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ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	Adverse Event
AYA	Adolescents and Young Adults with Cancer
BAA	Business Associates Agreement
CFR	IRB Code of Federal Regulations
CI	Confidence Interval
DECIDES	<u>D</u> eciding about <u>E</u> nrolling on a <u>C</u> linal <u>I</u> ntervention trial: <u>D</u> ecision aid for <u>E</u> ducation and <u>S</u> upport
DECIDES+ coach	DECIDES intervention with coach-assisted support
EPIC	Electronic Health Record
NCI	National Cancer Institute
PHI	Protected Health Information
SAE	Significant Adverse Event
T1	Time Point 1: Baseline Assessment
T2	Time Point 2: Post-Intervention Assessment
T3	Time Point 3: Semi-Structured Qualitative Interview

ABSTRACT

Context:

Adolescents and young adults with cancer (AYA) have limited involvement in treatment decision-making, do not fully understand cancer treatments (including clinical trials), and are vulnerable to acute distress undermining their decision processes at diagnosis. Research on how to increase involvement of AYA in treatment decision-making may be critical for addressing observed disparities in AYA enrollment in clinical trials and cancer outcomes, but few empirical studies have examined decision process or addressed AYA engagement in the cancer treatment decision.

Objectives:

Specific aims of the proposed study are to establish DECIDES acceptability, usability, and feasibility, evaluate preliminary efficacy for improved decision-making processes, and identify implementation strategies for future dissemination.

Study Design:

This study will use mixed methods in a hybrid design to evaluate a web-based decision support intervention (DECIDES = AYA Deciding about Enrolling on a Clinical Intervention Trial: Decision Aid for Education and Support) to increase involvement and improve decision-making processes for AYA, their caregiver(s), and oncology health care providers.

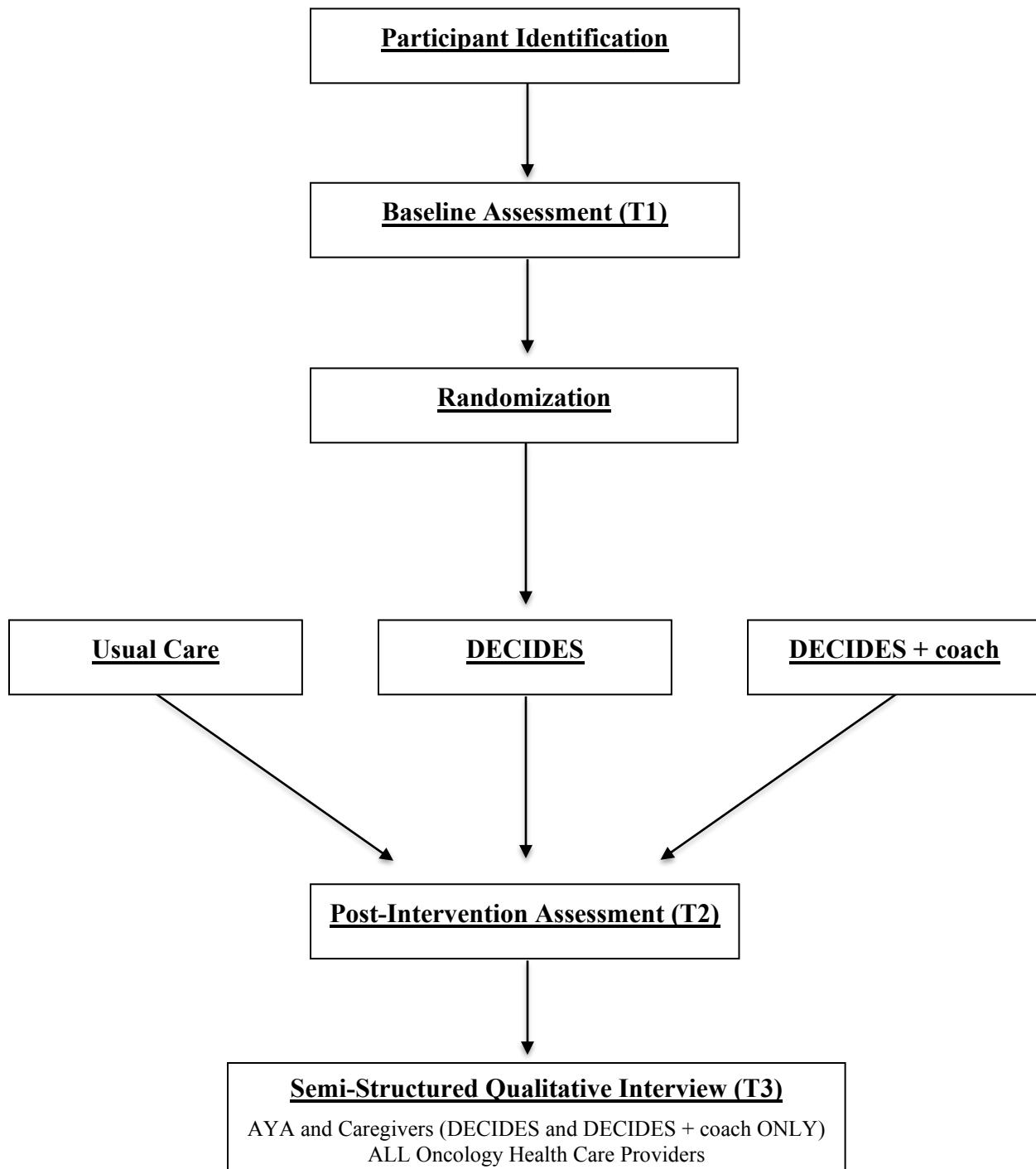
Setting/Participants:

We expect to enroll up to 65 family units in order to produce 50 evaluable family units, consisting of AYA (ages 15-24 years that are within six weeks of receipt of a new or relapsed leukemia/lymphoma, solid tumor, or brain tumor diagnosis at the Children's Hospital of Philadelphia) and their caregiver(s) (primary and secondary, if applicable) that are randomized to participate in Usual care (n=10 family units), DECIDES (n=20 family units), or DECIDES + coach (n=20 family units). AYA that are 18 and older may participate alone, without a caregiver. Approximately 25 oncology health care providers that participate in decision-making about cancer treatment with enrolled AYA and caregiver(s) will be invited to participate in this study.

Study Interventions and Measures:

DECIDES is a developmentally appropriate engaging and interactive web-based decision aid that has been designed to addresses health literacy and includes components to increase knowledge of cancer and cancer treatments (including clinical trials), address attitudes to cancer treatments (including clinical trials) and weigh perceived barriers and benefits of standard treatment or a cancer clinical trial relative to values. We will evaluate indicators of acceptability and feasibility, as well as barriers and facilitators to implementation, and compare decision-making involvement, shared decision-making, and decision processes for AYA, caregiver(s), and oncology health care providers.

FIGURE 1: STUDY DIAGRAM



1 BACKGROUND INFORMATION AND RATIONALE

Approximately 21,400 adolescents and young adults (AYA) ages 15 to 29 years were diagnosed with cancer in 2000, which is nearly 3 times that of patients diagnosed in the first 15 years of life.⁽⁷⁾ Contrary to younger age groups, 5-year survival and mortality reduction rates for AYA with cancer have remained stagnant.^(7,9,19) Reasons for this disparity are multi-factorial and include reduced participation in therapeutic clinical trials, which may reduce direct medical benefits and hinder treatment advances.⁽¹⁰⁻¹²⁾ The National Cancer Institute has advanced initiatives to increase AYA's access to cancer clinical trials, but emerging evidence indicates that AYA do not experience shared decision-making⁽²⁰⁾ and are less likely to enroll when offered a clinical trial.^(13,21)

AYA Development and Medical Decision-Making. The American Academy of Pediatrics provides that children be involved in medical decision-making to the extent that they are capable.⁽⁷⁸⁾ Children as young as age nine may have the cognitive capacity to assent (i.e., engage in the decision-making process for clinical trials about participation);^(79,80) however, factors other than age contribute to competence in medical decision-making.⁽⁸¹⁾ Optimal AYA decision-making includes the ability to set adaptive goals, work on more than one goal at a time, and overcome obstacles that might arise while evaluating options.⁽⁸²⁾ AYA decision-making abilities may be similar to that of adults when they are properly educated about the diagnosis and provided information about treatment options;^(86,83) although, the way in which participation is framed must be appropriate to cognitive capacity and level of maturity.^(84,85) In these circumstances, even younger AYA can manifest fundamental abilities needed for informed decision-making about medical treatments, such as the ability to weigh future consequences of their decisions, and the cognitive maturity to make such decisions based on their experience with cancer, personal values as emerging adults, and their acceptance of the possibility of death.⁽⁸⁶⁾

AYA involvement in clinical trial decisions is important but limited. Our research found that AYA involvement in clinical trial decision-making at diagnosis was more limited than preferred;⁽¹⁾ a recent review of the literature echoes this finding.⁽²²⁾ Highlighting the critical importance of improving decision-making processes in addressing AYA clinical trial enrollment, and consistent with other studies,^(23,24) AYA described presentation of information as ineffective in promoting understanding of treatment options, and caregivers and providers were challenged to maintain AYA engagement in treatment planning. Involvement in medical decision-making may have positive effects on AYA adaptation,⁽²⁵⁻²⁷⁾ but understanding of complex AYA clinical trial decision-making processes is only emerging.⁽²⁵⁻²⁹⁾ While most AYA have capacity,⁽³⁰⁾ shared decision-making with caregivers and providers varies.^(25-29, 31) Snethen and colleagues⁽³¹⁾ described developmental patterns of parent-child research decision-making,⁽³¹⁾ and Whitney and colleagues⁽³²⁾ outlined a decisional priority model in which characteristics of cancer clinical trial decisions interact with potential for cure to inform AYA involvement.

Unique aspects of AYA decision-making about cancer clinical trials. Newly diagnosed AYA and their caregivers are given extensive, complicated information on diagnosis, treatment, and clinical trials in context of intense emotions at diagnosis and short time allotted for decision-making.^(33,34) Relapse initiates new worries and distress. Thus, deficiencies in understanding are prevalent among parents who enroll their child on a cancer

clinical trial,^(35,36) and adolescents and parents need support to distinguish clinical trials from standard treatment.^(33,37-39) Youth with cancer and their parents are motivated to participate in research;⁽⁴⁰⁻⁴²⁾ yet, AYA note enrollment barriers of fear of toxicity, preference for standard treatment, and lack of family support.^(43,44)

Decision interventions may support AYA involvement in cancer treatment decisions.

AYA and their primary caregivers may benefit from the promise of decision support tools that increase understanding of cancer and cancer treatments, and clarify values vis-à-vis clinical trial enrollment.^(25,45) Decision interventions, primarily designed to support shared (patient, caregiver, and health care provider) decision-making for decisions of equipoise, provide a framework for decision-making regarding cancer clinical trial enrollment.^(45,46) Further, increased decision satisfaction and self-efficacy and decreased decision conflict and regret result from decisions that align with values.^(6,47,48)

Development and evaluation of interventions to improve decision-making for AYA and their families is critical.⁽⁴⁹⁻⁵¹⁾ The proposed study is highly innovative, as it is the first in the United States to use “best practice” mixed methods to test a rigorously developed decision support intervention for AYA and their primary caregivers⁽⁵²⁾ in the context of real time (versus hypothetical or retrospective) cancer treatment decision-making.^(53,54) Findings from a recent Australian-based pilot study assessing a parent and adolescent cancer clinical trial decision aid (retrospective to the actual decision) indicate benefit and relevance, but further evaluation is needed to assess the impact on families making an active treatment decision including whether to enroll in a clinical trial.⁽⁵⁵⁾

1.1 Relevant Literature and Data

Data from our series of mixed method studies examining pediatric clinical trial decision-making informed DECIDES development and the proposed measurement strategy, study design, and value clarification exercise.^(1,56-58)

1.1.1 Pediatric Research Participation Questionnaire (PRPQ-AYA)

This study capitalizes on our federally-funded measure, the Pediatric Research Participation Questionnaire, modified to assess attitudes to cancer clinical trials for AYA and their caregivers.^(1,56-58) Results support a 4-factor structure, and reliability and validity, for caregivers (direct benefit, mistrust, trust in the health care team and safety of research, and opportunity cost) and AYA (mistrust/no perceived benefit, safety of research/perceived benefit, direct benefits/practical considerations; altruism, access to treatments, and practical issues, and social support for research participation). Perceived barriers and benefits are particularly relevant to AYA clinical trial decision-making and inform the DECIDES value clarification exercise.

1.1.2 AYA Cancer Clinical Trial Decision-Making

We evaluated AYA with cancer, primary caregiver, and oncology provider Phase III clinical trial decision-making experiences.⁽¹⁾ From content analysis, AYA perceived that they had no role (38.4%) or a minor role (30.8%) in the clinical trial enrollment decision; they conveyed a sense of resignation because they viewed themselves as relying on their parents to make treatment decisions at diagnosis. Caregivers and providers felt challenged to include AYA in the treatment decision-making process at diagnosis, and providers noted uncertainty in how

to provide balanced information about treatment options and minimize coercion. AYA and caregivers who refused a Phase III clinical trial cited prolonged treatment with limited benefit, but many AYA and caregivers did not accurately remember whether the cancer treatment had been standard of care or on a clinical trial.

1.1.3 DECIDES Development

In collaboration with our stakeholders, and using The NCI Health Communication Model,⁽⁵⁹⁾ we followed the Informed Medical Decisions Foundation procedures⁽⁴⁻⁶⁾ to develop DECIDES. First, we outlined content in storyboard format based on: 1) Health Belief Model and Theory of Reasoned Behavior;^(2,3) 2) review of the literature on AYA with cancer; 3) results of our studies of AYA decision-making and the PRPQ measure of perceived benefits and barriers to clinical trial enrollment;^(1,56-58) (4) stakeholder input from our hospital's AYA Patient Steering Committee, their primary caregivers, and a Scientific Advisory Committee; (5) recent AYA decision support for AYA recommendations;⁽¹⁸⁾ and (6) decision aid development guidelines and decision support research in adult oncology.⁽⁴⁻⁶⁾ DECIDES is web-based with multi-model, graphically interesting content written for low health literacy. Content includes information to increase knowledge of cancer, treatment, and clinical trials, fact or fiction to address attitudes about cancer treatment and clinical trials, a value clarification exercise to consider goals for life vis-à-vis goals for treatment, and resources to increase knowledge and improve decision processes. Results of the value clarification exercise, and perceived treatment barriers and benefits, are emailed to the provider. The last step in DECIDES development entailed revision of the website components in an iterative process based on feedback from scientific experts and stakeholders.

1.2 Compliance Statement

This study will be conducted in full accordance all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

2.1 Primary Objective (or Aim)

The primary objective of this study is to assess the acceptability and feasibility of DECIDES using mixed methods and use results to inform implementation strategies for future dissemination.

Hyp 1a. Based on AYA, caregiver(s), and oncology health care provider ratings, and usage analytics, DECIDES will be acceptable and feasible during treatment decision-making within 6 weeks of diagnosis.

Hyp 1b. Qualitative interviews with AYA and caregiver(s) (randomized to DECIDES and DECIDES + coach) and oncology health care providers will confirm acceptability and feasibility ratings and provide specific information regarding timing, utility, barriers/facilitators, ease of use, and modifications to DECIDES for future implementation.

Hyp 1c (exploratory). DECIDES + coach will be rated more usable than DECIDES alone.

2.2 Secondary Objectives (or Aim)

The secondary objective is to evaluate preliminary efficacy of DECIDES using a randomized trial.

Hyp 2a. AYA randomized to DECIDES and DECIDES + coach will report greater involvement in and shared decision-making than AYA assigned to Usual Care.

Hyp 2b. AYA and caregiver(s) randomized to DECIDES and DECIDES + coach will report more positive decision-making processes (greater knowledge of their cancer and clinical trials, more balanced attitudes toward clinical trials, and more decision certainty, satisfaction and self-efficacy) compared with those assigned to Usual Care.

Hyp 2c. For DECIDES and DECIDES + coach participants who are offered enrollment on a clinical trial, the enrollment decision (yes/no) will align with AYA values.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

This is a 3-arm, mixed methods, hybrid design trial. We expect to enroll up to 65 family units to produce at least 50 evaluable family units that are randomized to participate in one of the following intervention groups:

- Usual Care (n=10)
- DECIDES (n=20)
- DECIDES + coach (n=20)

3.1.1 Participant Identification

Oncology health care providers and the psychosocial services team in the Division of Oncology at the Children's Hospital of Philadelphia will assist in the identification of AYA patients with newly diagnosed or relapsed leukemia/lymphoma, solid tumors, or brain tumors who are within six weeks of diagnosis/relapse. Potentially eligible AYA patients will be referred to the DECIDES study team to assess eligibility criteria. If applicable, eligible AYA and their caregiver(s) will be contacted for enrollment. Oncology health care providers of enrolled AYA and caregiver(s) will also be invited to enroll in the study.

3.1.2 Intervention Groups

Family units of AYA and caregiver(s) are randomized (after the completion of baseline assessment) to participate in Usual Care (access to oncology health care providers for information and education), DECIDES (usual care plus independent access to website), or DECIDES + coach (usual care plus coach-supported access to website).

Oncology health care providers that enroll in the study are not randomized to participate in the intervention.

3.1.3 Assessment Time Points

All AYA and caregiver(s) that enroll to participate in the study will complete an electronic baseline assessment at time of enrollment (prior to randomization) and again at post-intervention (i.e., approximately six-weeks after date of randomization). Additionally, AYA and caregiver(s) randomized to DECIDES or DECIDES + coach will also complete an audio or video-recorded semi-structured qualitative interview with a member of the study team via Microsoft Teams after the post-intervention assessment.

Oncology health care providers of enrolled AYA and caregiver(s) will be invited to preview the DECIDES website, participate in an electronic rating scale and complete an audio-recorded semi-structured qualitative interview with a member of the study team via Microsoft Teams.

3.2 Study Duration, Enrollment and Number of Sites

3.2.1 Duration of Study Participation

Study participation is expected to last approximately two months for AYA and caregiver(s), beginning at the time of consent.

Study participation is expected to last approximately 30-45 minutes for oncology health care providers, beginning at the time of consent.

3.2.2 Total Number of Study Sites/Total Number of Subjects Projected

This study will be conducted at the Children's Hospital of Philadelphia and will enroll up to 65 family units of (1) AYA alone [≥ 18 years old], (2) Dyads [AYA ages 15-24 years old + Primary Caregiver], or (3) Triads [AYA ages 15-24 years old + Primary Caregiver + Second Caregiver]. We expect to produce at least 50 evaluable family units.

We will approach all oncology health care providers of enrolled AYA and caregiver(s) for participation in the study and expect to enroll approximately 25 of them. Oncology health care providers that have multiple AYA/caregiver(s) enrolled will only be asked to participate once in the study procedures.

3.3 Study Population

The study will include:

- AYA (ages 15-24 years) newly diagnosed or relapsed with cancer that are receiving treatment for a leukemia/lymphoma, solid tumor, or brain tumor in the Division of Oncology of the Children's Hospital of Philadelphia, and their caregiver(s) (primary and secondary, if applicable). AYA that are 18 and older may participate without a caregiver.
- Oncology health care providers that participate in decision-making about cancer treatment with enrolled AYA and caregiver(s).

3.3.1 Inclusion Criteria

AYA

- 1) Ages 15-24 years old.
- 2) Newly diagnosed or relapsed with a leukemia/lymphoma, solid tumor, or brain tumor within six weeks of study enrollment.
- 3) Ability to read and speak English.
- 4) If <18 Years Old: Parental/guardian permission to participate (informed consent).

CAREGIVER

- 1) Parent or Legal Guardian of a participating AYA.
- 2) Ability to read and speak English.

ONCOLOGY HEALTH CARE PROVIDER

- 1) Oncology health care provider involved in decision-making about cancer treatment with enrolled AYA patients and caregiver(s).
- 2) Ability to read and speak English.

3.3.2 Exclusion Criteria

AYA

- 1) Inability to read or speak English.
- 2) Pre-existing cognitive deficits (based on provider assessment) that result in impaired reading or decision-making capacity (i.e., developmental disability).
- 3) AYA patient is a ward of the state or any other agency, institution, or entity.
- 4) If <18 Years Old: No Parental/Guardian permission to participate (informed consent).

CAREGIVER

- 1) Foster parent or child advocate (i.e., caregiver is not biological parent or legal guardian).
- 2) Inability to read or speak English.

ONCOLOGY HEALTH CARE PROVIDER

- 1) Oncology health care provider that is not involved in decision-making about cancer treatment with enrolled AYA patients and caregiver(s).
- 2) Inability to read or speak English.

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 AYA and Caregiver(s)

4.1.1 Participant Identification

Health care providers and the psychosocial services team in the Division of Oncology at the Children's Hospital of Philadelphia will assist in the identification of potentially eligible patients newly diagnosed with leukemia/lymphoma, solid tumor, or brain tumor during weekly team meetings. Potentially eligible AYA patients will be referred to the DECIDES study team. If AYA and caregiver(s) meet all eligibility criteria, they will be invited to participate in the study. Informed consent/assent for participation will be obtained by phone or in-person during an outpatient oncology clinic visit or inpatient hospital stay.

4.1.2 Baseline Assessment (T1)

After providing informed consent/assent to participate in the study, AYA and caregiver(s) will complete an electronic baseline assessment via REDCap. The assessment will be completed either in-person on an iPad during an outpatient oncology clinic visit or inpatient hospital stay, or a link to the REDCap assessment will be emailed to participants to complete remotely (if needed).

4.1.3 Assignment to Intervention Group

Following completion of the baseline assessment, AYA and caregiver(s) will be randomly assigned to participate in one of the following conditions:

Usual Care

AYA and caregiver(s) assigned to participate in the Usual Care group will have access to their oncology health care providers and other members of the health care team for questions related to cancer and cancer treatment (as per usual).

DECIDES

In addition to usual care, AYA and caregiver(s) assigned to participate in the DECIDES group will receive a flyer that includes goals of the decision support intervention and instructions for accessing the DECIDES website. AYA and caregiver(s) will receive a text message reminder to review DECIDES, and the oncology health care provider will be informed of enrollment and the value clarification exercise results.

DECIDES + coach

In addition to usual care, AYA and caregiver(s) assigned to participate in the DECIDES + coach group will work with a coach (clinical research coordinator for this study) to review the DECIDES website in-person. The coach will guide the value clarification exercise with AYA and caregiver(s) separately and together. AYA and caregiver(s) will receive a text message reminder to review DECIDES, and the oncology provider will be informed of enrollment and the value clarification exercise results.

4.1.4 Post-Intervention Assessment (T2)

All AYA and caregiver(s) (assigned to Usual Care, DECIDES, or DECIDES + coach) will complete an electronic post-intervention assessment via REDCap. The assessment will be completed either in-person on an iPad during an outpatient oncology clinic visit or inpatient hospital stay, or a link to the REDCap assessment will be emailed to participants to complete remotely (if needed).

4.1.5 Semi-Structured Qualitative Interview (T3)

AYA and caregiver(s) (assigned to DECIDES or DECIDES + coach) will complete an audio or video-recorded semi-structured interview remotely via Microsoft Teams with a member of the study team.

4.2 Oncology Health Care Providers

4.2.1 Electronic Rating Scales

Oncology health care providers of enrolled AYA and caregiver(s) will preview the DECIDES website and complete the Systems Usability Scale (SUS)^(36,71). This will be emailed to them to complete remotely or can be administered remotely by a member of the study team during the semi-structured qualitative interview.

4.2.2 Semi-Structured Qualitative Interview

Oncology health care providers of enrolled AYA and caregiver(s) will complete an audio or video-recorded semi-structured interview remotely via Microsoft Teams with a member of the study team.

4.3 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care. The study team will document whether or not each subject completes the study.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Electronic Health Record Review

Medical information will be abstracted from the AYA patients' electronic health record (EPIC) for the following purposes:

- Enrollment Decision
- Demographics
- Diagnosis, date of diagnosis, age at diagnosis
- Intensity and types of treatments received (Using the Intensity of Treatment Rating-III)

5.2 Self-Report Measures

Demographics: Variables will be collected based on AYA and caregiver(s) self-report and review of the patients' electronic health record. Demographic variables include age, gender, race/ethnicity, education/work, health care, and family history.

Intensity of Treatment Rating Scale (ITR-3): The revised version of a reliable and valid method for classifying pediatric oncology treatment protocols. This scale, completed by a medical provider, categorizes the intensity of pediatric cancer treatment from least through most intensive based on treatment modality and stage/risk level for the patient. ⁽⁹⁹⁾

Acceptability of the Decision Aid: A study-team developed measure used to obtain acceptability ratings from AYA and caregiver(s) (assigned to DECIDES or DECIDES + coach only). This measure is based on The Ottawa Hospital's measure of acceptability ratings regarding comprehensibility of components of a decision aid, its length, pace, amount of information, balance in presentation of information about options, and overall suitability for decision making. ⁽⁶⁾

Systems Usability Scale (SUS): This is a cost-effective, 10-item scale that is widely used to obtain a reference score for participants' view of a product's usability. This scale includes 10 statements that are scored on a 5-point scale of strength of agreement. Final scores can range from 0 to 100, in which higher scores indicate better usability. AYA and caregiver(s) (assigned to DECIDES or DECIDES + coach only) and oncology health care providers will complete this scale. ^(36,71)

Control Preferences: This scale assesses patient decision-making preferences and roles (i.e., patient's preferred role [baseline] versus the role they actually played in making a treatment decision [post-intervention]). This scale has been adapted for use in this study to assess caregiver decision-making preferences and roles, as well (i.e., caregiver's preferred role of patient [baseline] versus the role the patient actually played in making a treatment decision [post-intervention]). Decision-making preferences and roles are evaluated using three categories: 1) patient led, 2) shared, or 3) oncologist/caregiver led. ^(74,75)

Physician Decision Making Scale: A 5-item scale that measures physician involvement in medical decision-making. Items are rated on a 3-point scale ranging from 1 ("Yes, definitely") to 3 ("No"). Higher scores reflect lower involvement in decision-making. ⁽¹⁰⁰⁾

Shared Decision-Making Questionnaire (SDM-Q-9): This is a brief, valid, and reliable 9-item questionnaire that measures the degree to which patients are involved in the process of decision-making (for preference-sensitive decisions, in which there are several treatment options for a particular disease) from the perspective of the patient. The SDM-Q-Doc (Physician Version) has been adapted for use in this study to measure the degree to which patients are involved in the process of decision-making from the perspective of the caregiver. Items are scored on a 6-point scale ranging from "completely disagree" (0) to "completely agree" (5), and a total sum score is calculated (ranging in values between 0-45). ⁽⁹⁴⁾

Adolescent and Young Adult Health Outcomes and Patient Experiences (AYA HOPE) Survey: Information needs are assessed using thirteen items from the AYA HOPE study survey. Participants indicate if they need more information on a range of topics related to cancer medical care and support services. The response options ("I need some more information" and "I need much more information" are collapsed and categorized as "unmet information need"; while the response options "I have enough information" and "Does not

apply" are collapsed and categorized as "met information need". Unmet information need (count) is categorized as low (0-3), intermediate (4-8), or high (9-13).^(76,77)

Knowledge of Clinical Trials: This is a 25-item true/false rating assessment used to assess participant understanding of clinical trials and informed consent processes.⁽⁶⁴⁾

Pediatric Research Participation Questionnaire (PRPQ): The PRPQ is a 12-item questionnaire for AYA (age 15-29) and caregivers (of AYA) about participation in a clinical trial. Items are rated on a 5-point scale, ranging from "not at all" (1) to "extremely" (5).^(15,16)

Decisional Conflict Scale: This is a valid and reliable 16-item scale, delivered in statement format (Version A), that measures personal perceptions of: uncertainty in choosing options; modifiable factors contributing to uncertainty (i.e., feeling uninformed, unclear about personal values, and supported in decision making); and effective decision making (i.e., feeling the choice is informed, values-based, likely to be implemented, and expressing satisfaction with the choice). Items are rated on a 5-point scale ranging from "strongly agree" (0) to "strongly disagree" (4). Higher scores indicate higher decisional conflict.

Satisfaction with Decision Scale: This is a valid and reliable 6-item instrument that measures patient satisfaction with a health care decision. The scale provides an efficient measure to evaluate decision-assisting technologies or patient-provider interactions aimed at involving patients in decision-making. Higher scores indicate higher satisfaction with the decision that was made.⁽⁶⁶⁾

Decision Self-Efficacy Scale: This is a valid and reliable 11-item instrument that measures self-confidence in one's abilities in decision-making (including shared decision-making). Items are rated on a 5-point scale, ranging from "not at all confident" (0) to "very confident" (4). Higher scores indicate higher self-efficacy.⁽⁶⁷⁾

Decision Regret Scale: This is a valid and reliable 5-item instrument that measures distress or remorse after a (health care) decision. Items are rated on a 5-point scale, ranging from strongly agree (1) to strongly disagree (5). Items 2 and 4 are reverse coded so that for each item, a higher score will indicate more regret.⁽⁷²⁾

PROMIS Profile: 25, 29, and Parent-Proxy The PROMIS measures assesses physical function mobility, depressive symptoms, fatigue, peer relationships, pain intensity, and pain interference. The PROMIS Pediatric Profile (25 items) is intended for use with those under age 18; the PROMIS Profile (29 items) is intended for use with those over age 18; and the PROMIS-Parent Proxy Profile (25 items) is a parent-report measure.⁽⁹⁶⁻⁹⁸⁾

Distress Thermometer: The Distress Thermometer is from the National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology for Distress Management. It is an illustration (thermometer) used with patients to rate the number that best describes how much distress they have been experiencing in the past week, ranging from "no distress" (0) to "extreme distress" (10).

Affective Slider (AS): This is a digital self-reporting tool composed of two slider controls for the quick assessment of arousal (top) and pleasure (bottom) on a continuous scale. The

AS does not require written instructions. The scale is intentionally displayed using a neutral chromatic palette to avoid bias in rating (due to emotional connotation of colors). ⁽⁸⁷⁾

Affective Orientation (AO15): This is a valid and reliable 15-item measure used to assess how people use feelings and emotions to guide their behavior. Items are rated on a 5-point scale, ranging from strongly disagree (1) to strongly agree (5). Higher scores reflect greater awareness of emotions. ⁽⁸⁸⁾

Developmental Task Questionnaire (DTQ): The adolescent version of the DTQ is a 9-item self-report questionnaire that assesses adolescents' perceived developmental status; whereas the young adult version includes 8 items that assess developmental tasks for emerging adulthood. Items are rated on a 3-point scale ranging from "not yet started" (1) to "already developed" (3). Both adolescents and young adults are also asked to rank how important it is for them to achieve each of the normative developmental tasks on a 3-point scale, ranging from "not important" (1) to "very important" (3). ^(89,92)

Consideration of Future Consequences (CFC): This valid and reliable 12-item measure is used to assess the extent to which people consider distant versus immediate consequences of potential behaviors. Items are rated on a 5-point scale ranging from "extremely uncharacteristic" (1) to "extremely characteristic" (5). The CFC is scored so that higher numbers indicate a greater consideration of future consequences. ⁽⁹⁰⁾

Psychosocial Maturity Inventory (PMI): This is a 30-item self-report measure for AYA used to evaluate developmental aspects of maturity (i.e., self-reliance, self-concept, and work orientation). Items are rated on a 4-point scale, ranging from "agree strongly" (1) to "disagree strongly" (4). ⁽⁹⁵⁾

Emotion Regulation Questionnaire (ERQ): This is a valid and reliable 10-item measure used to assess processes of emotion regulation (cognitive reappraisal and expressive suppression). Items are rated on a 7-point scale ranging from "strongly disagree" (1) to "strongly agree" (7). The average score of items in the cognitive reappraisal subscale is calculated and the average score of items in the expressive suppression subscale is calculated. Higher scores indicate the greater use of that particular emotion regulation strategy, whereas lower scores indicate less frequent use. ⁽⁹¹⁾

Family Assessment Device (FAD): The Problem Solving subscale of the FAD includes 5 items that are rated on a 4-point scale ranging from "strongly agree" (1) to "strongly disagree" (4), with higher scores indicating more problematic functioning. ⁽⁹³⁾

5.3 Semi-Structured Qualitative Interview

A semi-structured, qualitative interview guide designed by the study team for use with AYA and caregiver(s) (assigned to DECIDES or DECIDES + coach), and oncology health care providers. The purpose of the interview is to obtain further information from participants about the process of treatment decision-making and their experience using DECIDES, the decision aid. Participants will be interviewed by a study team member via remote video conference software (Microsoft Teams). All interviews will be audio and/or video recorded and professionally transcribed (by a CHOP-approved vendor with a BAA in place), and the interview data will be analyzed.

Table 1. Measures

Construct	Measure	Administration	
		T1	T2
Demographics	Electronic Health Record; AYA/Caregiver Self-Report	AYA, CG	
Treatment Intensity	Intensity of Treatment Rating Scale (ITR-3) ⁽⁹⁹⁾	PR	
Acceptability ^(D)	Acceptability of the Decision Aid ⁽⁶⁾		AYA, CG
Usability ^(D)	The Systems Usability Scale ^(36,71)		AYA, CG, PR
AYA Involvement in Shared Decision-Making	Control Preferences ^(74,75)		AYA, CG
	Physician Decision-Making Scale ⁽¹⁰⁰⁾		AYA, CG
	Shared-Decision Making Questionnaire (SDM-Q-9) ⁽⁹⁴⁾		AYA, CG
Knowledge	AYA Hope Survey: Information Need ^(76,77)	AYA, CG	
	Knowledge of Clinical Trials ⁽⁶⁴⁾	AYA, CG	AYA, CG
Attitudes to Clinical Trials	Pediatric Research Participation Questionnaire	AYA, CG	AYA, CG
Alignment of Decision with Values	(PRPQ) ^(15,16)		AYA, CG
Decision-Making	Certainty	Decisional Conflict Scale ⁽⁶⁵⁾	AYA, CG
	Satisfaction	Satisfaction with Decision Scale ⁽⁶⁶⁾	AYA, CG
	Self-Efficacy	Decision Self-Efficacy Scale ⁽⁶⁷⁾	AYA, CG
	Regret	Decision Regret Scale ⁽⁷²⁾	AYA, CG
Health-Related Quality of Life	PROMIS Parent Proxy Profile-25 ⁽⁹⁸⁾	CG	CG
	PROMIS Pediatric Profile-25 ⁽⁹⁷⁾	AYA (15-17)	AYA (15-17)
	PROMIS-29 Profile ⁽⁹⁶⁾	AYA(18-24)	AYA(18-24)
*Distress	Distress Thermometer ⁽⁷³⁾	AYA, CG	AYA, CG
*Valence and Arousal	Affective Slider ⁽⁸⁷⁾	AYA, CG	
*Awareness of Feeling Emotions	Affective Orientation (AO15) ⁽⁸⁸⁾	AYA, CG	
*Developmental Status	Developmental Task Questionnaire ^(89,92)	AYA	
*Psychosocial Maturity	Consideration of Future Consequences ⁽⁹⁰⁾	AYA, CG	
	Psychosocial Maturity Inventory ⁽⁹⁵⁾	AYA	
	Emotion Regulation Questionnaire ⁽⁹¹⁾	AYA, CG	
*Problem-Solving	Family Assessment Device (FAD): Problem-Solving ⁽⁹³⁾	AYA, CG	
Semi-Structured Qualitative Interview ^(D)	DECIDES Interview Guide		AYA, CG, PR

* = Covariate

(D) = measure for participants randomized to DECIDES or DECIDES + coach only

T1 = Pre-Intervention; T2 = Post-Intervention; AYA = Adolescent/Young Adult; CG = Caregiver; PR = Health Care Provider

6 STATISTICAL CONSIDERATIONS

Demographic characteristics and all measurements will be summarized.

6.1 Primary Endpoints

Hyp 1a. We will perform descriptive analyses of responses to the acceptability questionnaire. Click behavior, participation rate, and time to DECIDES implementation will be summarized to describe feasibility.

Hyp 1b. We will use qualitative descriptive methods ⁽⁶¹⁾ to evaluate acceptability, usability, and feasibility. Interviews with AYA, caregiver(s) and oncology health care providers will be audio and/or video-recorded and transcribed. Constant comparative methods (using Atlas.ti) will be used to simultaneously gather and rigorously analyze data using two coders to ensure coding reliability.

Hyp 1c. Feasibility measures such as participation rate and summary score for the Systems Usability Scale will be summarized for DECIDES alone and DECIDES + coach separately, along with 95% confidence intervals (CIs). We expect that participation rate and usability score will be higher for the DECIDES + coach group.

6.2 Secondary Endpoints

The secondary objective is to evaluate preliminary efficacy of DECIDES using a randomized trial.

Hyp 2a and Hyp 2b. Because all measures are continuous, the primary analyses will be summarizing mean and 95% CI by groups and two-sample t test comparing groups for the post-intervention outcome measures. With the sample size of 20 family units for each DECIDES group and 10 family units for usual care, we will have 80% power to detect an effect size of 1.26 (that is, mean difference between the two groups is 1.26 x Standard Deviation).

Hyp 2c. Each AYA and caregiver will have two value scores: Σ factors endorsed as supporting enrollment/ Σ factors endorsed as not supporting enrollment. Consistency of value to enrollment decision will be evaluated with Tetrachoric correlation with 95% CI.

7 SAFETY MANAGEMENT

7.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

7.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, Significant Adverse Events (SAEs) are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. Adverse Events (AEs) that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

8 STUDY ADMINISTRATION

8.1 Treatment Assignment Methods

8.1.1 Randomization

We will enroll up to 65 family units to achieve 50 evaluable family units that are randomized to three groups with a 1:2:2 ratio for usual care, DECIDES, and DECIDES +

coach. The randomization will be stratified by two age categories, under 18 years old and 18 years or older, and we expect 50% of the AYA patients in each of the two strata. For each stratum, we use a blocked randomization of block size of 5. The statistician will generate the randomization sheet for assigning patients into intervention groups.

8.2 Data Collection and Management

The data collection and management plan is consistent with CHOP Policy A-3-6: Acceptable Use of Technology Resources that defines the requirements for encryption and security of computer systems.

- Identifiable data will be collected as part of this study. This data includes full names/initials, dates of birth, addresses, telephone numbers, and e-mail addresses. However, participants will be identified by alphanumeric code only. This precautionary step allows for the electronic transfer of data without using data encryption techniques. At each stage of data collection and maintenance, measures are taken to ensure that all identifying information is taken out of data archives, and any hard copies of data that could identify participants are stored in locked file cabinets with restricted access, and that data files are password protected. Participant identification numbers are used that do not reveal the identity of participants (e.g., no use of birth dates, initials, social security numbers, etc.). Identifiable data will be stored in a locked cabinet at one of the research buildings at CHOP, and only members of the research team will have access to the data. If the results of this study are presented at scientific meetings or published in professional journals, they will not contain information that could be used to identify patients, parents, or family members.
- Electronic survey data will be collected and stored using REDCap (Research Electronic Data Capture) database, a secure web-based software database supporting clinical and translational research databases. The database will be password-protected, stored, and backed up on a daily basis by CHOP's Research Institute. REDCap provides data management functionality; including automated export procedures for seamless data downloads to Excel and commonly used statistical packages (SPSS, SAS, Stata, R). The database will incorporate range checks and between-variables consistency checks to ensure quality control. The system will signal the presence of questionable or potentially incorrect items. After data cleaning and quality assurance procedures are completed, pertinent sets of data will be exported into SPSS for statistical analysis.
- Electronic interview data will be collected and audio and/or video-recorded using Microsoft Teams (Office 365), CHOP's preferred HIPAA compliant video conference platform. Microsoft Teams utilizes 2-factor authentication, data encryption, and restriction on anonymous users joining a meeting, making it an appropriate application to facilitate sensitive video conversations and protect PHI. This application will be utilized to connect the study team personnel with study participants during the semi-structured qualitative interview. Microsoft Teams provides an interoperable cloud-based video meetings service that connects multiple users across different devices and platforms. Every Microsoft Teams member on the study team has a private "meeting room" in the Microsoft Teams cloud to schedule and host video meetings. In the event

that participants experience WIFI connectivity issues during the interview, Microsoft Teams provides a telephone number that participants can call directly into the Microsoft Teams private “meeting room” using their phone, as needed.

- Interview recordings (audio and/or video recordings containing participant identifiers) will be transferred from Microsoft Teams to a CHOP password-protected desktop computer on the Principal Investigator’s shared drive through a secure upload. The study team will use a CHOP-approved vendor for professional transcription services (that has a BAA with CHOP in place). Transcribed interview data will be stored on a CHOP password-protected desktop computer, on the Principal Investigator’s shared drive, and loaded into ATLAS.ti© software to facilitate data organization and content analysis. After all analyses are complete, the files will be destroyed, and personal identifiers will not be retained with the data. All computerized study databases for questionnaire data will be kept on a secure Windows NT server located at one of the hospital’s research buildings. This server is also protected by a firewall to reduce the risk of unauthorized access to study information.

8.3 Confidentiality

All data and records generated during this study will be kept confidential in accordance with CHOP’s Institutional policies and HIPAA on subject privacy. Neither the Investigator nor other site personnel will use records and/or data collected for any purpose other than conducting the study.

The following steps will be taken to maintain confidentiality: (1) subject identity will be coded using numbers keyed to a master list; (2) coded data will be entered directly into files that will be password protected, (3) all project staff will be trained in the importance of confidentiality, and will certify in writing to protect subject confidentiality; and (5) if the results of the study are published, data which might reveal the identity of any particular subject will be disguised. Subjects will be informed about the limits of confidentiality (e.g., in cases in which a subject is in danger to themselves or others). No identifiable data will be retained or used for future studies. The investigator will obtain a data use agreement between the provider (the PI) of the data and any recipient researchers (including others at CHOP) before sharing a limited dataset (PHI limited to dates and zip codes).

8.4 Regulatory and Ethical Considerations

8.4.1 Risk Assessment

This is a low-risk study. Data collection involves contact with all participants either remotely over the phone or in person in clinic. As to be expected following the receipt of a new cancer diagnosis or relapse, the education and information related to cancer and treatment that is delivered via DECIDES may increase distress for AYA and caregiver(s). All participants will be informed of this risk prior to participation and will be informed of the right to discontinue participation if they are uncomfortable with the study. If participants become upset or report clinically significant levels of depression and/or anxiety (as defined by norms on the PROMIS scales), Dr. Lamia Barakat (clinical psychologist, Director of Psychosocial Services for the Cancer Center, and PI) will assess the level of distress of the

patient and determine the need for additional psychosocial support. If additional psychosocial support is needed, Dr. Barakat will initiate follow-up for the patient's social worker for further assessment and intervention. There is also a slight risk of breach of privacy and confidentiality, as with all studies, despite our very careful safeguards to protect data as described above. If required by law, confidential information may be revealed.

8.4.2 Potential Benefits of Trial Participation

This research does not offer direct medical or psychological benefits to participants. Participation in this study may indirectly improve AYA and caregivers understanding of cancer, cancer treatments (including clinical trials), and involvement in treatment decisions. The knowledge gained from this study may help researchers determine if the DECIDES website is helpful for AYA, caregivers, and oncology health care providers that are working together to make decisions about cancer treatment.

8.4.3 Risk-Benefit Assessment

As the risks of the research are appropriately characterized as "minimal risk", they are reasonable in spite of the anticipated lack of direct medical or psychological benefit to subjects. The potential benefits from knowledge gained through this study and the indirect benefits of helping newly diagnosed or relapsed AYA, caregiver(s), and oncology health care providers making treatment decisions in the future outweigh the minimal risks associated with participation.

8.5 Recruitment Strategy

Oncology health care providers and the psychosocial services team in the Division of Oncology at the Children's Hospital of Philadelphia will assist in the identification of potentially eligible patients newly diagnosed with leukemia/lymphoma, solid tumor, or brain tumor during weekly team meetings. Potentially eligible AYA patients will be referred to the DECIDES study team. If AYA and caregiver(s) meet all eligibility criteria, they will be invited to participate in the study. Informed consent/assent for AYA and caregiver participation will be obtained by phone or in-person during an outpatient oncology clinic visit or inpatient hospital stay.

Following AYA and caregiver study participation, the study team will contact their oncology health care provider and if they meet all eligibility criteria, they will be invited to participate in the study.

Recruitment and enrollment will be tracked using a password protected Excel spreadsheet.

8.6 Informed Consent/Assent and HIPAA Authorization (AYA/Caregivers)

Informed consent/assent will be obtained from AYA and caregiver(s) prior to the beginning of the study during outpatient visits, inpatient admissions, or verbally by phone. A study team member will discuss the procedures and consent forms with potential participants individually. In order to assure that the potential participant understands the study, the team member will review the consent, in its entirety, with the AYA and their caregiver(s) and will encourage them to ask questions throughout the process. The individuals will also be reminded that participation is voluntary and will not affect their care. There are no time

constraints on the consent process. The potential participants will be allowed to take as much time as they need to ask questions and decide if they would like to participate.

If consent/assent is being conducted in-person and the potential participant agrees to participate, the In-Person Signature Page of the consent forms will be signed and dated by the potential participant and the research team member and stored in a regulatory binder maintained by the study coordinator. A copy of the consent forms will be provided to the participant for their records.

8.6.1 Consent with Waiver of Documentation

If consent/assent is being conducted over the phone, we will use Consent with Waiver of Documentation (verbal consent/assent). The study team will complete the Documentation of Consent Page of the consent form, which will be stored in a regulatory binder maintained by the study coordinator. A digital or paper copy of the verbal consent form will be provided for participants' records. Additionally, AYA who are 17 at time of consent and turn 18 during the study period will be re-consented. At the start of the semi-structured qualitative interview, a re-consent conversation will be audio and/or video-recorded to confirm that AYA/caregiver(s) agree to recording of the interview).

8.7 Informed Consent (Oncology Health Care Providers)

Informed consent will be obtained from oncology health care providers of enrolled AYA and caregiver(s). A study team member will discuss the procedures and consent forms with potential participants individually. In order to assure that the potential participant understands the study, the team member will review the consent, in its entirety, and will encourage them to ask questions throughout the process. The individuals will also be reminded that participation is voluntary and will not affect their employment or performance evaluation, and their responses will not be shared with their supervisors. There are no time constraints on the consent process. The potential participants will be allowed to take as much time as they need to ask questions and decide if they would like to participate.

If consent is being conducted in-person and the potential participant agrees to participate, the In-Person Signature Page of the consent forms will be signed and dated by the potential participant and the research team member and stored in a regulatory binder maintained by the study coordinator. A copy of the consent forms will be provided to the participant for their records. At the start of the semi-structured qualitative interview, the re-consent conversation will be audio and/or video-recorded to confirm that oncology health care providers agree to recording of the interview.

8.7.1 Consent with Waiver of Documentation

If consent is being conducted over the phone, we will use Consent with Waiver of Documentation (verbal consent). The study team will complete the Documentation of Consent Page of the consent form, which will be stored in a regulatory binder maintained by the study coordinator. A digital or paper copy of the verbal consent form will be provided for participants' records. At the start of the semi-structured qualitative interview, the re-consent conversation will be audio and/or video-recorded to confirm that oncology health care providers agree to recording of the interview).

8.8 Payment to Subjects

8.8.1 Families (AYA and Caregivers)

To compensate for their time and effort, AYA and caregiver(s) will be paid as a single-family unit via a pre-loaded bank card (hereafter referred to as a ClinCard) or an Amazon e-gift card. Per Clinical Trials Financial Management policy, the ClinCard will be given in person or mailed to families after they are enrolled in the study, or an Amazon e-gift card will be delivered electronically. If the ClinCard is sent via mail, families will be instructed to contact the study coordinator (via phone/email) to confirm receipt of the ClinCard before funds are disbursed. If the ClinCard is delivered in person, families will be asked to provide their signature as confirmation of receipt. Families that receive an Amazon e-gift card via email will be asked to confirm receipt of the e-gift card with the study coordinator. Both confirmation of ClinCard receipt and stipend payments will be tracked in an Excel file (managed by the study coordinator). Families will receive the following stipend amounts at the following time points, based on group assignment:

Families randomized to Usual Care will receive \$50 across two time points.

- Time Point 1: \$25 after completion of the baseline assessment.
- Time Point 2: \$25 after completion of the post-intervention assessment

Families randomized to DECIDES will receive \$70 across three time points.

- Time Point 1: \$25 after completion of the baseline assessment
- Time Point 2: \$25 after completion of the post-intervention assessment
- Time Point 3: \$20 after completion of the semi-structured qualitative interview

Families randomized to DECIDES + coach will receive \$70 across three time points.

- Time Point 1: \$25 after completion of the baseline assessment
- Time Point 2: \$25 after completion of the post-intervention assessment
- Time Point 3: \$20 after completion of the semi-structured qualitative interview

8.8.2 Oncology Health Care Providers

Oncology health care providers will not be compensated for their participation in the study.

9 PUBLICATION

Results of the study will be disseminated via conference abstracts and peer reviewed journal publications.

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