Characterizing and Addressing Financial Toxicity in Adolescents and Young Adults with Cancer

This study has completed the first phase of beta testing the intervention to determine logistical processes, and will now move to the full pilot study with an accrual goal of n=60 AYAs. During the beta testing, 18 individuals were screened, representing 11 AYAs, and of these 11 AYAs, 6 screened positive and moved on to receive the intervention. The intent of the beta phase was to establish processes and procedures to identify, enroll, and navigate participants to the intervention, including to our community partner, the Patient Advocate Foundation (see below). We have established such procedures as reflected in the study procedures here, and will now move forward with the full pilot study.

Aim 1: Among AYAs receiving cancer treatment or diagnosed with cancer in the last 6 months, to screen for financial and health-related social health needs (HRSN). We will administer a baseline needs assessment to all eligible AYAs and caregivers who consent to participate in the study. The survey will assess financial distress, HRSN, and the participant's desire to receive support to address unmet needs.

Aim 2: Among AYAs with a positive social health screen, to determine the feasibility and utility of direct provision and navigation to community resources on reducing financial distress and HRSN.
We will deliver the resource provision and navigation intervention to as many as N=30 AYAs and assess feasibility by evaluating program completion (6-months), participant-reported acceptability. We will gather evidence of efficacy by measuring change in average financial distress score between baseline and 6-month time points; and by measuring change in HRSN score.

Study Overview: Through the knowledge gained during the Columbia Nursing Pilot Award, and the interview data from n=20 AYAs and caregivers about their financial experiences and healthrelated social needs during cancer treatment, we have developed the preliminary components of an intervention to reduce financial distress and health-related social health needs (HRSN) for AYAs and caregivers. We will conduct a baseline needs assessment among all eligible and interested AYAs with cancer, and caregivers; then, we will deliver the intervention to AYAs and caregivers who screen positive for financial or HRSN and assess the feasibility and efficacy of the intervention. Feasibility will be assessed through participation and completion rates, and participant feedback; the impact of the intervention will be explored by the change in financial distress and improvement in HRSN scores.

Subjects and eligibility: We will enroll up to 60 AYA and caregiver pairs; non-paired AYAs will also be eligible to participate (see Human Subjects). AYAs who were diagnosed with cancer or began treatment for cancer within the past 6-months or those who are still on first treatment for cancer (non-relapse) will be eligible to participate; caregivers will be eligible to co-participate with an enrolled AYA. We will aim to recruit across age (15 - 25, 26 - 39), race/ethnicity, and language to

achieve at least representativeness of the AYA catchment in upper NYC. Given our preliminary data on younger AYAs, we will make every attempt to oversample from the 15 – 25 and related caregivers to ensure an understanding of potentially unique needs for these younger AYAs.

Procedures: We will obtain consent from interested participants; all will complete the baseline financial and HRSN assessment (Table 1), and those who screen positive (defined below) will receive the intervention.

Table 1: Proposed Measures and Brief Description

Measure	Brief description and completion time	Analytic approach	Aim(s)
Sociodemographic assessment	Participant-reported Includes race, ethnicity, sex, age, employment status, household income, insurance type, education completed, health literacy,[1] relationship status, and relation to AYA, if applicable (5-min)	Each discrete covariate approached as categorical	1
Financial distress measures	AYA: Original Cost measure, Financial burden survey (optional)(10-min)	Scored and analyzed as continuous scale (range	1
	Caregiver: InCharge/Personal Financial Wellness Scale (PFWS), Financial burden survey (optional) (10-min)	depends on final number of items)	
Financial and health related social needs (HRSN) assessment	Household material hardship (HMH),[2] out-ofpocket costs, coping behaviors (NCI-2021-03567) (5-min)	Each covariate approached as categorical	1
Global Health (Physical, Mental & Social Health)	PROMIS Global Health[3] (18y and older): 10items PROMIS Pediatric Global Health[4] (< 18 years): 9-items scored on Likert scale (5-min)	Scored and analyzed as categorical scale	1
Resilience	Connor-Davidson Resilience Scale (CD-RISC-10): 10-items (5-min)[5]	Scored and analyzed as continuous scale (range depends on final number of items)	1
Feasibility measures	Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM)[5] scored on a 5-point Likert scale, 12-items (5-min)	Scored and analyzed as categorical scale	2

Aim 1 and 2: AYAs and Caregivers:
We will conduct a baseline needs assessment among n=60 AYAs/caregiver pairs, and then, among those who screen positive for financial and HRSN, we will administer the Financial Education/Financial Navigation (FE/FN) intervention to tracas many as 30 AYA and caregiver pairs; up to N=45 participants will be included *to allow for non-paired AYAs*. English and Spanish language preferers will be eligible.

The process for the intervention will include the following:

Baseline assessment (all participants): Each AYA or caregiver will complete a baseline financial and social health risk assessment. Surveys will be completed using a secure, REDCap link either via a virtual platform (e.g. zoom or WhatsApp, both encrypted) using a REDCap link, or in-person

either using an iPad or paper version, per the participant's preference and comfort level. The study coordinator will be available to navigate the participant through the questions, if needed.

Positive screen: AYAs will be considered "positive screens for financial/HRSN" if they meet any of the following criteria: (*screening status will be determined within 1 week of study enrollment*)

- AYA who scores < 22 on the COST measure, below the median score in validation studies for financial distress[8]
- Caregiver who scores "high" on the PFWS measure (score range 1-4)[9]
- AYA or caregiver who respond "yes" to any of the 4 material hardship domains (food, housing, transportation, energy)
- AYA or caregiver who respond "yes" to the question asking if they have unmet financial or social needs that they would like help addressing.

Participants with a "positive screen" as above will proceed with the intervention. *Those who do not screen positive will be given a resource sheet that has been developed with the social work team at CUIMC and will be asked to complete a follow-up assessment 6-months after initial study entry (+/- 1 month).*

We have established partnerships with local CBOs through the HICCC Community Outreach & Engagement (COE) Core, and the Patient Advocate Foundation (PAF). PAF is a nonprofit organization geared towards solving the issues faced by patients facing chronic illness. They have a case management program that is available to the public, but patients often are unaware or unable to connect with PAF for various reasons, our research shows. In this study, we will identify patients experiencing financial or health-related social needs and then connect them directly with PAF and their case management team. We will share minimal information (patient name, age, diagnosis, and needs for which they screened positive) and patient preferred contact phone number with PAF to ensure their team is aware that our enrolled participant is in need of case management services. This Data Use Agreement (attached) will allow us to share minimal information between teams to ensure resource referrals are made for the patient and to understand and study how we can better improve this care delivery intervention. From prior qualitative research, we have developed this intervention and training and monitoring procedures to ensure intervention fidelity. These are all organizational capabilities both locally within our community and through national collaborations.

In our beta testing phase, we learned that for some AYAs and caregivers, connecting by telephone with PAF is perceived to be difficult; some participants never connected with the organization to receive needs navigation support. We have explored the use of a digital network of community resources that is publicly available through findhelp.org, and in this next phase of development, we will incorporate this platform to understand participants' perception, uptake, and engagement with findhelp.org.

Therefore, when participants who screen positive are contacted to assess their interest in continuing with the intervention, we will offer connection to PAF and findhelp.org. As in the beta testing, we will conduct monthly check-ins with participants and will ask if they accessed findhelp.org, if they used the search engine to identify community resources, if they connected with the community partner, and what the outcome of the connection was. These data will be important to inform future scaling of the intervention and understand the capacity of findhelp.org in addressing unmet financial and social needs.

Intervention Group:

1. AYAs with self-reported or caregiver-reported HRSN, specifically food or transportation insecurity, will be given a direct provision (e.g. voucher) to support immediate costs by the coordinator.
2. AYAs with self-reported or caregiver-reported HRSN will be navigated by the coordinator to our partner community-based organization (Patient Advocate Foundation, publicly available via a phone or web-based access) who will conduct their standard intake assessment and subsequent navigation with the individual patient and, if participating, the caregiver.
    a. The study team will communicate at regular intervals (weekly, more often as needed) with PAF team to notify them of newly-participating subject. Study team will share subject's name, age, language preference, and reported needs from the needs assessment to facilitate PAF in determining the case manager who will be in contact with the subject throughout the study period.
    b. PAF will share information with the study team including but not limited to: number of contacts with subject, uptake with recommended resources, need for additional support services, outstanding needs, and resolved needs.
    c. Study team will follow-up with the AYA, and if applicable, caregiver, at least monthly for 6-months for a brief structured survey interview to assess participant satisfaction, needs addressed, and need for additional navigation or support.

    3. Given the limitations identified in our beta testing in connecting participants with PAF, as well as PAF is not available to non-U.S. citizens, the study team will offer the AYA/caregiver the resource sheet, as described above, and will further provide direct navigation support to the findhelp.org website, which is a repository of locally-available resources that can be sorted by citizenship.

As with those who do not have a positive screen, another needs assessment survey, including 12-items to assess the acceptability, feasibility, and implementability of the intervention, will be administered to all participants at 6-months.

Identification and Recruitment of Eligible AYA Participants and Caregivers

AYA patients and caregivers will be recruited through the AYA Program at CUIMC. This collaborative clinical effort includes the Division of Pediatric Hematology/Oncology/Stem Cell Transplantation, and the Division of Hematology/Oncology. We also have existing collaborations with Gynecologic Oncology and will recruit through their division. We will leverage these collaborations to identify and recruit eligible participants. To avoid selection bias, a list of potentially-eligible patients will be created from the electronic health record (EHR) every month. All potentially-eligible participants will be screened for participation; however, we will review accrual data monthly and if certain groups are underrepresented (age, race/ethnicity, tumor type), we will make every attempt to improve our recruitment strategies to these groups of patients. A TRAC request will also be submitted for the results of the SDOH screener implemented in the Pediatric Oncology and Breast Oncology clinic. The SDOH screener is a part of SOC and has been in-progress of undergoing integration into oncology clinics at CUIMC. These results will be used to justify our target groups. Patients on the original list created from the EHR that screened positive for food, transit, or housing insecurity will be recruited for the study.

As a Minority/Underserved NCI-Community Oncology Research Program (NCORP) institution, we have established procedures in place for partnering with the clinical teams, utilizing patientfacing recruitment materials, and ultimately recruiting more than 40% of clinical study participants from racial/ethnic minority backgrounds. We will actively promote the study at CUIMC and will hold informational sessions with primary clinical teams to introduce the study. After initial discussions with the primary clinical teams through flyers, emails, or telephone, we will approach the AYAs and caregivers to present and discuss the research study.

All eligible patients be recruited one of two ways:

1. Patients will be approached by a treating clinician to gauge interest in the study. The patient will provide permission to the clinician to have us approach them about participation in the study prior to contacting the patient.

2. The PI will contact the treating physicians to introduce the study and inquire about allowing access to their patients. Before the research team contacts the patient, the research team will review a TRAC report (with an approved HIPAA form D - preparatory to research) and select eligible individuals. The treating physicians will be asked to view and approve a list of potential patients gathered from the TRAC request.. Eligible patients identified through this process will first be sent the introductory letter via postal mail or email. The letter, signed by the relevant medical director of the clinic that the treating physician of the patient (potential subject) is from, will explain that the purpose of the study. The letter will explain what is being asked of them, highlight the voluntary nature of the participation, and that non-participation will not impact their relationship with their provider. The patient will be asked to opt-out if they are not interested in participating. If, after 1 week, there is no response from the patient, we will make contact by telephone to assess interest in participation - up to 3 calls. Patients interested in participating will be consented over the phone or in person.

<u>Informed Consent and Enrollment</u>
We will replicate procedures for minimal risk research using verbal consent procedures as are currently utilized for a similar study currently in place (3P30CA013696-45S2; IRB AAAT2937) to recruit, consent and retain AYA participants and caregivers.

Eligible participants (who have not opted out) will be approached by a member of the research team either in person (clinic or hospital), or by telephone/video; participants will have the option to decline further information at that time.

The research team will then begin with a concise and focused presentation of the key information about the research study including risks and benefits, study goals, and methods. The informed consent process will present the research study information in sufficient detail. The participant will also have time to ask questions and discuss the information provided with their family. If, after being introduced to the research and having had the opportunity to ask questions, participants are willing to participate, the study team will obtain and document the consent of the AYA and caregiver, and assent for AYAs < 18 years, and provide them with the information sheet either in paper form or electronically, depending on participant preference. Participants will be informed that they have the right to stop participating in the study at any time. AYA participants <18 years

will be required to have parental participation; all other AYA participants will be encouraged, but not required, to identify a caregiver.

Consent may take place either through in-person or over the phone or a videoconference. When electronically sending the verbal information sheet, all communication will be transmitted from an approved University Email System. Participants have reported this to reduce the burden and increase their satisfaction with our ongoing research studies that utilize this approach.

To encourage study recruitment and retention as applicable, AYA and caregiver participants will each be offered gift card(s) to thank them for their time. These will be available as either physical gift cards or e-gift cards, depending on participant preference.

Compensation will be as follows: $25 for Aim 1, a baseline needs assessment (25 minutes). $100 for Aim 2, a one-time voucher to address food or transportation needs. $25 per time point completed (max $150) for Aim 2, monthly assessments x5 (15-45 min); 6-month follow-up (15-20 min).

To reduce participant burden and given COVID-19 restrictions, study operations will be conducted virtually wherever possible. We will utilize existing procedures for AAAT8368, Dr. Beauchemin's CUSON Intramural Pilot Award study, offering remote consent form signing and survey participation using REDCap® database. This procedure includes sending a secure link to a participants' email or mobile phone number, and the participant is able to view and sign the consent remotely, or able to complete surveys remotely, as study procedures indicate. This has been reported by participants to reduce the burden and increase their satisfaction with our ongoing research studies that utilize this approach.

Table 2: Study recruitment goal and compensation for each aim

Related Study Aim and Brief Description	Expected commitment	Compensation
Aim 1: Screening for financial and health-related social needs. (N = 60 AYA; N = 60 caregivers)	Baseline needs assessment (25 min)	$25
Aim 2: Financial and HRSN Navigation Pilot (N = 30 AYA; N = 30 caregivers)	One-time voucher to address food or transportation needs	$100
Aim 2: Financial and HRSN Navigation Pilot (N = 30 AYA; N = 30 caregivers)	Monthly assessments x5 (15 – 45min); 6-month follow-up (15 – 20min)	$25 per time point completed (max $150)

C.2. Potential Risks and Adequacy of Protection Against Risks

Aim 1

Physical risks: There are no physical risks to subjects in the proposed study.

Psychological risks: There is a possibility of anxiety or emotional distress for the AYAs or caregivers because of Aim 1 participating in surveys and, for Aim 2 financial/HRSN intervention, about cancer care, finances, and financial toxicity. Family finances are known to be a source of stress. The emotional risk of anxiety because of participating in surveys about this topic is expected to be minimal based on data from our prior research. There may be emotional risk of anxiety or distress because of discussing and learning about financial aspects of cancer care, including insurance, medication co-payment assistance, household material hardship, or other financial considerations and resources. However, prior work on this topic has revealed that patients and family members are eager to discuss this subject and do not report significant stress or anxiety because of participation; furthermore, patients and caregivers participating in prior studies on financial toxicity have identified an opportunity to speak about financial stresses as being beneficial to them. Participants may decide at any time and for any reason not to participate in the proposed study. To protect against this risk, those who express discomfort or stress during the survey or intervention will be referred to a psychosocial clinician for evaluation.

Privacy risks (AYAs, caregivers): There is a risk of privacy violation or loss of confidentiality; however, this is anticipated to be minimal given that survey data will be collected using an institutional approved program (REDCap®), and that survey data will not be linked to patient data except in a locked datafile with codes to link patient information. This will only be used to collect clinical data for AYA participants (cancer type, date of diagnosis, treatment regimen). To protect PHI, participants will be approached and consented to enrollment in private settings, and surveys will be administered either through a unique link sent to the participant's email or mobile phone, per participant preference; if neither is preferred, a study team member will be available to conduct the survey using a tablet in a private space in clinic. All study form hard copies will be kept in participants' study files in locked drawers to which only the designated study team member has a key. All electronic data will be kept on secured servers as managed by the Columbia University School of Nursing.

Survey Data will be collected using a RedCap® database. Confidentiality of each patient will be maintained, although chart review of the patients' histories will be required. All study participants will be assigned a unique study ID. Their survey responses will be linked to this study ID. All study information will be stored in locked file cabinets and in password-protected computer files. Only authorized study personnel will have access to these files. This is a minimal risk study focused on collection of patient-reported survey data for research. There is a small risk of release of medical data that is not intended.

C.3. Potential Benefits of the Proposed Research to Human Subjects and Others

We hope that participation in Aim 2 may provide some benefit to subjects enrolled by reducing financial and HRSN; this is however a feasibility study and therefore this is not the primary outcome measure of Aim 2. In other research of this nature, we have found that participants appreciate the opportunity to discuss their worries about finances as pertains to cancer care. Thus, subjects may find the experience of participating in the interviews to be beneficial in this

fashion. This study represents minimal risk to participants. Thus, the anticipated minimal risks are justified in balance with the importance of the knowledge to be gained and the potential future benefits to patients.

C.4. Importance of Knowledge to be Gained and Justification for Human Subjects

Survivors of cancer are at risk of financial toxicity, and AYAs are disproportionately affected by this negative adverse effect of cancer treatment. Though measures exist for adults with cancer, and interventions are currently being tested and demonstrated early reduction of financial toxicity among adult cancer patients, to design measures and interventions to reduce financial toxicity among this vulnerable population, we need to understand their unique experience with financial costs of care and subsequent financial toxicity. AYAs with cancer, their parents, caregivers, and healthcare team members for AYAs with cancer represent the sole source of this information, and thus this research cannot be

C.5 Inclusion of Women and Minorities

This study does not focus on any particular race, ethnicity, or gender. No potential research subjects will be excluded from enrollment on the basis of race, ethnic origin, or gender. This study focuses on AYAs (age 15 – 39 years) with cancer and will enroll racial and ethnic minorities in a manner that is proportional to the proportion of racial and ethnic minorities diagnosed with AYA cancer at CUIMC; currently over 40% of AYAs with cancer treated at CUIMC identify from racial or ethnic minority groups. As an NCI Minority-Underserved NCI Community Oncology Research Program, the HICCC has a robust infrastructure in place to recruit and retain underserved minority patients onto clinical trials. This includes availability of translation services (in case bilingual study members are unavailable), Community Outreach and Engagement Core collaborations within the HICCC and across the local community near the institution, including Northern Manhattan, Washington Heights/Inwood (of whom nearly 80% of the population identify as Hispanic/Latinx), and Harlem.

The study sample for each Aim will be from the same source population, the AYA patient population at HICCC, which broadly reflects the HICCC catchment area (81% Hispanic/Latinx or non-White; 46% foreign-born; 20% below the poverty line).

Aim 1 will include surveys that will be available in 2 language (English, Spanish) which represent the most frequent languages spoken at CUIMC.

Based on HICCC tumor registry data, we expect eligible AYA participants will be approximately 55% female and 45% male. Caregiver participation is expected to be a majority female as mothers are more likely to contribute research study information compared with fathers in our and others experience. However, because we include caregivers or other partners, we do not expect the traditional 75% female/25% male ratio; we anticipate 60% female and 40% male. Racial and ethnic minority participants will be eligible to participate. On the basis of HICCC tumor registry, we expect that approximately 50% of enrolled AYAs will be non-Hispanic White, and the other 50% non-White (20% Black/African American, 2% Asian, and 28% Other or more than one Race). We expect that approximately 40% of enrolled AYAs will be Hispanic/Latinx, 55% Non-Hispanic, and 5% Unknown. Because of the current underrepresentation of non-White patients in the financial toxicity literature, and because of the current catchment area diversity at

HICCC, we expect and will aim to achieve an overrepresentation of Black/African American and Hispanic/Latinx participants compared with national averages.

For the Key Stakeholder discussions (Aim 3, will occur at later date), target populations for enrollment include members of the healthcare team (physicians, nurse practitioners, nurses, psychologists, child life specialists, social workers), who provide care for AYAs with cancer, and AYA patient advocates who have intimate knowledge about AYA cancer. No potential research subjects will be excluded from enrollment on the basis of race, ethnic origin or gender. Given the gender breakdown of the pediatric and medical oncology workforce at HICCC, we expect a slight overrepresentation of women in the eligible healthcare team sample. We will intentionally attempt to sample male clinicians when possible. We will purposefully sample to target a racial/ethnic minority breakdown reflective of the HICCC provider population

C.7 Data and Safety Monitoring

The frequency and complexity of risks associated with these studies are overall expected to be minimal. As such, the PI, Dr. Melissa Beauchemin, and the CUIMC IRB will oversee Data and Safety Monitoring for the proposed studies. We will proactively review and evaluate the appropriateness of the data that is being generated from the proposed research aims, specifically Aim 2, intervention feasibility testing. This information will be utilized to inform process measures for future studies. We will check the quality of our data monthly to assess for 1) intervention fidelity, 2) appropriate measurement of outcomes, 3) assess for adverse events, 4) analyze reasons for attrition, 5) examine feasibility and acceptability, and 6) ensure that we are generating data that is reproducible in future studies.

Study activity	**Month 1**	**Month 2**	**Month 3**	**Month 4**	**Month 5**	**Month 6**
Approach, consent, and conduct baseline assessments for all eligible participants (i.e. AYAs diagnosed with cancer in the last 6 months or still on treatment)	X					

Among participants with a positive social health screen, we will deliver the resource provision and navigation intervention with Patient Advocate Foundation or findhelp.org. Among participants who do not screen positive, we will provide a resource sheet	X					
Monthly check-in. Conduct a brief survey with participants who have received navigation intervention to assess participant satisfaction, needs addressed, and need for additional navigation or support		X	X	X	X	
6-month survey. Contact all participants to complete needs assessment survey; for intervention group, also assess acceptability, feasibility, and implementability of the intervention						X

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