Implementing a Patient-Centered Intervention to Reduce Cancer Patients Financial Toxicity

NCT: NCT04314284

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P50 I Can PIC- Aim 2

PI: Mary Politi
IRB ID #: 202003033

Project Details

1. Demographics

1.1 Project Title:
Implementing a Patient-Centered Intervention to Reduce Cancer Patients' Financial Toxicity

1.2 Short Title (required):
P50 I Can PIC- Aim 2

1.3 Project is primarily:
Social Science/Behavioral (includes History/Anthropology)

1.4 Type of Study:
Other Interventional

1.4.a Is your research study one in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (NIH clinical trial definition).
Yes

1.5 Select how you plan to obtain consent:
- Sign a consent document or a consent letter
- Script for use either in person or over the phone with no signature

2. Source(s) of Support

2.1 Source(s) of Support

Type/Source	Grant Title	Name of PI on Grant	Status
Federal Agency NIH, National Cancer Institute (NCI)	Implementing a Patient-Centered Intervention to Reduce Cancer Patients' Financial Toxicity	Mary Politi	AWARDED

3. Research Team

3.1 Principal Investigator

Name	E-mail	Title	School
Mary Politi	mpoliti@wustl.edu	Prof of Surgery (Public Health Sciences)	School

3.2 Team Members

Research Team Members

Role	Name	Role Desc	Student	Email	Title	School	Department	Co
PI	Mary Politi, PHD		No	mpoliti@wustl.edu	Prof of Surgery (Public Health Sciences)	School of Medicine	Surgery - Public Health Sciences (PHS)	
	Abigail Barker, PHD, PHD		No	arbarker@wustl.edu	Research Assistant Professor	Brown School	Brown School Administration	
	Krista Cooksey, BA, CER		No	kcooksey@wustl.edu	Pub Health	School of	Surgery - Public Health	

					Res Coord II	Medicine	Sciences (PHS)	
	Aimee James, BA, MA, MPH, PHD		No	aimeejames@wustl.edu	Prof of Surgery (General Surg)	School of Medicine	Surgery - Public Health Sciences (PHS)	
	Lindsay Kuroki, MD		No	kurokil@wustl.edu	Asst Prof of Ob & Gyn	School of Medicine	Obstetrics and Gynecology - Oncology	
	Esther Lu, PHD		No	esther@wustl.edu	Assoc Prof of Surgery (Public Health Sciences)	School of Medicine	Surgery - Public Health Sciences (PHS)	
	Christine Marx, MA		No	marxc@wustl.edu	Sr Public Health Res Coord	School of Medicine	Surgery - Public Health Sciences (PHS)	
	Sarah Pritchard, BA, MSW, MPH		No	sarahrpritchard@wustl.edu	Research Manager	Brown School	Brown School Administration	

Team Member Financial Interest

Name	Financial Interests
Mary Politi, PHD	none
Abigail Barker, PHD, PHD	none
Krista Cooksey, BA, CER	none
Aimee James, BA, MA, MPH, PHD	none
Lindsay Kuroki, MD	none
Esther Lu, PHD	none
Christine Marx, MA	none
Sarah Pritchard, BA, MSW, MPH	none

4. Other Institutional Reviews/Requirements

4.1 Do any of the objectives of this study involve the diagnosis, prevention, screening, evaluation, treatment or support of cancer patients?
Yes

4.2 Are more than 30% of the patients involved in this study likely to have an active cancer diagnosis?
Yes

4.11 Will a Certificate of confidentiality be used for this research?
Yes, certificate automatically issued by funding agency

4.12 Does this project need to be registered on ClinicalTrials.gov?
Yes

4.12.a Who is the Responsible Party for registering this study in ClinicalTrials.gov?
Principal Investigator

4.20 Mark all that apply to your study:

1. Protocol

1.1 Is there a separate, written protocol that will be submitted in addition to this form? (Note: a grant application is not considered to be a protocol)
No

1.2 Select up to three key words below that best describe this research study:
- Oncology
- Public Health

1.3 Provide a short summary/abstract of the purpose and procedures of the study proposed in this IRB application.

- DO NOT include information on studies not proposed in this application.
- Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.
- DO NOT cut and paste technical abstracts from source of support applications that may not be understood by a general audience.

The purpose of this study is to incorporate feedback from cancer patients and providers to adapt, implement, and test

an intervention. The intervention aims to prompt screening for financial distress, facilitate discussions about care costs with cancer patients, support health insurance selection, and ultimately reduce cancer patients' financial toxicity associated with cancer care [1-3]. This intervention is an online decision tool called I Can PIC (Improving Cancer Patients' Insurance Choices).

This study will evaluate I Can PIC's impact on patient care among newly-diagnosed patients with gynecologic, colorectal, or lung cancer. At the start of Aim 2, we will conduct a historic control survey of 100 patients with newly-diagnosed gynecologic, colorectal, or lung cancer to explore whether and how treatment costs are discussed with them. We will then conduct a brief training with oncologists to talk about screening for financial distress and discussing costs with patients. The training will consist of a brief 15 min presentation delivered in-person or virtually. Next, we will conduct a pilot intervention study where patients will complete I Can PIC, then complete a survey after their next oncology appointment. 3-6 months from recruitment, patient participants will complete a follow-up survey. 3 and 6 months after beginning recruitment, we will give the providers real-time feedback about how often they screened for financial distress and referred patients to I Can PIC.

1.4 Specify your research question(s), study aims or hypotheses:
We propose to modify the I Can PIC decision aid based on stakeholder feedback and to implement it as part of usual care, along with screening for financial toxicity and cost discussions.

The goal of this study is to evaluate the refined I Can PIC's impact on gynecologic, colorectal, and lung cancer care using a between subjects design.

1.5 Background and significance and/or Preliminary studies related to this project:
Cancer patients often pay substantial out-of-pocket costs for care, with some spending as much as 10-20% of their annual income on healthcare expenses [4,5]. Some new cancer therapies cost thousands of dollars per month, of which a large portion can fall on patients [6,7]. In a recent study of 9.5 million cancer patients, more than 40% depleted their savings and assets within two years of diagnosis [8]. Out-of-pocket costs are rising due to longer survival times, rising prices of new cancer treatments, and insurance cost-sharing increases [5]. Financial toxicity can exacerbate health disparities; those with low income and those uninsured or underinsured have more difficulty managing the costs of cancer treatment and adhering to care plans [9, 10].

Despite patients' overwhelming concerns about care costs, providers often miss opportunities to discuss costs with them [11,12]. Although costs often impact cancer patients' treatment decisions [13], particularly when treatments lead to similar health outcomes [14], costs are not often included in patient materials. Discussing out-of-pocket expenses with patients can lower their costs without impacting cancer outcomes [15]. Yet providers often feel inadequately trained to have cost conversations. Providers often hesitate to address costs of care because costs can vary considerably across patients [11,16]. In our prior work, fewer than half of providers discussing breast cancer surgery addressed relative costs of treatment.

We also found that patients without guidance find it difficult to choose an adequate health insurance plan [17-19], particularly when viewing monthly premiums and plan features without a cost calculator. Lower health insurance literacy and suboptimal insurance led many to delay or forgo needed care [19, 20].

We developed and tested I Can PIC to help cancer patients understand insurance terms and options, consider care costs, talk to providers about financial needs, and identify financial resources or insurance to help offset care costs. I Can PIC provides plain language education at an accessible reading level, uses Medical Expenditure Panel Survey (MEPS) data to estimate annual costs patients might incur across plan types, and allows users to input their plan details to compare cost.

1.6 Literature cited/references (if attaching a grant enter N/A):
1. Gordon LG, Merollini KMD, Lowe A, Chan RJ. A Systematic Review of Financial Toxicity Among Cancer Survivors: We Can't Pay the Co-Pay. The Patient. 2017;10(3):295-309.
2. Zafar SY, Abernethy AP. Financial toxicity, part I: a new name for a growing problem. Oncology (Williston Park, NY). 2013;27(2):80.
3. Fessele KL. Financial toxicity: Management as an adverse effect of cancer treatment. Clin J Oncol Nurs. 2017;21(6):762-764.
4. Bernard DS, Farr SL, Fang Z. National estimates of out-of-pocket health care expenditure burdens among nonelderly adults with cancer: 2001 to 2008. Journal of Clinical Oncology. 2011;29(20):2821-2826.
5. Carrera PM, Kantarjian HM, Blinder VS. The financial burden and distress of patients with cancer: Understanding and stepping-up action on the financial toxicity of cancer treatment. CA: A Cancer Journal for Clinicians. 2018;68:153-165.
6. Davidoff AJ, Erten M, Shaffer T, et al. Out-of-pocket health care expenditure burden for Medicare beneficiaries with cancer. Cancer. 2013;119(6):1257-1265.
7. Singleterry J. Costs of Cancer. American Cancer Society Cancer Action Network;2017.
8. Gilligan AM, Alberts DS, Roe DJ, Skrepnek GH. Death or Debt? National Estimates of Financial Toxicity in Persons with Newly-Diagnosed Cancer. The American journal of medicine. 2018;131(10):1187-1199.
9. Abbott DE, Voils CL, Fisher DA, Greenberg CC, Safdar N. Socioeconomic disparities, financial toxicity, and opportunities for enhanced system efficiencies for patients with cancer. J Surg Oncol. 2017;115(3):250-256.
10. Shankaran V, Jolly S, Blough D, Ramsey SD. Risk factors for financial hardship in patients receiving adjuvant chemotherapy for colon cancer: A population-based exploratory analysis. Journal of Clinical Oncology. 2012;30(14):1608-1614.
11. Kelly RJ, Forde PM, Elnahal SM, Forastiere AA, Rosner GL, Smith TJ. Patients and physicians can discuss costs of cancer treatment in the clinic. Journal of Oncology Practice. 2015;11(4):308-312.
12. Jagsi R, Ward KC, Abrahamse PH, et al. Unmet Need for Clinician Engagement Regarding Financial Toxicity After Diagnosis of Breast Cancer. Cancer. 2018.
13. Zafar SY, Peppercorn JM, Schrag D, et al. The financial toxicity of cancer treatment: a pilot study assessing out-

of-pocket expenses and the insured cancer patient's experience. The oncologist. 2013;18(4):381-390.
14. Wong Y-N, Egleston BL, Sachdeva K, et al. Cancer patients' trade-offs among efficacy, toxicity and out-of-pocket cost in the curative and non- curative setting. Medical care. 2013;51(9).
15. Zafar SY, Ubel PA, Tulsky JA, Pollak KI. Cost-related health literacy: a key component of high-quality cancer care. Journal of oncology practice. 2015;11(3):171-173.
16. Schrag D, Hanger M. Medical oncologists' views on communicating with patients about chemotherapy costs: A pilot survey. Journal of Clinical Oncology. 2007;25(2):233-237.
17. Politi MC, Kaphingst KA, Liu JE, et al. A Randomized Trial Examining Three Strategies for Supporting Health Insurance Decisions among the Uninsured. Med Decis Making. 2016;36(7):911-922.
18. Housten A, Furtado K, Kaphingst K, et al. Stakeholders' perceptions of ways to support decisions about health insurance marketplace enrollment: a qualitative study. BMC Health Services Research. 2016;16(1):634.
19. Zhao J, Mir N, Ackermann N, Kaphingst KA, Politi MC. Show Me Health Plans: Dissemination of a Web-based Decision Aid for Health Insurance Plan Decisions. Journal of Medical Internet Research. 2018;In press.
20. Smith KT, Monti D, Mir N, Peters E, Tipirneni R, Politi MC. Access is necessary but not sufficient: factors influencing delay and avoidance of health care services. Medical Decision Making Policy and Practice. 2018.
21. MacQueen KM, McLellan E, Kelly K, Milstein B. A codebook development for team-based qualitative analysis. Cultural Anthropology Methods Journal. 1998;10:31-36.
22. Coffey A, Atkinson P, eds. Making sense of qualitative data: Complementary research strategies. Thousand Oaks, CA: Sage Publications; 1996.
23. Dzewaltowski D, Glasgow R, Klesges L, Estabrooks P, Brock E. RE-AIM: Evidence-based standards and a Web resource to improve translation of research into practice. Annals of Behavioral Medicine. 2004;28(2):75-80.

1.7 Describe EACH of your participant populations

- Include description of any control group(s)
- Specify the Inclusion/Exclusion criteria for EACH group

Providers are eligible to participate in the study if they are medical or surgical oncologists who treat patients with gynecologic, lung, or colorectal cancer. The providers who will participate include:
Adult (18+) patients diagnosed with first, primary gynecologic, lung, or colorectal cancer within the past 5 months, who are English-speaking will be eligible to participate. This must be a first, primary diagnosis. They must also be patients of one of the participating medical or surgical oncologists. We will exclude patients who cannot give informed consent due to cognitive or emotional barriers.

1.8 Check all materials/methods that will be used in recruiting participants:

- Telephone script
- Ads/Brochures/Posters/News Release/Fliers
- Email or letters
- Medical Records or Other PHI

Attachment Name	Category	Version	Date Attached
I Can PIC Flyer-man.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	2	01/08/21
P50_HC_Patient letter_102620.rtf	Recruitment: Email or letters	5	10/27/20
P50_PI_Provider Call Script_2 11 2020.rtf	Recruitment Script: Phone	1	03/04/20
P50_PI_Patient letter_102620.rtf	Recruitment: Email or letters	5	10/27/20
P50_PI_Provider screening email_2 11 2020.rtf	Recruitment: Email or letters	1	03/04/20
P50_PI_study information sheet_patients_102620.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	4	10/27/20
Step 1_P50_HC_Screening script_102620.rtf	Recruitment Script: Phone	14	10/27/20
P50_HC_study information sheet_102620.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	4	10/27/20
I Can PIC Flyer-woman.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	2	01/08/21
P50_PI_Screening script_031221.rtf	Recruitment Script: Phone	13	03/18/21

1.8.b List the individual data elements you will access from the medical records (or other source of PHI) to identify potential participants for recruitment and, if applicable, any individual data elements that you will include on a screening log prior to consent.
- We will review medical records for names, age, telephone numbers, mailing addresses, language spoken at home, cancer type, date of cancer diagnosis, cancer stage, cancer treatments and completion, cancer clinician name, and cancer survivorship status from the medical record.
- In the phone screening survey we will collect age, language, cancer diagnosis, cancer type, and time since cancer diagnosis data to confirm eligibility.
- For those who choose to review the consent information sheet over the phone, we will ask for their email address after consent.

- For those who choose to review the consent information sheet online, we will ask for their email address after confirming their eligibility with the screening survey.
- On the screening log we will record age, cancer type, date of cancer diagnosis, cancer clinician name, phone number, email address (if participant gives permission), and mailing address. We will also note in the screening log if participants give us permission to email them.

1.8.c What is the plan for individual identifiers obtained to identify participants and, if applicable, those identifiers maintained on a screening log prior to consent?
Identifiers for those who do NOT enroll will be destroyed at the earliest opportunity, consistent with the conduct of the research (for example when recruitment and enrollment are completed.)

1.8.d Does the research team agree that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule?
Yes

1.10 Describe where the consent discussion will occur (check all that apply):

- Private room or area
- By phone

1.11 Participants and/or their legally authorized representative will have (check all that apply to the consent process and explain process in Question 1.12 below):

- As much time as they desire to consider enrolling in the study, including:
    - An opportunity to thoroughly review the consent materials with knowledgeable members of the research team, and with family and/or friends as appropriate
    - Sufficient time to have all of their questions answered

1.12 Provide a description of the enrollment and consent process in sequential order and address EACH of the bulleted points below:

- Describe each study population separately including control population
- Describe when recruitment and consent materials are used
- Indicate how much time individuals will have to consider participation
- Use THIRD person active voice. For example, "the principal investigator will identify potential participants, the study coordinator will discuss the study with participants over the telephone and schedule the first study visit, etc..."
- Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process

For the historic control survey, the WU research staff will screen the patients of participating providers through EPIC to identify potentially eligible patients. They will retrieve the phone numbers and mailing addresses of potentially eligible patients so WU research staff can contact them. When possible based on appointments scheduled in advance (e.g., not same-day add-ons), WU research staff will mail potential participants a letter explaining the study's purpose and procedures so they have background about the study to review before being approached for consent. A week after mailing the letter, WU research staff will contact candidates by telephone to review the study and assess interest and eligibility. To confirm eligibility, WU research staff will ask for the potential participants' age, comfort reading and writing in English, cancer diagnosis, and time since cancer diagnosis.

If the potential participant is eligible and interested, WU research staff will ask if the participant would prefer to complete the survey in-person, over the phone, or online at home. If the participant chooses to complete the survey over the phone, WU research staff will review the phone consent information sheet with the participant. If the participant chooses to complete the study online, WU research staff will record their permission to send them emails, and send them a test email to confirm the email given is correct. Once staff receive confirmation from the participant they will send a link to the survey, in which the consent information is on the first page of the survey. The participant will indicate consent by clicking to the next page. If the participant chooses to complete the survey in-person, WU research staff will review the informed consent document when they meet with them in person in a private room. The potential participant can take as much time as they would like to consider their participation.

For the second part of this study, the study populations include 15 BJC medical or surgical oncologists who treat patients with gynecologic, colorectal, or lung cancer, and 80-100 of their patients who have been diagnosed with gynecologic, colorectal, and lung cancer. Participating providers will give their permission for WU research staff to review their patients' medical records and contact them about the study.

Eligible providers will be identified by the WU study team. The WU study team will contact eligible providers by phone or email to assess interest. For eligible and interested providers, WU research staff will review the consent information over the phone or send it via email (whichever the participant prefers). They will have as much time as they want to consider their participation in the study. At the time of enrollment, WU research staff will confirm participants' contact information (telephone/address/email address). Informational flyers will be distributed to participating providers to remind them of this study and the I Can PIC website and resources.

For the patient population, the WU project coordinator will screen the patients of participating providers through EPIC to identify potentially eligible patients of the participating providers. They will retrieve the phone numbers and mailing addresses of potentially eligible patients so WU research staff can contact them. When possible based on appointments

scheduled in advance (e.g., not same-day add-ons), WU research staff will mail potential participants a letter explaining the study's purpose and procedures so they have background about the study to review before being approached for consent. A week after mailing the letter, WU research staff will contact candidates by telephone to review the study and assess interest and eligibility. To confirm eligibility, WU research staff will ask for the potential participants' age, language, cancer diagnosis, and time since cancer diagnosis.

If the potential participant is eligible and interested, WU research staff will ask if the participant would prefer to complete the survey in-person, over the phone, or online at home. If the participant chooses to complete the survey over the phone, WU research staff will review the phone consent information sheet with the participant. If the participant chooses to complete the study online, WU research staff will record their permission to send them emails, send them a test email to confirm the email given is correct. Once staff receive confirmation from the participant they will send a link to the survey, in which the consent information is on the first page of the survey. The participant will indicate consent by clicking to the next page. If the participant chooses to complete the survey in-person, WU research staff will review the informed consent document when they meet with them in person in a private room. The potential participant can take as much time as they would like to consider their participation. At the time of enrollment, WU research staff will confirm participants' contact information (telephone/address/email address).

In summary this is how recruitment materials will be used:
- When possible, patient letters and study information sheets will be mailed to potential participants in the historic control and pilot intervention groups so they have background about the study to review before being approached for consent.
- Recruitment call scripts will be used to contact potential participants in the historic control and pilot intervention groups to screen them for interest in eligibility.
- The online consent information sheet will be used with those participants in the historic control and pilot intervention groups who want to complete the study online. It will be the first page of the consent.
- Phone consents will be used with those participants in the historic control and pilot intervention groups who want to complete the study over the phone.
- Informed consents with PHI information will be used with those participants in the historic control and pilot intervention groups who want to complete the study in-person.

1.13 Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.

Describe study populations separately if they will be participating in different procedures

DESCRIBE:

- Control populations, if applicable
- Any randomization, if applicable
- What participants will be asked to do/what happens in the study (in sequential order)
- The time period over which procedures will occur
- Long-term follow-up and how it occurs

At the start of this study, we will conduct a historic control survey of 100 recently diagnosed gynecologic, colorectal, and lung cancer patients. They can complete the survey in-person, over the phone, or online. The survey will take approximately 15 minutes to complete. It will ask about their knowledge of health insurance and confidence communicating about care costs. WU research staff will will collect participants' distress assessment data, insurance status and other health conditions data from the electronic medical record in EPIC. At the time of enrollment, WU research staff will confirm participants' contact information (telephone/address). If they give us permission to email them we will document this in our records. They will receive a $10 gift card as a thank you for their time.

Then, we will train 15 BJC gynecologic, colorectal, and lung cancer care providers in using I Can PIC and discussing costs with patients in a brief 15 min presentation that can be delivered in-person or virtually. Providers will complete a survey before and after their brief training at the start of the study. These surveys will take approximately 5-10 mins to complete in total. During the study, at 3- and 6- months, we will give providers on the percent of time that they screened for financial distress and referred patients to I Can PIC. This information is collected from the patient participants' surveys. At the end of the study, we will examine adoption, implementation, and maintenance measures. Providers will receive a $50 gift card at the end of the study.

Next, we will recruit 100 gynecologic, colorectal, and lung cancer patients of the providers we trained over a 9 month period. At the time of enrollment, WU research staff will confirm participants' contact information (telephone/address). If they give us permission to email them we will document this in our records. Next, they will use I Can PIC. This will take approximately 10-15 mins. After their next appointment with their provider, they will complete a brief survey online about their knowledge of health insurance and confidence communicating about care costs. WU research staff will provide their survey to participants via phone, email, or in-person. The survey will take about 10 mins. Participants will receive a $20 gift card for reviewing I Can PIC and completing the survey.

Patient participants who choose to complete the study in person may view I Can PIC on a tablet provided by us in the clinic or at our office. Then after their appointment, they can complete the survey on a tablet provided by us in the clinic or at our office. If they choose to complete it over the phone, we will email them the link to I Can PIC and then call them when it is time to complete the survey. If they wish to complete it online, we will email them the link to I Can PIC, and then the survey after their appointment. WU research staff will collect participants' distress assessment data, insurance status and other health conditions data from the electronic medical record in EPIC. After 3-6 months, participants will receive a follow-up survey which they can complete in-person, online, or over the phone. WU research staff will will collect participants' distress assessment data, insurance status and other health conditions data from the electronic medical record in EPIC. This survey will take about 10 mins to complete. Once it is done, we will mail them a $10 gift card.

1.14 Will participants be randomized?
No

1.15 Will any of the following be used to collect information from the participant or others?

- Screening questions or screening/eligibility questionnaires
- Surveys
- Questionnaires
- Stimuli
- Any other written assessments

Yes

Attachment Name	Category	Version	Date Attached
P50_PI_post-intervention survey_patients_05 20 2020.docx	Subject Data Collection Instruments	5	05/20/20
P50_PI_3-6 month follow-up survey_patients_05 20 2020.docx	Subject Data Collection Instruments	6	05/20/20
P50_PI_Screening Survey_031121.docx	Subject Data Collection Instruments	3	03/18/21
P50_PI_pre training survey for providers_2 28 2020.docx	Subject Data Collection Instruments	1	03/04/20
P50_HC_historic control survey_05 20 2020_v2.docx	Subject Data Collection Instruments	5	05/20/20
P50_PI_follow-up survey for providers_2 28 2020.docx	Subject Data Collection Instruments	1	03/04/20

1.16 Does this project involve creating any audio, video, or photographs?
No

1.17 Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?
Examples:

- Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.
- Participants will be provided with false information regarding the particular behaviors of interest in the research.
- Procedures include a confederate pretending to be another participant in the study.
- Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.
- Study is designed to introduce a new procedure (or task) that participants are not initially told about.

No

1.18 Indicate any payments or reimbursements to participants (check all that apply)

- Gift or Debit Card

1.19 Does this study have a plan to have an individual or committee review combined data from all participants on a periodic basis (such as summary or aggregate safety and/or efficacy data)?
No

1.20 What have you done to minimize any risks?

- No forseeable risks

1.21 What are the potential benefits related to this project for:

- the participant (if any)
- benefits to society (if any)

There are no direct benefits to participation. Our goal is that the knowledge gained will benefit cancer patients and survivors in the future who are managing health care costs. Participants may feel a sense of contribution to their community and to others. They could also learn about health insurance terminology and care costs resources through participating in the study.

The results of this study will inform efforts to implement I Can PIC in a hospital system. Given that risks to participants are minimal, they do not outweigh these potential benefits.

1.22 Provide a summary of the analysis methods you will use, including, if applicable, the data points or outcomes you will analyze.
Descriptive statistics will be calculated for all variables and RE-AIM outcomes. Data will be examined for effectiveness outcomes between historic controls and intervention groups in a multivariable regression model controlling for up to 4 independent covariates (e.g. age, health literacy, insurance status, cancer type). The 3-6

month follow-up survey will be also conducted for the intervention group. The change in patient's outcomes between the first time point (after viewing I Can PIC) and the 3-6 month follow-up will be examined in a multivariable regression model controlling for up to 4 independent covariates (e.g. age, health literacy, insurance status, cancer type). We will examine the change in clinicians' responses to the surveys at the first time point and at the completion of the study in a regression model.

1.23 Provide the rationale or power analysis to support the number of participants proposed to complete this study.
All outcomes of patient participants are measured at screening for historic controls and at post-intervention for intervention groups. Power estimates are dependent on the effect size of each outcome, defined as the mean difference between two groups divided by the standard deviation. Using a two-tailed two-group t-test, a sample size of 80 patients with newly diagnosed breast, lung, or colorectal cancer in the intervention group and 80 historic controls has at least 80% power to detect an effect size of as small as 0.45 at a 0.05 level of significance. We will recruit up to 100 patients in each group (intervention and historic control) since we expect that some patients will drop out/not complete the surveys or follow-up. Powers were calculated using Power Analysis and Sample Size (PASS 15) software.

1.25 Will any data from this project be stored for use in future research studies?
No

1.26 Does this project involve the collection or use of biological samples or genetic data?
No

1.27 Are you requesting institutional certification to contribute human data or samples to a repository or database for broad sharing (public or restricted access)?
No

2. Participants

2.1 Will there be any adult participants?
Yes

2.1.a How many adult participants do you expect to consent or enroll under a waiver for this project?
215

2.1.b What is the age of the youngest adult participant?
18.0

2.1.c What is the age of the oldest adult participant?
No age limit

2.2 Will there be any minor participants?
No

2.3 Will there be any emancipated minor participants?
No

2.7 Do you plan to recruit/enroll non-English speaking people?
No

2.8 Do you propose to enroll any of the following in this study as participants?

- Employee of the PI or employee of a research team member
- Individual supervised by PI or supervised by member of research team
- Individual subordinate to the PI or subordinate to any member of the research team
- Student or trainee under the direction of the PI or under the direction of a member of the research team

No

2.9 Is this project about pregnant women?
No

2.10 Will this project involve fetuses?
No

2.11 Does this project involve the use of fetal tissue from any source?
No

2.12 Does this project recruit adult participants who may be incompetent or have limited decision-making capacity on initial enrollment into the study?
No

2.13 Does this project involve prisoners as participants?

No

3. Performance Sites

3.1 Indicate type of site(s) where research will occur (check all that apply):
- Hospital
- Academic Institution

3.2 Where will project procedures take place (check all that apply)?
- School of Medicine
- Barnes Jewish Hospital (BJH)

3.3 Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?
No

5. Privacy & Confidentiality

5.1 Indicate your plans to protect the privacy interests of the participants during the conduct of the study (check all that apply):
- Only the minimum necessary private information is collected for the purposes of the study
- Any procedures or interventions conducted as part of the study will be conducted in private setting to the extent possible
- Recruitment/consent will occur in a private setting
- Participants will be able to ask questions in a private setting

5.2 Are you collecting or using the Social Security Number of any participants for any purpose?
Yes

5.2.a Provide the intended usage of SSN:
- To provide compensation to participants

5.3 Project uses paper or hard copy consents, surveys, data collection forms, research subject binders, or other hard copy materials (check all that apply):
Yes
- All materials are stored in secured environment
- Access is limited to research team members only

5.4 Project collects, stores and/or transmits electronic data on mobile devices, desktop computers, servers including cloud servers, email, or any other information in electronic form (check all that apply):
Yes
- Password protected
- Access is limited to research team only
- Data are encrypted
- Data in Redcap

5.5 Project collects or uses biologic specimens (check all that apply):
No

5.6 Identify any additional protections in place for data and or samples (check all that apply):
- Formal research staff training process