 at both 0 and 6 months) and quality of life was 62% (median 7 at both 0 and 6 months).

Financial Toxicity

The percentage of participants with moderate/severe financial hardship was high (70% at baseline) and decreased marginally to 63% at 6 months. Improvements were seen in items such as "I am able to meet my monthly expenses" (40% reported improvement), "I feel in control of my financial situation" (31% reported improvement), and "I am satisfied with my current financial situation" (31% reported improvement).

Psychosocial Outcomes: Self-Esteem, Mastery, Engagement, and Stress

We observed only minimal (±1) changes in measures of self-esteem, mastery, engagement, and stress from baseline to 6 months. The proportion with high self-esteem decreased from 5% to 0%; percentage with higher mastery was mostly unchanged from 55% to 56%; engagement scores above the median 18 (on a 6-30 scale with higher scores indicating higher engagement) changed from 100% at baseline to 94%; and the proportion with low stress decreased from 60% to 40%.

Qualitative Findings

Table 3 summarizes common themes from patient interviews and includes illustrative patient excerpts. Most participants had a positive impression of CLC, noting satisfaction with legal support received, the personalized nature of the legal care plan, emotional validation, and positive interpersonal interactions. Together, these accounts underscore the dual benefit of legal support, offering practical assistance while reinforcing a sense of control and

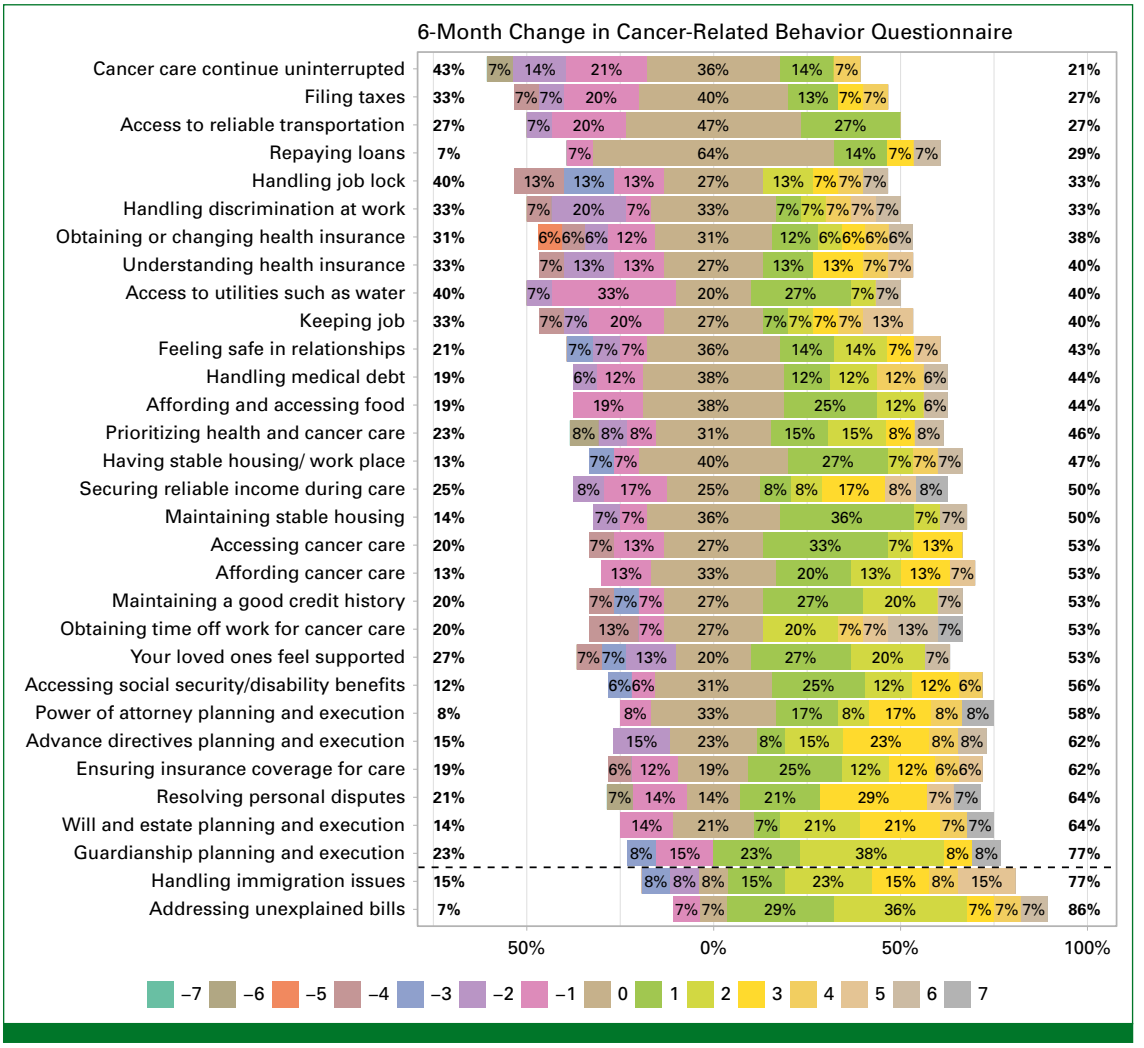

FIG 1. Participants' comfort with accessing care and legal-related tasks over time (brown = 0, no change on a 1-9-point scale in comfort with tasks at 6 months *v* baseline; positive numbers represented to the right of brown denote improvement in comfort levels at 6 months; negative numbers represented to the left of brown denote worsening). Each item on the *y*-axis begins with "How comfortable are you with/that…."

emotional security during an otherwise vulnerable period. Constructive feedback from participants included advocating for earlier access to legal care, including their care partners, and balancing cancer and treatment-related load with fully considering legal services.

CLC staff reported that engaging in the trial was meaningful and gratifying to them. They were able to proactively and directly work with the clinical team to address HHLNs, that otherwise would have gone unaddressed and progressed to a stage for which legal intervention would no longer be a viable option.

DISCUSSION

In this pilot study, embedding proactive legal support into routine oncology care for patients with advanced colorectal cancer was feasible, acceptable, and associated with increased comfort with cancer care access and health-related legal tasks such as addressing unexplained bills, guardianship planning, and ensuring insurance coverage. Despite not specifically selecting for or requiring individuals to have sociolegal needs, CLC attorneys identified a median of 3 HHLNs per participant. Participants noted very high satisfaction with the interpersonal relationships with CLC staff, felt empowered and supported, and suggested to include their informal care partners in future work. Together, these data support MLPs as an important resource to improve care experiences and outcomes, while providing input on the design of future trials and implementation efforts.

The primary finding of the study—that the CLC intervention was feasible and acceptable to participants—is notable and should be interpreted in the context of the history of MLPs in oncology, and the need for systematic research and implementation. In a prescient piece published in the *Journal of Clinical Oncology* in 2006, Fleishman et al claimed *attorneys as the newest member of the cancer treatment team*,[33] and legal

TABLE 3. Themes Identified During Participant End-of-Study Qualitative Interviews Regarding Experiences on the COLLABS Trial

Theme	Description and Illustrative Quotations
Feeling empowered, emotionally validated, and at peace	Several participants emphasized the depth and personalization of the CLC interactions. Several emphasized how the individualized nature of the intervention helped them navigate uncertainty and make informed choices. One described being "amazed at how much [the attorney] was able to invest his time in helping just one person… it felt like I was walking away with enough information to make decisions." Echoing similar sentiments, another participant shared, "I avoided a lot of dead ends I would've hit trying to do my own research," highlighting the appreciate for expertise and guidance provided by the legal team The intervention also appeared to support emotional well-being, with one participant reflecting on the empowerment that resulted from validation: "I was told… that my attitude toward life is very positive and inspiring… For them to say 'you've got the right approach,' I appreciated that." Another said, ''Every time I spoke with someone from CLC, I felt empowered and important. They truly made me feel cared for.'' Others noted the peace of mind that legal planning enabled for loved ones: "If anything were to happen to me… my [loved one relationship] doesn't have to worry about much."
Recommendation for earlier integration in disease course	Participants expressed frustration that they were introduced to legal services only as part of the research study, rather than earlier in their treatment journey. One participant commented, "I was kind of mad that I didn't know about [CLC] from my care team before this study. It feels like it should be in your welcome packet."
(Happy) surprise at legal issues identified and advice for the future provided at screening visit	Highlighting the value of proactive legal screening, one participant, initially unaware of any legal needs, was counseled on employment protections that they later leveraged, and also later received formal estate planning services. They noted "There were more [legal] needs uncovered during consultation than I had expected. That was an eye-opener.''
Desire for hybrid (virtual and in-person) interventions	While the fully virtual delivery provided convenience, one participant suggested that the lack of in-person interaction may have diminished engagement or clarity, remarking, "Some of the things that CLC offered, I found difficult to tackle… maybe there would be more structure if a few of [the appointments] were in person."
Intervention did not align with clinical need or clinical course	Some described the volume of information as difficult to act on, particularly when not aligned with their immediate needs. One participant shared, "CLC provided a lot of information/resources that I didn't follow through with… because it didn't fit with my current situation." Another reflected on the challenge of aligning study touchpoints with their clinical course, noting, "The timing of when I was meeting with CLC coincided with parts of my treatment that made my assessment points really difficult - unnecessarily so."
Supporting informal caregivers	Several participants mentioned how their caregivers often sat in with them for the meetings with CLC, and CLC willingly helped the caregiver as well. Their issues were often intertwined. Patients reported feeling guilt over burdening their loved one with taking time off work, helping care for the patient, and dealing with extra household tasks, and recommended the caregiver be included formally in the intervention In one case, a primary caregiver regularly joined CLC calls. Through these conversations, it emerged that she was unaware of her rights as a caregiver. She was provided guidance and resources to take caregiver leave under the FMLA and Minnesota's ESST law One stated, "I almost feel like they helped my wife more than me. She needed it more."

Abbreviations: CLC, Cancer Legal Care; ESST, Earned Sick and Safe Time; FMLA, Family and Medical Leave Act.

needs among cancer survivors have been well described.[14] In addition, the need for legal advocacy and intervention has intermittently come to light with particularly powerful stories.[34] However, the field has overall been held up by inconsistency in rigorous reporting and study.[5,35-38] Much of previous work has focused on identifying vulnerable patients with active legal issues, who might be more receptive to MLPs.[5] We recruited and studied the intervention in a population that was at different points in their cancer care, did not specifically seek or require patients to have HHLNs, and still demonstrated feasibility and acceptability—highlighting that the intervention may have broad applicability. Although we offered participants the option for in-person legal care, all screening and follow-up interactions with CLC were remote, although one participant retrospectively thought they would have liked an in-person meeting. The virtual delivery bodes well for future efforts focusing on patients in remote areas with often poor legal representation, referred to as legal deserts. A question and concern while designing the study was how patients in the midst of often-intensive cancer treatment would view an intervention that may not exactly apply to their situation. However, participants largely approved of the various facets of implementation outcomes. One participant noted that the intervention was not fully aligned with their immediate concerns, and a couple reported feeling overwhelmed by the volume of legal guidance and had difficulty acting on recommendations alongside ongoing cancer treatment. These findings reflect the need for some flexibility in the intervention, possibly with some part of the intervention available on demand. The 20% rate of attrition over 6 months in this study has two important implications. First, it can help with sample size calculations for future studies. Second, despite patient attrition, informal care partners can continue to have needs, such as transferred medical debt, even after a patient passes away. This highlights the importance of including care partners—more than two thirds of whom experience financial distress—[39]in future work, as also emerged in qualitative interviews.

This study provides other important takeaways for future studies evaluating MLPs, summarized in Appendix Table A4. First, despite no requirement for baseline sociolegal concerns in this study and all patients being insured and

receiving cancer care (thus selecting for those with potentially lower HHLNs), HHLNs were prevalent (median of 3, and CLC attorney's uncovered hidden HHLNs in more than 70% of participants). This aligns with previous work where three in four patients with cancer initiating cancer treatment had HHLNs.[2,40] This indicates that patients with cancer undergoing cancer care are particularly vulnerable to HHLNs, and while selecting the most vulnerable patients for interventions may sometimes be necessary and appropriate (especially given limited legal care capacity), HHLNs are pervasive and any individual with cancer may benefit from services. In our own clinical and legal experience, seemingly well patients and families can fall off a legal or financial cliffs during cancer care. Relatedly, while we did not require patients to be recently diagnosed in this study, participants in this study and in previous work expressed broad recommendations for having access to services earlier in their cancer course.[20] Previous work has sought to screen patients for HHLNs,[12,41-43] such as with the I-HELP acronym (Income, Housing and utilities, Education and Employment, Legal status, and Personal and family stability), often through social work, care coordinator, or nursing teams.[42-44] As the field evolves, a critical next step is to understand local care patterns, capacity, and pathways to assess how best to screen for needs and harmonize the efforts of the medical team including social work, financial navigation teams, community organizations, and formal legal care organizations. Indeed, even in the current work, legal work was driven by providing emotional support and administrative support to participants, in addition to formal legal care. Second, one of the motivations of this work was to evaluate and eventually nominate an efficacy outcome for future MLP studies. Previous studies have used a range of outcomes, including treatment initiation and completion, financial toxicity and well-being outcomes, and return on investments for health systems.[2,5] One of the issues in choosing an outcome(s) is that legal issues can often take time (months or years) for improvement or resolution, and ideally a sufficiently long time horizon should be chosen to reflect impacts, although short-term benefits can certainly be seen. Given the heterogeneity of needs and experiences, we believe a combination of comfort with health-related legal tasks, care access, and financial toxicity are the most relevant patient-centered outcomes. The relative stability of financial toxicity measures and some psychosocial outcomes over time in the current study should be interpreted in the context of these measures often getting worse over time,[45] thus, stability may actually denote protection. For a health system that might be investing resources, return on investment, for example, recouped costs from previously denied insurance claims, is an important outcome. One MLP embedded into a palliative care model clinic recovered more than $900,000 USD in overturned benefit denials across 3 years.[46] Since piloting insurance appeals work in 2019, CLC has closed 143 complicated insurance matters with a 94% success rate. Of the 143 closed matters, success included protecting or recovering $4,211,877.18 USD in health, disability, or life insurance benefits that had initially being denied to 72 clients by their insurance company. The individual client dollar amount ranges from $150 to $565,000 USD, with an average recovery/protection of $58,498.29 USD per client. These are bills clients would have had no way to pay on their own and would have been written off as charity care by the system and likely bankruptcy filing for many of these clients. Third, this was a pilot, single-arm trial, and ideally randomized trials with a control arm (eg, usual care, or enhanced usual care with social work support) can compare the resources/impact/return on investments between the groups. In a previous randomized controlled trial of standard-of-care versus an enhanced navigation intervention supported by legal advocacy in over 200 patients with lung and breast cancer, outcomes (timely cancer treatment and PROs) were similar between arms.[2] This may have been due to lower levels of legal concerns in the population, better than expected navigation support in the usual care arm, and contamination of usual care arm with the intervention. Finally, much of the previous MLP work has been done in the Northeastern United States.[5] Since legal organizations may have state-based practices, multicenter studies may require partnership with multiple legal organizations across states, making central organizations such as National Center for MLP critical.

Broader than the direct patient-centered outcomes achieved by an MLP as in the current initiative, academic MLPs have unique missions including educating trainees, creating interprofessional learning environments, and enhancing the evidence base through research, all of which we achieved through the current work.[47,48] They can also pursue policy and systemic advocacy, research and evaluation, and evaluate sustainable funding mechanisms. Because MLPs hold a unique position to encounter a variety of legal issues from a large number of patients and analyze the intersection of those legal issues with systemic and policy causes, MLPs can be a powerful driver of system change. For example, recently enacted legislation in Minnesota—the Debt Fairness Act—was supported by CLC. CLC used aggregate client data and anecdotal stories, gathered from the previous 5 years of its Insurance Claims and Advocacy Resolution Program, to inform state leaders of the need for the legislation. Additionally, CLC facilitated client storytellers who shared their experiences of medical debt with state leaders, one of whom testified to legislative committees and spoke to the media about his experience with medical debt. During the study conduct, the oncology care team noticed salient evolutions that went beyond the study—with consideration of patient HHLNs even off trial, more prevalent and effective communication with patients about costs and HHLNs, and more of a sense of teamwork between the interdisciplinary oncology care team, as has been previously described.[49] A key agenda for the current academic MLP, in addition to further research, is to evaluate sustainable funding models with potentially leveraging recent CMS Community Health Integration and Principal Illness Navigation codes.[50]

This study has limitations. First, as a single-site pilot with a small urban and predominantly White cohort residing within a single state over a 6-month period with state-specific labor and insurance laws, findings may not be applicable to other populations, settings, or durations. The duration of study did not allow for a comprehensive assessment of long-term legal outcomes, such as recoupment of funds, which often have a longer horizon. The small sample size did not allow us to formally explore how cancer characteristics (eg, stage, previous treatment, time since diagnosis etc) affected HHLNs. Second, our efficacy measures were exploratory in nature and may have been influenced by external events unrelated to the intervention. The relative stability of some psychosocial outcomes over the study is of unclear clinical significance without a control arm. However, the consistency of high engagement and positive feedback paired with illustrative qualitative insights provides a compelling foundation for future iteration.

In conclusion, the pilot clinical trial conducted through an academic MLP demonstrated that proactive legal support is both feasible and acceptable within oncology care. The intervention helped both uncover and address often hidden HHLNs, and was viewed by patients as a valuable component of their care experience. The legal team's work went beyond simply addressing legal issues; they often supported individuals with administrative burdens and by providing emotional support. As cancer programs expand efforts to identify and address social and legal needs, integrating legal expertise as part of interdisciplinary teams represents an important next step in delivering truly comprehensive and person-centered care.

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Colorectal Cancer Legal and Administrative Burden Support (COLLABS): A Pilot Clinical Trial

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APPENDIX

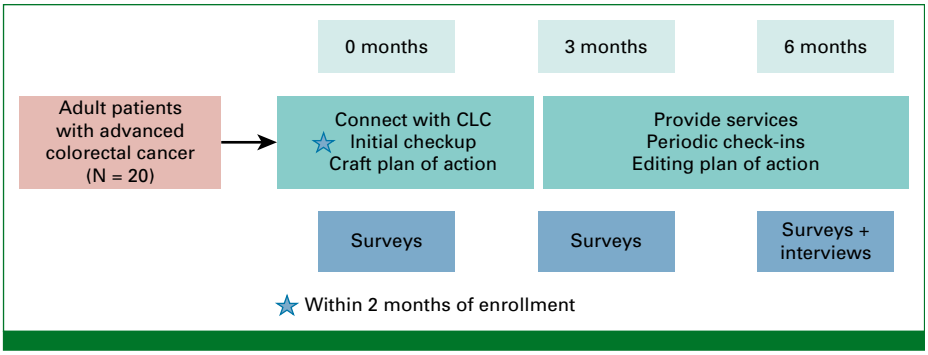

FIG A1. Schematic overview of the CLC intervention delivered over a 6-month period. CLC, Cancer Legal Care.

TABLE A1. Survey Instruments Used

Instrument Name	Data Collected	Scoring Summary
PSS-4	Perceived stress (4 items)	Range: 0-16; higher scores indicate more stress; score ≥6: high levels of self-perceived stress but cutoffs can be context dependent
COST	Financial hardship (12 items; 11 scored)	Range: 0-44; higher scores indicate lower financial toxicity; ≥26: mild/no financial hardship, 13-25: moderate financial hardship, <13: severe financial hardship
RSE	Self-esteem (10 items)	Range: 10-40; higher scores indicate greater self-esteem; with low self-esteem (10-25), medium self-esteem (26-29), and high self-esteem (30-40)
LET	Life engagement/purpose (6 items)	Range: 6-30; higher scores reflect greater engagement; no standard cutoff with context-dependent interpretation
Pearlin Mastery Scale	Sense of control/mastery (7 items)	Range: 7-28; higher scores indicate greater mastery; <18: lower mastery but cutoffs can be context dependent
Spitzer Uniscale (UNISCALE)	Overall quality of life (1 item)	Range: 0-10; higher scores indicate better quality of life
NCCN's distress thermometer	Cancer-related distress (1 item)	Range: 0-10; higher scores indicate greater distress
CBI-B version	Self-efficacy for coping with cancer (12 items)	Range: 12-108; higher scores indicate greater self-efficacy and comfort
Cancer-Related Behavior Questionnaire	Comfort with cancer-related behaviors (31 items)	No summary score; higher item responses indicate greater comfort
CLC Services Questionnaire[b]	Acceptability, appropriateness, feasibility (12 items), and likelihood to recommend (1 item)	5-point Likert scale; higher scores indicate more favorable perceptions
PSN-I[a]	Interpersonal experience and satisfaction with CLC contact (9 items)	Range: 9-45; higher scores indicate greater satisfaction; but no specific cutoffs

Abbreviations: CBI-B, Cancer Behavior Inventory-Brief; CLC, Cancer Legal Care; COST, Comprehensive Score for Financial Toxicity, v2; LET, Life Engagement Test; NCCN, National Comprehensive Cancer Network; PSN-I, Patient Satisfaction with Interpersonal Relationship with Navigator; PSS-4, Perceived Stress Scale-4; RSE, Rosenberg Self-Esteem Scale.
[a]Administered at 3 and 6 months.
[b]Adapted from Weiner et al.[31]

TABLE A2. Detailed Participant Sociodemographic and Clinical Characteristics

Characteristic, N = 20	No. (%)
Age, years	
≤30	0 (0)
31-45	7 (35)
46-60	7 (35)
61-75	5 (25)
75+	1 (5.0)
Sex	
Male	12 (60)
Female	8 (40)
Nonbinary	0 (0)
Race	
Asian	0 (0)
Black	2 (10)
White	18 (90)
Ethnicity	
Hispanic/Latino	1 (5.0)
Non-Hispanic/Latino	19 (95)
Unknown/decline to answer	0 (0)
Urban/rural residence	
Urban	20 (100)
Rural	0 (0)
Travel time to CSC	
<15 minutes	2 (10)
15-30 minutes	9 (45)
31-60 minutes	7 (35)
More than 60 minutes	2 (10)
Household annual income, USD	
Under $15,000	6 (30)
$15,000 to $25,000	2 (10)
$25,000 to $50,000	4 (20)
$50,000 to $100,000	2 (10)
More than $100,000	6 (30)
Highest education	
High school diploma	3 (15)
Associate's degree	7 (35)
Bachelor's degree	6 (30)
Advanced degree	4 (20)
Occupation status	
Full time	9 (45)
Part time	3 (15)
Retired	0 (0)
Long-term leave of absence due to cancer	8 (40)
Unemployed	0 (0)
Occupation	
Arts, entertainment, recreation	2 (10)
Health care and social assistance	4 (20)
Trade, transportation, utilities	1 (5.0)
Repair and maintenance	1 (5.0)
Religious organization	2 (10)
Professional and science	2 (10)
Finance	2 (10)
Long-term leave of absence due to cancer	2 (10)
Retired	1 (5.0)
Other	3 (15)
Marital status	
Single, never married	6 (30)
Partnered or married	12 (60)
Divorced	1 (5.0)
Widowed	1 (5.0)
Living arrangements	
Alone	5 (25)
With adult care partner, no dependents	13 (65)
With adult care partner and dependents	2 (10)
Did patient have a designated care partner, and if yes, who?	
Partner/spouse	13 (65)
Child	2 (10)
Sibling	0 (0)
Parent	2 (10)
Grandchild	1 (5.0)
No designated care partner	2 (10)
Insurance status	
Medicaid	1 (5.0)
Medicare	4 (20)
Private	15 (75)
Colorectal cancer stage	
III	7 (35)
IV	13 (65)
Time since diagnosis	
<1 year	4 (20)
1-2 years	5 (25)
2-4 years	6 (30)
More than 4 years	5 (25)

Abbreviation: USD, US dollars.

TABLE A3: Participant Legal Issues Identified and Addressed

S. No.	Client Identified Matters at Baseline	CLC Identified Matters at Baseline	Issues at 3-Month Follow-Up	Issues at 6-Month Follow-Up	Total Amount of Legal Work and Visit Time	Description of Legal Services Provided
1	Estate planning, housing, loans	Employment	SSDI	NA	4 hours	(1) Estate planning; (2) housing; (3) loans; (4) employment; (5) SSDI
2	NA	Employment, estate planning	NA	NA	3 hours 30 minutes	(1) Estate planning; (2) employment
3	Insurance—bill from ambulance; SSI backpay; SS benefits for children; housing	SSDI application; caregiver employment rights	Estate planning; housing; insurance—bill from ambulance	Housing	11 hours 30 minutes	(1) Insurance—bill from ambulance; (2) SS benefits: SSI backpay, SSDI application, and SS benefits for children; (3) housing; (4) estate planning; (5) caregiver employment rights
4	NA	NA	NA	NA	2 hours	NA
5	Medical malpractice (home health issue); products liability; death with dignity, hair prosthesis	Estate planning, food security, public benefits	NA	None—in need of psychosocial support connected with resource at clinic	8 hours 30 min	(1) Informed and gave attorney referrals for medical malpractice (home health issue) and products liabilities claim; (2) counseled regarding death with dignity in and outside of Minnesota; (3) evaluated insurance concerns regarding hair prosthesis; (4) counseled client regarding estate planning and achieving estate planning goals; (5) identified food insecurity; (6) evaluated other public benefits available to client
6	Public benefits; SSI/SSDI	Food security	SS appeal	SS appeal	18 hours 15 min	(1) SSI/SSDI; (2) public benefits; (3) SSI/SSDI appeal; (4) food security; (5) financial resources
7	NA	Estate planning	NA	NA	3 hours	(1) Estate planning
8	Insurance	Estate planning	Estate planning, insurance	Estate planning	3 hours 45 minutes	(1) Estate planning; (2) insurance
9	Employment	Estate planning, medical debt	Estate planning	NA	2 hours 15 minutes	(1) Employment; (2) estate planning; (3) medical debt
10	NA	Estate planning	NA	NA	2 hours	(1) Estate planning
11	Housing; unemployment	Estate planning	SSDI; estate planning	NA	4 hours	(1) Housing; (2) unemployment; (3) estate planning; (4) SSDI

(continued on following page)

TABLE A3: Participant Legal Issues Identified and Addressed (continued)

S. No.	Client Identified Matters at Baseline	CLC Identified Matters at Baseline	Issues at 3-Month Follow-Up	Issues at 6-Month Follow-Up	Total Amount of Legal Work and Visit Time	Description of Legal Services Provided
12	Insurance—bill from home health; insurance—navigating out of network care; estate planning	SSDI	Insurance—unexpected bill from fairview	NA	12 hours 45 minutes	(1) Insurance—bill from home health; (2) insurance—navigating out of network care; (3) estate planning; (4) SSDI; (5) insurance—unexpected bill from fairview
13	NA	NA	NA	NA	2 hours	NA
14	Estate planning; financial assistance—medical bills	NA	Estate planning	NA	4 hours 15 minutes	(1) Estate planning; (2) financial assistance—medical bills
15	Estate planning	NA	NA	NA	2 hours 30 minutes	(1) Estate planning
16	NA	Estate planning	Employment—rights	Insurance—out-of-network bills; insurance—loss of employment	2 hour 45 minutes	(1) Estate planning; (2) employment—rights; (3) insurance—out-of-network bills
17	NA	Insurance—acupuncture coverage; estate planning	Estate planning; insurance—dental and vision	NA	3 hours 45 minutes	(1) Insurance—acupuncture coverage; (2) estate planning; (3) insurance—dental and vision
18	Estate planning	NA	Estate planning		2 hour 45 minutes	(1) Estate planning

Abbreviations: CLC, Cancer Legal Care; NA, not applicable; SSDI, social security disability insurance; SSI, supplemental security income.

TABLE A4: Considerations for Future Clinical Trials Evaluating MLPs

Considerations	Example
Overarching MLP logistics	
Electronic medical record integration	More formal integration of legal organization into health system, with formal documentation privileges, to ease communication with care team, and be a part of the care team
Payment models	Health system, legal organization ± payers working together on innovative payment models, leveraging navigation support billing codes and recouped costs
Longer follow-up time	Long follow-up periods (1-2 years) with proactive collection on resource use (attorney time etc) and savings to calculate ROI. This longer follow-up period would also allow for a demonstrated effectiveness of the intervention by seeing resolution of the client's ability to obtain benefits, resolve insurance disputes, or resolve workplace issues. These are often long-lived matters that can take considerable time to resolve. In the instant study, work on behalf of a client with a complicated Social Security matter continued beyond the close of the study
Considering local context and law	When legal help beyond general information is needed, local, state-based partnerships are often the most effective means of meeting those needs. Reasons include the distinct nature of each state's laws and protections, the fact that lawyers are licensed to practice only in specific states, and most long-lived MLPs providing representation services (as opposed to information and resource providing) are hyperlocalized
Participants and design	
Participant selection on the basis of cancer/treatment characteristics	More similar in cancer type/stage/time since diagnosis/treatment approach, to minimize variation due to cancer and treatment trajectory
Control arm	Usual care or enhanced usual care. For example, providing participants a hard copy or digital information packet containing information and resources regarding the most common legal needs experienced by patients with cancer and caregivers with option to consult with a lawyer
Screening to identify persons most likely to benefit	Screen for health-related social needs. Through COST tool, for example
Separately considering prevention and treatment trials	Selection and identification of one study group (prevention group) more likely to be at risk of future legal issues using screening tools and a second (treatment group) to evaluate the impact of early intervention *v* reactive support on a patient's likelihood of accumulating debt, following through with treatment plan, having continuity of insurance coverage, receiving disability benefits, and retaining employment
Interdisciplinary teams	MLP supported by community health worker/financial navigator/social work services, to prioritize each members strengths and role. Local context is essential to ensure smooth interaction/communication/role clarity between with these teams, which has to be locally determined For example, financial navigation has many interpretations. Clarity around the issues for which financial navigators and social workers can provide help distinct from the help lawyers more appropriately provide not only illustrates the wide range of financial issues patients with cancer face, but helps to better understand which helper is best for each issue. While social workers, financial navigators, and lawyers all work with financial assistance/benefit programs and insurance issues, the type of help each can provide is distinct. For example, helping patients understand and apply for the cancer center's financial assistance program as well as available county programs is solidly in the wheelhouse of social work and financial navigation; while helping a patient appeal their Social Security disability denial is in that of lawyers. While all three professions can help locate insurance coverage, explain coverage and the confusing aspects of it, and counsel on how to minimize their out-of-pocket costs, lawyers are the appropriate referral for appealing a denial of cancer care, securing retroactive coverage, and securing in-network coverage for an out-of-network provider. With regard to debt, social workers and financial navigators can help locate grants available to the patient and help create payment plans
Outcomes assessed	
Completed cancer care and cancer-related outcomes (survival)	In addition to capturing what we care about most, it may help leverage payer/quality care incentives
Comfort with tasks	Among measures, "comfort with …" may be the most sensitive to change with proactive legal support. If other measures (eg, financial toxicity, stress, coping etc) remain stable, the control groups measures may actually worsen. But we should note that improving broad PROs is challenging
ROI for patient and/or health system	Clearly defining ROI expectations 1. If ROI refers to the financial benefit to the health system, then perhaps focusing on legal issues that result in compensated care such as resolving insurance denials and billing disputes (clear ROI can be demonstrated if a longer study time is provided for these often long-lived matters) or increasing patient access to insurance coverage by Social Security disability benefits (immediate Medicaid coverage for SSI benefits, 24-month wait period for Medicare coverage for SSDI) or maintaining employment-based coverage by ensuring employment protections are complied with by employer 2. If ROI refers to a patient's quality of life, then a wider range of legal/social needs can be addressed such as housing/food security through increased access to public benefits, estate planning topics such as powers of attorney, guardianship for minor children, beneficiary designations, employment protections, in addition to public benefits (SSI/SSDI) and insurance and medical billing concerns

Abbreviations: COST, Comprehensive Score for Financial Toxicity; MLP, medical-legal partnerships; PRO, patient-reported outcome; ROI, return on investment; SSDI, social security disability insurance; SSI, supplemental security income.