Partners Human Research Committee

Detailed Protocol

TITLE: Understanding and Improving Health Insurance Coverage among Long-Term Follow-Up Study Cohort Participants

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I. BACKGROUND AND SIGNIFICANCE

a. Historical Background

Childhood Survivors are a growing population in need of medical surveillance. Children diagnosed with cancer have experienced improved survival rates over time, with more than three-fourths becoming long-term survivors.[1] However, survivors of childhood cancer often face new and continued health care challenges and require ongoing care to monitor and treat long-term effects of their cancer and treatment throughout adulthood. Ongoing medical treatment and surveillance, with access to quality healthcare and coverage, are critical.

Although quality health insurance coverage is critical to this population, it has been complex to obtain. Given their ongoing health care needs, obtaining and navigating health insurance coverage is vital to ensure access to needed survivorship care. However, this can be difficult for individuals with pre-existing conditions such as a cancer diagnosis, who have historically faced denials of coverage, steep premiums, or "job lock" that keeps them from changing jobs for fear of losing coverage.[2,3] At the same time, childhood survivors have had higher rates of uninsurance, unmet health care needs, and burdensome costs.[4-10] These survivors are also less likely than siblings to be employed, married, and have a higher household income.[11-13] Dr. Park found that childhood survivors and siblings had similar rates of coverage, yet they differed by types of coverage and experiences obtaining coverage.[4] Uninsured survivors in particular were more likely to experience financial burdens from medical care that affected their care utilization.

Health care reform offers opportunities for childhood survivors to obtain quality coverage. The ACA[14] was signed into law in 2010 and is intended to increase access to affordable, quality health care. ACA policies offer considerable opportunities for populations with pre-existing conditions like childhood survivors to obtain coverage and improve access to needed care. Dr. Park and colleagues delineated the implications of specific ACA provisions for insurance coverage for childhood survivors.[15]

Although the ACA has increased coverage rates, uninsurance and underinsurance may remain a problem for childhood survivors. The ACA and other unprecedented changes to the health care landscape offer both opportunities and risk to childhood survivors regarding insurance adequacy and underinsurance. From Dr. Park's 2011-2012 CCSS (Childhood Cancer Survivor Study) health insurance survey we found that childhood survivors lacked awareness about the ACA[16] and had concerns that the ACA would increase their costs and threaten their quality and continuity of coverage.[5, 16,17] While the ACA requires coverage with no out-of-pocket costs for preventive services with "A" or "B" U.S. Preventive Services Task Force (USPSTF) ratings, these guidelines are not based on survivor-specific preventive guidelines and, as such, may not cover personalized screening recommendations.[18]

Limitations in health insurance literacy can make choosing and using health insurance challenging. With the complex and confusing array of evolving insurance designs, being able to understand and navigate insurance benefits is crucial for survivors to obtain the health care they need. However, many people have inadequate understanding of available insurance benefits and resources, and have limited health insurance literacy (i.e. perceived knowledge, ability, and confidence to make informed decisions about choosing and using health insurance).[19] Vulnerable populations, such as those with low income and poorer health, are more likely to have limited health insurance literacy.[20-22] Understanding specific insurance benefits and larger ACA policies may help survivors maximize coverage and prevent unmet need and burdensome costs.

Patient navigation interventions help patients overcome health care barriers. Patient navigation is a patient advocacy approach that was introduced in 1990, by Dr. Harold Freeman, to decrease high rates of breast cancer death among Black women in Harlem.[28] Patient navigation aims to reduce cancer disparities and negative health outcomes among vulnerable patient populations. Patient navigators were envisioned as proactive patient advocates who provided logistic and emotional support to promote patients' access to timely care.

Existing navigator programs offer limited assistance with understanding and managing health insurance benefits and costs. The US healthcare system is complex. Even with reform under the ACA, understanding insurance options remains complicated and a source of frustration for consumers.[24] While addressing insurance barriers to accessing care may be a component of some navigator programs, navigators focused specifically on helping patients understand and use their insurance benefits are rare. Navigator services mandated by the ACA in health insurance exchanges are available to help consumers choose and enroll in coverage, but their reach does not extend beyond enrollment. Many exchange enrollees have sought navigation services post-enrollment to help understand their new insurance plans, but such post-enrollment services are unavailable.[25] At the same time, cost-sharing under the ACA will continue to increase as coverage was not stabilized by Congress via payments to insurers to

reduce costs for consumers. Survivors in particular are going to need comprehensive assistance with insurance in future years.

b. Previous Studies

Childhood survivors and health insurance. In 2005 Dr. Park published findings in the *Journal of Clinical Oncology* demonstrating that CCSS survivors, compared to siblings, were significantly more likely to be uninsured and have difficulties obtaining health insurance.[4] In 2009-2010 she conducted in-depth interviews with a subset of CCSS survivors[2,5] and with Drs. Kirchhoff, Donelan, and Kuhlthau found that survivors had low coverage expectations, had difficulties understanding how to utilize their coverage, and inevitably worried about future health care costs. This team surveyed a randomly selected sample of CCSS participants and siblings about their health insurance coverage and perspectives about the ACA.[26,27] Survivors were significantly less likely to have employer-sponsored coverage (79.4% vs. 86.0%; p=0.04) and more likely to be covered by Medicaid/State (12.3% vs. 4.4%; p=0.002). 15.4% of survivors vs. 1.6% of siblings had recently been denied insurance (p<0.001). Survivors were more likely to borrow money to pay medical expenses (17.3% vs. 9.0% siblings; p=0.002) and not fill a prescription due to cost (15.7% vs. 9.0% siblings; p=0.02). Only 27.3% of survivors and 26.2% of siblings reported familiarity with the ACA. Concerns about the ACA included costs, decreased access to quality coverage, and employment. The majority of survivors, across different types of insurances, indicated strong interest in an insurance education program.

Recent study team reports of childhood survivors' underinsurance and its effects on financial burden and health care utilization. Dr. Kuhlthau led analyses describing patterns of health insurance coverage and care accessibility and affordability in an NHIS sample of adult childhood cancer survivors compared to adults without cancer during 2010-2014. Significantly more childhood survivors reported being uninsured, delaying medical care (24.7% vs 13.0%), needing but not getting medical care (20.0% vs 10.0%), and having trouble paying medical bills (40.3% vs 19.7%), compared to controls (ps<0.0001).[28] In 2017, Dr. Park and the study team published findings in JAMA Internal Medicine and JCO documenting that, compared to siblings, childhood survivors were significantly more likely to endorse indications of being underinsured, including being 84% more likely to borrow money because of medical expenses, 80%more likely to worry about being unable to pay for a needed treatment, and 74% more likely to worry they wouldn't be able to afford to fill a prescription. In addition, childhood survivors were more likely to report spending a higher percentage of their income on out-of-pocket medical costs. Survivors reported spending almost more than $1000 annual out-of-pocket costs compared to siblings. A higher percentage of income spent on out-of-pocket medical costs was significantly associated with survivors' problems paying medical bills (OR, 8.9; 95% CI, 4.4 to 18.0); deferring care for a medical problem (OR, 3.0; 95% CI, 1.6 to 5.9); skipping a test, treatment, or follow-up (OR, 2.1; 95% CI, 1.1 to 4.0); and thoughts of filing for bankruptcy (OR, 6.6; 95% CI, 3.0 to 14.3).[29,30]

Intervention and program development with childhood cancer survivors. Dr. Park has studied the health behaviors and perceptions of childhood cancer survivors.[31-34]

She directed an NCI-funded trial to decrease smoking rates among 796 CCSS smokers that was found to be efficacious.[31] She published a qualitative paper that had shaped the intervention,[33] as well as a process evaluation paper which examined intervention characteristics associated with cessation success.[32] Dr. Park also has extensive experience conducting qualitative research to inform survivorship program development.[35-38] Dr. Kirchhoff is leading the development and testing of a childhood cancer survivor transition program with a focus on the provision of survivorship care plans for patients and families.[39]

Health insurance and individuals with chronic conditions. Dr. Kuhlthau has extensive experience studying health insurance issues for individuals with chronic conditions, including Medicaid populations and groups with high expenditures.[40-51] She has also studied unmet need, a commonly used measure of underinsurance.[52-54] She conducted work on the private health insurance and work-life benefit systems for children with chronic conditions[55,56] which resulted in guides for employers, families, and state employees. Dr. Galbraith's work has demonstrated that children and families with chronic conditions are vulnerable to health insurance designs with high levels of cost-sharing and may reduce use of needed care due to cost.[57-59] Dr. Kirchhoff published on coverage gaps, financial burden, and medical costs, and their impact on access to care among childhood, adolescent and young adult cancer patients and survivors.[60-62]

Effects of new insurance designs and health reform policies. Dr. Galbraith led one of the first studies of health insurance exchange plans, which documented problems for exchange enrollees with financial burden and unexpected costs;[63] this study also identified challenges with understanding and choosing plans for families, many of whom wished for greater assistance navigating plan options.[23] Dr. Galbraith has conducted studies of unmet health care need and financial burden among children and families with chronic conditions in high-deductible and other insurance plans.[59, 64-66] She has examined the impact of increased cost-sharing on health care decision making and use of recommended health care services.[67-72] She is conducting a trial to evaluate how a price transparency tool can help high-deductible plan enrollees manage costs.

Peer counselor and navigator-based interventions. Dr. Park directed a smoking cessation trial, in collaboration with the Long-Term Follow-Up (LTFU) study at St. Jude Children's Research Hospital, in which she trained childhood cancer survivors to be smoking cessation peer counselors and deliver a phone-based intervention.[32] Dr. Galbraith conducted a randomized trial of a patient navigator intervention to reduce readmissions for high-risk patients discharged from a safety-net hospital.[72,73] Dr. Donelan has conducted extensive survey research examining patient barriers to cancer screening and follow-up and physician referral communication with patients.[74-77] She examined the effectiveness of a patient navigation program in improving minority patients' follow-up of an abnormal mammogram.

c. Rationale of Proposed Research

Health care reform under the Patient Protection and Affordable Care Act (ACA) offers considerable opportunities for childhood cancer survivors to obtain coverage and improve access to needed care. However, in the general population, many people have low understanding of available insurance benefits and resources, and have limited health insurance literacy (i.e. perceived knowledge, ability, and confidence to make informed decisions about choosing and using health insurance). Misperceptions about which services require out-of-pocket costs may lead some enrollees to avoid services that are in fact exempt from cost sharing. Even with coverage protections from the ACA, barriers to obtaining quality coverage (e.g., in states without Medicaid expansion) and accessing needed care may remain for childhood survivors. Understanding and navigating insurance benefits is crucial for cancer survivors to obtain the health care they need. In this new post-reform landscape, the degree to which coverage and costs have changed for childhood cancer survivors is still largely unknown.

d. Study Site Roles

The sites in this study, MGH, St. Jude Children's Research Hospital, and the University of Utah will each have different, complementary roles. The Partners IRB will be the IRB of record for this study, and the collaborating IRBs of St. Jude and the University of Utah will CEDE review to the Partners IRB. Site and IRB roles are described below.

MGH Site Roles
As the IRB of record and lead site for this study, MGH will be responsible for the development and regulation of all study-related materials, documents, assessments, and interventions. For Phase 1 of the study, MGH will be specifically responsible for the facilitation of advisory board and participant focus group interviews, and the qualitative analysis this data. Utilizing the data garnered from these interviews, MGH will further develop and tailor the intervention content (though MGH will work with collaborators on this aspect of the study, MGH will lead in the development and final submission of this piece).

For Phase 2 of the study, MGH will be responsible for the delivery of the intervention content. Through the platform of MGH telehealth (Zoom), approximately 40 intervention arm participants (recruitment processes are described below) will receive brief health insurance educational sessions by a health insurance navigator. MGH will be responsible for the training and supervision of the navigator.

For Phase 3 of the study, MGH will be responsible for the facilitation and analysis of exit interviews conducted with the Phase 2 intervention arm participants (MGH will not be conducting the exit interviews. See University of Utah Phase 3 roles for more information).

St. Jude Site Roles
As one of the collaborating sites for this study, St. Jude will be responsible for all recruitment activities. St. Jude Children's Research Hospital is the site of the Long-Term Follow-up Study (LTFU), and study participants will be exclusively recruited from the

eligible members of this cohort. St. Jude will be responsible for recruiting, randomly selecting, and consenting participants for the focus group interviews, the open pilot of the study intervention, and the pilot randomized trial. Once recruited and consented, St. Jude will securely send relevant participant information to the study staff at the University of Utah and MGH.

University of Utah Site Roles

As one of the collaborating sites for this study, the University of Utah will be responsible for all participant assessments during the study. During Phase 1 of the study, after receipt of participant information from St. Jude, the University of Utah will coordinate with MGH to set up and schedule participant focus groups. For the open pilot of the study, St. Jude will distribute baseline and follow up surveys to participants and will lead all quantitative analyses of these assessments. Lastly, the University of Utah will schedule and facilitate exit interviews with all open pilot participants and will securely send qualitative data to MGH for analysis. The University of Utah will also be responsible for remuneration of subjects during all phases of the study.

For Phase 2 of the study, the University of Utah study roles mirror those of Phase 1, with the distribution of baseline and follow-up surveys to participants, and the collection and analysis of said data.

For Phase 3 of the study, the University of Utah and MGH will coordinate to schedule exit interviews with the Phase 2 intervention arm participants.

II. SPECIFIC AIMS

Aim 1: To develop a psychoeducational health insurance navigation program (HINP).

A1a: To qualitatively assess LTFU participants' reports of 1) barriers to accessing and using quality health insurance2) resources to support health insurance access and use, 3) navigation program content, 4) intervention structure and dose, 5) program delivery, 6) program acceptability, 7) aspects of coverage that are not well understood *A1b:* Aim 1b: To qualitatively assess approximately 3 advisory boards' and approximately 10 individual experts' feedback 1) barriers, 2) resources, 3) content, 4) intervention structure and dose, 5) delivery and 6) selection criteria *A1c:* To pilot the intervention with LTFU participants (approximate n=10).

Aim 2: To conduct a videoconferencing-based pilot randomized trial of the HINP (n= approximately 80).

A2a: To assess the feasibility (number of eligibles enrolled and sessions completed) and acceptability (satisfaction, perceived support) of participants undergoing the HINP.

A2b: At 3-month post-program follow-up, to assess the efficacy of the HINP to assist participants with accessing and utilizing coverage and managing costs. Primary

outcomes are 1) health insurance literacy and 2) financial distress related to medical costs

A2b Hypothesis: The HINP, compared to enhanced usual care, will improve participants' health insurance literacy and decrease financial distress.

Aim 3: To refine the HINP program for future use.

A3a: To explore HINP intervention arm participants' 1) satisfaction with the intervention, 2) recommendations for modifications on delivery modality, and 3) recommendations for intervention topics and content modifications.

Study Design Overview: The proposed study will take place in 3 phases and will involve a total of approximately 122 participants recruited from the Long-Term Follow-Up (LTFU) study cohort (See Section III below)-

- In Phase 1 we will develop a psychoeducational health insurance navigation program (HINP) through participant input and a series of advisory board meetings and individual interviews. We will also refine the program by recruiting a small group of LTFU study cohort members for an open pilot of the intervention.
- In Phase 2 we will pilot the feasibility, acceptability, and preliminary efficacy of the videoconferencing-based HINP with LTFU study cohort members.
- In Phase 3 we will further refine the program through study participant feedback.

Below we describe the activities for the three study phases. Detail on participant enrollment and consent procedures for all three phases is included in Section IV.

Phase 1

Participant Focus Groups

Four focus group interviews (approximately n=8 per group) will be conducted with randomly selected LTFU study participants (see Participant Focus Group Interview Guide); selection will be stratified according to Medicaid expansion status (Y/N), which we will determine based on participant demographic information from the LTFU data records. LFTU participants from the original and expansion cohort will be eligible and consented (Please refer to Sections III and IV for information on subject selection and consent procedures); we will assure inclusion of men and women. Groups will last about 60 minutes, and may be conducted through Zoom, a HIPAA compliant videoconferencing platform (see Maintaining Confidentiality in Section VII) or in-person. Participants will be provided $50 remuneration by the University of Utah. Groups will be co-facilitated by co-investigators via a semi-structured interview guide (See Participant Focus Group Guide). The interviews will be recorded.

Advisory Board Input on HINP

Three advisory board meetings will be conducted, specifically, with national oncology clinicians and researchers and Boston-based experts. These groups will be co-facilitated by investigators via a semi-structured interview guide that contains the following domains: 1) barriers, 2) resources, 3) content, 4) intervention structure and

dose, 5) delivery and 6) selection criteria (See Advisory Interview Board Guide). Advisory board meetings will also be conducted through Zoom Videoconferencing, via phone, or in person. The advisory board focus groups will be recorded and used for quality improvement purposes of the HINP.

Expert Individual Interviews
We will conduct approximately 10 30-minute individual interviews with experts at the intersection of health insurance, navigation, cancer, and survivorship. Experts will include clinicians, oncology social workers, and health insurance specialists. Interviews will be recorded and used for tailoring and improvement of the HINP. Individual interviews will be facilitated by investigators using a semi-structured interview guide containing the same domains as the advisory board interviews. These interviews will also be conducted through Zoom Videoconferencing via phone, or in-person.

For both Advisory Board and Expert interviews, we will assent experts for participation in the interviews (See Advisory Board Interview Guide)

Qualitative Analyses to Inform HINP Development
For qualitative analyses of focus group, advisory board meetings, and individual interviews, all data will be analyzed by MGH and Utah study staff using NVivo qualitative software. Content analyses will be conducted including a structural thematic framework, categories, and coding plan. For focus group data, a coding framework will be developed for themes and codes according to participants' feedback on 1) barriers to accessing and using health insurance 2) resources to support health insurance access and use, 3) navigation program content, 4) intervention structure and dose, 5) program delivery, 6) program acceptability, 7) aspects of coverage that are not well understood (See Participant Interview Guide) For advisory board and individual interview feedback, a coding framework will be developed for themes and codes according to the domains of: 1) barriers, 2) resources, 3) content, 4) intervention structure and dose, 5) delivery and 6) selection criteria. To ensure coding reliability, coding discrepancies for participant focus groups will be resolved through discussion and comparison of raw data. Coding will continue until a high level of reliability (Kappa= $\geq$0.80) is established. Co-investigators will provide an expert review of the results. For expert and advisory board interviews, a Rapid Analysis method will be used.

Open Pilot with Participants
With feedback from the focus groups, advisory boards, and individual interviews, results will be interpreted, summarized, and finalized; the investigators will refine the HINP. Then, approximately 5-10 participants will be randomly selected to participate as pilot subjects (Please see Sections III and IV for information on subject selection and consenting procedures). Aspects of the study that will be piloted include the surveys, intervention, and exit interview. Participants will be remunerated $20 for the completion of a baseline survey,a follow-up survey and the exit interview by the University of Utah. Final intervention and survey modifications will be made.

Phase 2

Pilot Trial Design

We will recruit and randomize approximately 80 LTFU participants to a health insurance navigation intervention or to enhanced usual care (Please see Sections III and IV for information on subject selection and consenting procedures). We have selected this sample size of approximately 40 per arm to enable evaluation of feasibility and acceptability goals as well as explore meaningful differences in the outcomes.[78] Surveys will be conducted at baseline and 3-month post program completion follow-up via REDCap or mail. All participants will be asked to complete a follow-up survey approximately 3-months after the HINP intervention period (in other words approximately 5-months post pilot trial enrollment).). After completion of the follow-up survey, HINP participants will be contacted for an exit interview (see Phase 3 below). Participants will be remunerated $20 for each survey and the exit interview by the University of Utah

Study Arms

Enhanced Usual Care

Enhanced usual care will consist of a mailed or online copy of a health insurance resource guide.

Navigation Intervention

The intervention will be delivered via synchronous videoconferencing (real-time delivery and communication between the navigator and the participant) by a trained patient navigator (See Intervention Fidelity in Section VI) and will consist of 4, 30-minute sessions delivered every week, over the span of one month (for intervention development purposes, the pilot sessions will occur every week, over the course of one month). The navigation intervention group will also receive a mailed copy of the brochure.

Proposed Navigation Intervention Structure and Content

The program will be delivered via videoconferencing by a navigator over a 1-month period. Accordingly, patient navigation is delivered until the desired endpoint is achieved; we propose that this will be accomplished with 4 navigation sessions (See Table 1: Proposed HINP Intervention). The proposed program content was informed by: 1) aforementioned research identifying childhood survivors' difficulties with accessing and utilizing one's coverage and managing costs, 2) CCSS health insurance survey, and 3) ACA provisions that are relevant to survivors (e.g., prevention services exempted from cost sharing, sources of available coverage and eligibility, benefits policies that have cost-related implications like OOP costs, and essential health benefits such as prescription medications. Based on advisory board and individual interview feedback, the content and tailoring of information will be modified.

Table 1: Proposed HINP Intervention
Session One: Learning About Survivorship Healthcare Needs
Sessions Two: Learning About Your Plan in Relation to Policy
Session Three: Navigating One's Own Plan

Phase 3

Exit Interviews

For HINP participants after the follow-up survey, the study co-investigators will conduct in-depth interviews (see Participant Exit Interview Guide) via videoconferencing with the 40 intervention participants to assess survivors' 1) satisfaction with the intervention, 2) recommendations for modifications on overall session topics and intervention content (e.g., physician communication, cost management strategies). and 3) recommendations for modifications on delivery modality (e.g., number and length of sessions, videoconferencing delivery). These will last about 20 minutes and participants will be remunerated $20 for their time by the University of Utah. The exit interviews will be recorded.

Exit interview data will be transcribed and analyzed using NVivo qualitative software. Content analyses will be conducted and co-investigators will provide an expert review.

III. SUBJECT SELECTION

Participants: Inclusion and Exclusion Criteria

LTFU study staff at St. Judy Children's Research Hospital keep updated participant contact records for this study, which allows for participants to be approached for additional research studies. For Phases 1 and 2, the LTFU study staff will recruit a total of approximately 122 participants from the Long-Term Follow-Up Study cohort. Phase 1 will involve recruitment of 32 participants for four focus groups and approximately 5-10 participants for the open pilot. Phase 1 participants will not be eligible for Phase 2 participation. For the focus group activities of this Phase, participants will be randomly selected stratified according to whether they reside in a state with or without Medicaid expansion, which LFTU staff will determine based on participant addresses available from the LTFU data records.

Phase 2 will involve recruitment of 80 randomly-selected participants for the pilot randomized trial. Participants will be randomly selected stratified according to whether they reside in a state with or without Medicaid expansion, which LFTU staff will determine based on participant addresses available from the LTFU data records.

Phase 3 participants will be recruited from the Intervention Arm of Phase 2 (approximately n=40).

For both Phases, we will exclude participants who : (1) do not have health insurance, (2) are under the age of 18, (3) are unable to give informed consent due to psychiatric or cognitive impairment as determined in consultation with study PI, patient navigator, or oncology social worker, and (4) do not have access to an smartphone, computer or tablet with internet access. Importantly, we will closely document and monitor the

numbers of individuals who are unable to participate given this final criterion, as it will further inform the feasibility of this intervention modality.

Sources of Subjects and Recruitment Methods

The Long-Term Follow-Up Study (LTFU) is an NIH-funded multi-institutional study of individuals who were diagnosed before 21 years of age with leukemia, CNS malignancies, Hodgkin's disease, non-Hodgkin's lymphoma, Wilm's tumor, neuroblastoma, soft tissue sarcoma, bone cancer or serious illness who survived at least five years after diagnosis. Eligible participants for the LTFU were identified through medical records and clinic lists at participating centers in the U.S., yielding a retrospectively ascertained cohort of adult childhood survivors with ongoing, longitudinal follow-up. The LTFU includes individuals diagnosed with cancer or serious illness between 1970-1999, recruited from over 25 pediatric oncology institutions in North America. Eligible participants for our study include 21,841 LTFU participants who are still alive and have available contact information.

IV. SUBJECT ENROLLMENT

Methods of Enrollment

Prospective participants for each phase of the study from the LTFU study cohort will be identified via LTFU records and recruited and consented at the CCSS Coordinating Center at St. Jude Children's Research Hospital (Supporting Facility for the LTFU) by LTFU staff. Prospective participants will receive an invitation to the study through email and mail (See LTFU Focus Group, Open Pilot, and Pilot Intervention Recruitment Letters). CCSS participants have consented to be contacted by the study and agreed to email communication by voluntarily providing us with their email address. St. Jude employs a system called Emma to administer and deliver email campaigns. Emma (myemma.com) is a secure email marketing platform that allows for multi-level campaigns with all or segments of our participants. It allows for contact management, simple HTML template design with piping and logical integration, tracking of email campaign receipts, errors, and opt-outs, and drilling down to review participant level activity If eligible and interested, prospective participants will read over an enclosed Research Consent Form, which they will have the option to either fill out via an online DatStat survey link (the system that St. Jude Children's Research Hospital uses for LTFU consenting procedures, see Data Management in V. Study Procedures) or to fill out the hard copy of the form and mail it back to LTFU staff at St. Jude Children's Research Hospital. Additionally, participants may also be recruited through telephone, with outreach being done by CCSS Coordinating Center, and a mailed version of the recruitment letter might be sent out, with instructions being provided for how to access the online consent portal. Potential participants will also be able to get more information about the study via a St. Jude website (which will also have a link to the online consent form). Following consent, the assignment of a unique study identification number to each participant, and randomization into intervention vs. control arms for Phase 2, participant information will be sent securely to Dr. Kirchhoff via SharePoint, an encrypted system used to transfer data. Dr. Kirchhoff's team will lead the focus group scheduling and survey facilitation, while both MGH and University of Utah study staff will

coordinate the navigation intervention. The study interventionist may contact consented participants via telephone and email in to schedule intervention sessions.

Informed Consent

For the participant focus groups, open pilot, and pilot trial, informed consent will be facilitated by LTFU study staff using an IRB approved consent form for each piece of the study (See Focus Group, Open Pilot, and Pilot Intervention Consent Forms. The consent form will describe the study in detail, including the purpose of the research, clinical procedures, risks and discomforts, benefits, reimbursements, and alternatives to participation. Confidentiality, the right of each subject to request further information, and the right of each subject to withdraw from the study at any time, is fully detailed in each consent form. Patients will be informed via the consent form that they can freely choose not to participate. We will exclude participants who, as determined by the study PI or navigator, are unable to give consent due to psychiatric or cognitive impairment. There will be two separate consenting procedures for Phase 1 of the study. One consenting procedure will be for the focus group participants (n=32), and one consenting procedure will be for the open pilot participants (n=10). For Phase 2 of the study, there will be a single consent form for the pilot randomized trial participants (n=80). The intervention arm participants of Phase 2 (n=40) constitute the Phase 3 participants, so they will be consented for Phase 3 during the Phase 2 consent process. There will be separate consent forms that correspond to the described procedures.

Intervention Assignment and Randomization

Pilot Trial

The CCSS Coordinating Center LTFU study staff will randomly select 80 participants among the LTFU cohort (original and expanded together). To do this, CCSS will use stratified random sampling, where we will divide the sample of LTFU participants into two groups: residing in a Medicaid expansion state or not. Random samples will then be selected from each of the two strata until 80 participants are consented and enrolled. The 80 selected participants will be randomized to either enhanced usual care (n=40), or the health insurance navigation intervention (n=40). After obtaining informed consent, participant information will be sent securely to Dr. Kirchhoff via SharePoint, an encrypted system used to transfer data. Dr. Kirchhoff's team will lead the pilot trial procedures.

V. STUDY PROCEDURES

	Recruitment and consent	**Scheduling activity**	**Procedures**	**Data - qualitative**	**Data – quantitative**
Phase 1					
Focus groups	LTFU staff identifies Medicaid vs. not Medicaid from LTFU records;	Kirchhoff team receives consented list from LTFU via SharePoint; they set up FG time	MGH runs FG via Zoom; records and transcribes the data	Per grant - Content analyses will be conducted by Drs. Park and	**None collected**

	Randomly selects and consents Goal: 4 FG x 8 people -> 32 or so participants	working with MGH team to schedule		the research assistant	
Open pilot	LTFU staff randomly selects & consents participants Goal: 5-10 participants	Kirchhoff team received consented list from LTFU via SharePoint; Kirchhoff team set up sessions with navigator	Kirchhoff team collects baseline and FU surveys via REDCap	Dr. Park and or/ study navigator and research assistant will conduct analyses	Per grant - Dr. Kirchhoff will lead the analyses of surveys; will receive additional data from LTFU study as needed (demographics, etc) via SharePoint
Phase 2					
Pilot	LTFU staff identifies Medicaid vs. not Medicaid from LTFU records; Randomly selects; Randomizes Participants after they consent Goal: 80 participants	Kirchhoff team receives consented list from LTFU via Sharepoint; Kirchhoff team set up sessions with navigator	Kirchhoff team collects baseline and FU surveys via REDCap	**None collected**	Per grant - Dr. Kirchhoff will lead the analyses of surveys; will receive additional data from LTFU study as needed (demographics, etc) via Sharepoint
Phase 3					
Exit interviews	No new recruitment	Kirchhoff team will help schedule the interviews	Exit interviews run by Utah team	Content analyses will be conducted by Drs. Park and Galbraith	**None collected**

Data Management, Collection, and Transfer

Recruitment

During the recruitment periods of each phase of the study, St. Jude will track and obtain consent through DatStat, which allows researchers to configure online mobile responsive web surveys with tailored logic checks and requirements, data pre-populating and piping, and portal access for quick reporting, analytics, and downloads. The system is HIPAA compliant and fully validated for 21 CFR Part 11. Once participants are consented to the study, their information will be sent to Dr. Kirchhoff and her team at the Huntsman Cancer Institute at the University of Utah via SharePoint. SharePoint is a secure file sharing service supported by the Huntsman Cancer Institute that is encrypted and HIPAA certified. It is password protected and Dr.

Kirchhoff's SharePoint file sharing can only be accessed by other investigators through invitation to ensure data privacy.

Quantitative Data

For the pilot trial, Dr. Kirchhoff's staff at the Huntsman Cancer Institute at the University of Utah will oversee the scheduling participants and will ensure the completion of the baseline survey and follow-up surveys for both Phase 1 and 2 of the study. Survey data will be collected via a secure web-based portal (REDCap). REDCap is maintained by the bioinformatics shared resource at the Huntsman Cancer Institute where Dr. Kirchhoff is an investigator. As such, she has access to survey and database support for REDCap for all data collection activities. Data transmissions will occur between Dr. Kirchhoff and the CCSS Coordinating Center and Statistics and Data Center via SharePoint to facilitate data access from the LTFU baseline and follow up surveys for inclusion in the statistical analysis (https://ccss.stjude.org/documents/original-cohort-questionnaires). Dr. Kirchhoff will lead the pilot study survey data management and analyses, and transmit analytic data to MGH using SharePoint. Data will be managed and cleaned by Dr. Kirchhoff's data manager and overseen by Dr. Kirchhoff.

Focus Group and Exit Interview Qualitative Data

Once the focus groups are scheduled by Dr. Kirchhoff's team, the data collection efforts will be led via MGH's Zoom program. The Phase 1 participant qualitative data will be collected and stored within MGH. Data will be collected by Dr. Park's team at Massachusetts General Hospital using recording devices. Audio recording files will be saved and uploaded into NVIVO software on Shared File Areas in the Partners network, which will only be accessible to IRB-approved study staff. NVIVO files will be sent securely via Partners Secure File Transfer or via SharePoint, which has been approved for use in this study. The Phase 3 qualitative data in the form of exit interviews will follow procedures detailed in Phase 1.

Advisory Board and Expert Interview Qualitative Data

After expert and advisory board interviews have taken place via Zoom, audio recordings will be stored on Shared File Areas in the Partners Network. Audio recordings will be directly uploaded into NVIVO and sent securely to study staff at the University of Utah for analysis.

Intervention Arm Components

Of the approximately 80 participants recruited for Phase 2 of the study, 40 will be randomized to enhanced usual care, and 40 will be randomized to the health insurance navigation intervention. As described above, the intervention arm will involve 4 sessions delivered by a navigator.

Intervention Fidelity

The patient navigator (PN) will undergo training by the Co-investigators and pilot sessions. The NCI, with support from the ACS, established the Patient Navigation Research Program (PNRP) to implement and evaluate patient navigator programs. The PNRP developed a navigation performance checklist with 3 quality indicators of care:[79,80] 1) participant interaction (e.g., established rapport), 2) care management (assessed subjects' understanding), and 3) intervention delivery (e.g., relevant information provided on insurance options, cost savings). Study investigators will review 15% of patient navigation encounters using these quality indicator criteria.

Assessments

Phase 1 Assessments
During the Open Pilot of the intervention, participants will complete a baseline survey and a 3-month post-program follow up survey. Participants will be remunerated $20 for the completion of each survey by the University of Utah. LTFU extracted medical record data will provide information on cancer diagnosis, age at diagnosis, years since diagnosis, and type of treatment. The open pilot will also involve an exit interview, which is described in further detail below.

Phase 2 Assessments
During the pilot trial, participants will complete a baseline survey, a 3-month post-program follow up survey. LTFU extracted medical record data will provide information on cancer diagnosis, age at diagnosis, years since diagnosis, and type of treatment.

Phase 3 Assessments
After the completion of the follow-up survey, investigators will conduct In-depth exit interviews with the 40 intervention arm participants to assess participants' 1) satisfaction with the intervention, 2) recommendations for modifications on overall session topics and intervention content (e.g., physician communication, cost management strategies)and 3) recommendations for modifications on delivery modality (e.g., number and length of sessions, videoconferencing delivery) . Participants will be remunerated $20 for their time by the University of Utah.

VI. BIOSTATISTICAL ANALYSIS

Analysis Plan

Qualitative Data
For qualitative analyses of participant focus groups advisory board meetings, individual expert interviews, and exit interviews, all data will be analyzed by MGH and University of Utah study staff using NVivo qualitative software. For qualitative analysis of advisory board and individual expert interviews, audio files will be uploaded into NVIVO software and analyzed using a Rapid Analysis method. Content analyses for the participant focus groups an exit interviews will be conducted including a structural thematic framework, categories, and coding plan. For focus group data, a coding framework will be developed. To ensure coding reliability, coding discrepancies will be resolved through

discussion and comparison of raw data. Coding will continue until a high level of reliability (Kappa= ≥0.80) is established. Co-investigators will provide an expert review of the results.

Focus Group Data*:* A coding framework will be developed for themes and codes according to participants' feedback 1) barriers to accessing and using health insurance 2) resources to support health insurance access and use, 3) navigation program content4) intervention structure and dose, 5) program delivery, 6) program acceptability, 7) aspects of coverage that are not well understood
Advisory Board and Individual Interview Data: A coding framework will be developed for themes and codes according to the advisory board feedback on 1) barriers, 2) resources, 3) content, 4) intervention structure and dose, 5) delivery and 6) selection criteria

Exit Interview Data: A coding framework will be developed for themes and codes according to participants' feedback on 1) satisfaction with the intervention, 2) recommendations for modifications on overall session topics and intervention content (e.g., physician communication, cost management strategies). and 3) recommendations for modifications on delivery modality (e.g., number and length of sessions, videoconferencing delivery)

Quantitative Data
For quantitative data, Dr. Kirchhoff's team at HCI will conduct the analyses with input from Dr. Park and her study team, and the LTFU study team. As discussed in Participants, we will sample by Medicaid expansion vs. non-expansion states. All analyses will be weighted using inverse sampling probabilities so that results are representative of the overall LTFU study cohort.

At baseline, all pilot participants will complete a baseline. The HINP navigator will use each participant's baseline survey responses to personalize and individualize sessions. At the 3-month post-program follow-up, participants will complete the Phase 1 survey Outcome questions, which will be asked within the 5-month time frame period after trial enrollment. Participants will also be asked questions below about feasibility and acceptability.

We will use descriptive statistics to report on the following endpoints: intervention feasibility (percent of participants enrolled), acceptability (satisfaction, perceived support) and efficacy (e.g., ACA familiarity, health insurance literacy, intention to adhere to recommended survivorship care, provider communication, and coverage status). Descriptive statistics will examine group differences at baseline; any imbalances will be adjusted. We will use chi square and independent t-tests to compare end-of-intervention changes in preliminary efficacy outcomes between the two groups. Although a 3-month post intervention follow-up period is brief, we will also conduct exploratory comparisons with other study outcomes to see if trends change in the expected direction. We will compare pre/end-of-treatment, within groups, with paired t-tests. In addition, we will use bivariate statistics to examine sociodemographic and cancer-related factors (type of

diagnosis, age at diagnosis, years since diagnosis, cancer treatment, chronic conditions[81], cancer treatment (e.g., cranial radiation yes/no, anthracycline exposure yes/no) associated with feasibility, acceptability and preliminary efficacy outcomes.

Outcomes

Primary Outcomes: Feasibility and Acceptability.

1. Feasibility: Number of eligible enrollees and number of sessions completed. 2. Acceptability*:* 4-point scales of satisfaction with navigation services (To what extent has this program met your needs? Did you get the kind of health insurance assistance that you wanted? How helpful has this program been for you?) and perceived support (emotional/informational scale of the Medical Outcomes Study social support survey, an 8-item scale widely used with cancer patients).[82-86]

Secondary Outcomes: Efficacy.

The ACS's National Patient Navigator Leadership Summit recommend patient-navigation outcome measures, which included: perceived knowledge, perceived confidence in overcoming barriers to care, and satisfaction with patient navigation services. Accordingly, we will measure: 1) health insurance literacy, 2) financial distress related to medical costs.
3) familiarity with healthcare reform policies, 4) insurance status (among those insured at study enrollment), and 5) discussion with providers about health care costs[63] and preventive services among those having a visit during this interval (2-item y/n questions).

Measures

To evaluate the pilot, we will use a mixed methods data collection approach, using both quantitative survey items and open-ended questions .[87] Most study measures will come from survey questions repeated from the 2011-2012 CCSS health insurance survey (see Appendix); some new questions will be added and are indicated as such. Survey development included a qualitative study conducted with a sample of LTFU participants,[5] modifications and inclusions of national survey questions[87-92] and a cognitive testing phase. Using data collected previously by the overall LTFU via abstraction of medical records, data will be used to provide information on cancer diagnosis, age at diagnosis, and cancer treatment. These data will be provided to Dr. Kirchhoff's team via SharePoint, an encrypted system used to transfer data. Data from the LTFU surveys will provide information on sociodemographic and medical history since cancer treatment, and presence of a medical late effects and chronic health conditions including second cancers. The measures will include the following:

Participant Characteristic Measures (see study surveys)

Characteristics: Age, Gender, Education, Race/Ethnicity, Partnership/Marital Status

Enabling Characteristics: State of Residence, Familiarity with ACA Policies

Health Insurance Literacy: Confidence in Understanding of Terms (e.g. Coinsurance), Confidence in Choosing, Comparing, and Using Insurance, Household and Personal Income

Need: Cancer Diagnosis, Age at Diagnosis, Years Since Diagnosis, Treatment Type, Recurrence of Primary Cancer, Second Malignancy, Other Chronic Conditions.

Outcome Measures

Insurance Coverage: Insurance Status, Difficulty or Denial in Obtaining Coverage due to Health History (within past 2 years), Difficulty Finding and Choosing a Plan

Underinsurance: Not Taking a New Job in Order to Keep Health Insurance, Difficulty Finding a Provider who Accepts Insurance/ Not Able to Obtain an Appointment as Needed, Unmet Healthcare Need Due to Cost, Provider Visits in Past Year, or Out of Pocket Healthcare Costs, Out of Pocket Healthcare Costs/Premium Costs, Problems Due to Medical Expenses, Worry Related to Medical Costs

Coverage-Related Variables: Current Coverage and Coverage History

VII. RISKS AND DISCOMFORTS

Psychological Risks

Individuals may find it stressful to answer questions about their experiences with health insurance coverage and care. The risks associated with these discussions are minimal, and do not rise above the level of harm encountered during daily activities.
The potential risks to subject include: 1) Discussing health insurance coverage and care and participating in a program to discuss these issues with the navigator and the patient navigator has the potential for increasing psychological vulnerability.

These risks will be described by the patient navigator and be clearly outlined in the consent form. Participants will be encouraged to discuss any concerns with the patient navigator. In the event of a psychiatric emergency, confidentiality may be suspended. If the patient navigator notes severe distress, Dr. Park will contact the participant to assess for safety and report concerns as soon as possible to the LTFU PI, Dr. Greg Armstrong, and the LTFU Project Director, Dr. Aaron McDonald, at St. Jude Children's Research Hospital. Participants will be informed of the limits of confidentiality at the beginning of the study.

Procedures for Minimizing Risk

Every effort will be made to minimize the study burden. The time commitment will be explained to all participants prior to the focus groups and pilot trial study consent. Every effort will be made to minimize the length and maximize the convenience or the pilot surveys completion.

Maintaining Confidentiality

There is a low risk that protected health information could be impermissibly disclosed or that the confidentiality of patient information may be breached. Stringent guidelines are established in order to assure the confidentiality of study subjects. A unique study identification number will serve as the primary identifier for study participants. Personal identifiers will not be part of the computerized data record. Names and addresses will be maintained in a password protected restricted data file accessible only to the principal investigator, study coordinator and designated personnel within the Data Coordinating Center. A hard copy of names and corresponding study ID numbers will be kept in a locked file cabinet within the CCSS Coordinating Center. The computerized file will only be used for generation of correspondence with the study subject. Personal identifiers will be removed from all survey booklets following completion of initial editing and scanning. Similarly, names will be removed from all LTFU abstracted information. Study participants are informed of the potential risks and benefits regarding the security of their personal information. MGH TeleHealth enables connection through virtual HIPAA-compliant videoconferencing technology including: phone, video, text, email, mobile applications and remote monitoring. These virtual visits are conducted via a Zoom videoconference platform. Zoom has been approved for use in this study by RISO review.

VII. POTENTIAL BENEFITS

The consent form for the overall LTFU study enrollment clearly states that there may be no direct benefit to the participants from study participation. For the pilot trial phase of the proposed study, participants in both groups will be given information that could improve their ability to access affordable coverage. Participants in the intervention group will also receive navigation support, for up to 4 phone-delivered sessions. As an alternative to the intervention, participants may explore health insurance support options at their current primary care center.

IX. MONITORING AND QUALITY ASSURANCE

Training of all Study Personnel in the Responsible Conduct of Human Studies

Prior to recruiting subjects or handling study data, all study personnel will be required to pass an NIH-approved course that reviews regulatory and informational documents on human subject protection and the responsible conduct of human studies. In addition, all study personnel will sign a statement of commitment to the protection of the rights and welfare of human subjects participating in research. In addition, all study staff must complete and submit Conflict of Interest (COI) Disclosure forms to their respective institutions.

Data Monitoring Plan

Survey data will be collected via Dr. Kirchhoff's team at the Huntsman Cancer Institute. Data will be collected via mailed/phone-based survey and through a secure web-based portal (REDCap). Data transmissions will be conducted between the CCSS coordinating

center and statistical center with Dr. Kirchhoff to generate the participant sample and to facilitate data access from the LTFU baseline and follow up surveys. While the majority of surveys will be done via web using REDCap, we will allow participants to complete the baseline and follow-up surveys through mail or phone to improve participation. To ensure security, participant data collected using paper and pencil records will be stored in a locked filing cabinet in a locked room at the Huntsman Cancer Institute at the University of Utah; electronic participant tracking databases will be stored on a secure server accessible only by IRB-approved members of Dr. Kirchhoff's study staff. Data collected on paper and pencil forms or through phone-based surveys will be thoroughly cleaned and entered into the electronic REDCap database with a 10% check; discrepancies will be resolved by Dr. Kirchhoff. Dr. Kirchhoff will lead the pilot study data management and analyses, and transmit analytic data to MGH using the Hartwell Center's FTA protocol (located at http://fta.stjude.org), which is a web-based interface with a secure 128-bit encrypted web connection. Only study staff will have access to the study data on Shared File Areas. Data quality (including sessions participated in for the intervention group, data missingness, and recruitment rates) will be monitored monthly. Interim data analysis will be conducted throughout the trial and results will be reported in the annual ACS progress report.

Adverse Events Reporting

Serious adverse events will be reported to Drs. Park and McDonald (LTFU PI) immediately. Dr. Park will be responsible for the reporting of any adverse events to the Massachusetts General Hospital Institutional Review Board. The MGH IRB requires that serious adverse events are to be reported to the IRB as soon as possible, but no later than 10 working days from the date on which the investigator became aware of the event. Non-serious adverse events are to be reported within 20 working days. The St. Jude IRB reviews reports of unanticipated events involving risks to participants and others. The level and rapidity of review will depend upon factors such as the seriousness of the event.

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