Official Title: Improving Care Coordination for Adolescents and Young Adults With Cancer: Implementing a Bridge Between Needs and Services
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PStudy Title: Improving care coordination for adolescents and young adults with cancer: implementing a bridge between needs and services

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Background, Rationale and Context

In the United States, many of the nearly 90,000 adolescents and young adults (AYAs) diagnosed with cancer each year do not receive services to address the full scope of needs they experience during and after cancer treatment.[1-6] AYAs' unmet needs result in negative outcomes, including distress,[3,4] poor health-related quality of life,[7] and high physical symptom burden.[2] The National Cancer Institute[8] and Centers for Medicare and Medicaid Services[9] increasingly advocate for the use of patient-reported outcome measures (PROMs) in practice to better address the needs of cancer patients. However, PROMs are unlikely to address patient needs if patients and providers find them difficult to use, or if they are not linked to available services and resources that will address identified needs. Indeed, such limitations have stymied the implementation of PROMs in routine cancer care[10-13] and their effect on downstream patient outcomes (e.g., improved symptom burden, quality of life, experience of care).[14-16]

To facilitate a systematic and patient-centered approach to delivering services and resources to address the unmet needs of adolescents and young adults (AYAs) with cancer, we developed in preliminary studies the AYA Needs Assessment & Service Bridge (AYA NA-SB). AYA NA-SB includes (1) a holistic PROM assessing AYAs' physical, psychosocial and practical needs and (2) a collection of referral pathways for connecting AYAs to services and resources based on the needs they report (see **Appendix A**).[17] To optimize AYA NA-SB's usability (i.e., ease of use) and usefulness (i.e., link to services), promote cancer programs' receptivity to AYA NA-SB implementation, and anticipate implementation strategies needed to facilitate AYA NA-SB's successful implementation and sustainment, we conducted usability testing, an ethnographic user and contextual analysis, and iterative prototyping workshops with a multidisciplinary design team.

Our development process culminated in an intervention with high usability and usefulness, characteristics we expect to promote AYA NA-SB's successful implementation and achievement of desired outcomes; however, AYA NA-SB's implementation and efficacy remain untested. Thus, through this study, we will evaluate AYA NA-SB's implementation and establish proof-of-concept. To avoid creating a tool that is only applicable to its high-resource testing environment, I will also plan for AYA NA-SB's potential scale-up across diverse health systems serving AYAs with cancer.

Objectives

Aim 1. Assess the implementation of AYA NA-SB. I will pilot AYA NA-SB in the North Carolina Cancer Hospital (NCCH), with a primary focus on implementation outcomes.

Aim 2. Establish proof-of-concept for AYA NA-SB. I will use pilot data to generate preliminary evidence on the extent to which AYA NA-SB addresses AYAs' reported needs.

Aim 3. Plan for AYA NA-SB's scalability and sustainability in diverse health systems. I will conduct annual 60-minute semi-structured qualitative interviews with AYA providers and program leaders from approximately 8 health systems to proactively address challenges and prepare for future AYA NA-SB scale-up and sustainability.

Methods and Measures

Design

- Aim 1/2: Single-arm feasibility pilot
- Aim 3: qualitative interviews

Setting

Aim 1/2: I will pilot AYA NA-SB in the North Carolina Cancer Hospital (NCCH). NCCH is a public, National Cancer Institute-designated Comprehensive Cancer Center located in central North Carolina, in a relatively metropolitan area. At NCCH, around 450 individuals ages 15-30 are diagnosed each year. About one third of these patients are treated in pediatric oncology and the remainder in adult oncology. NCCH's AYA program was established in 2015 with funding from a local nonprofit organization, the BeLoud Sophie Foundation. This funding was initially allocated towards hiring one fulltime employee (a social worker/program director) to provide AYA-specific care at NCCH. Since 2015, the program has evolved, hiring new AYA-specific staff members (e.g., nurse practitioner, fertility counselor) and expanding program activities and reach.

Aim 3: I will conduct interviews with providers and program leaders from AYA programs around the country.

Subjects selection criteria

- **Inclusion Criteria**
  Aim 1/2: AYAs with cancer ages 18 through 39 currently in treatment at NCCH
  Aim 3: AYA providers and program leaders from around the country
- **Exclusion Criteria**
  No exclusion criteria
- **Sample Size**
  - Aim 1/2
    - N=25-50 AYAs
    - N=25/arm has been proposed as the minimum threshold of sample size for aims related to instrumentation.[18] Given that this is a single-arm pilot study, we have determined that a sample size between 25 and 50 is appropriate.
  - Aim 3
    - N=8 AYA providers/ program leaders. Interviewees will be purposefully sampled such that they represent a range of health systems. As such, a sample size of 8 is expected to yield adequate data to meet the objectives of Aim 3.

Interventions and Interactions

Intervention (Aims 1, 2)

The intervention, AYA NA-SB, includes three components: (1) a needs assessment, (2) a map of referral pathways, and (3) implementation guidance **(Appendix A)**.

Needs assessment. The needs assessment portion of AYA NA-SB is a 57-item PROM which includes nine domains: (1) information, (2) cancer care team, (3) physical health, (4) emotional health, (5) sexual and reproductive health, (6) health behaviors and wellness, (7) work and education, (8) peer support and programming, and (9) finances and everyday needs.

Referral pathways. Each domain of the needs assessment triggers a specific referral pathway. For example, needs reported in the 'sexual and reproductive health' domain trigger a referral to a fertility counselor or specialist while needs reported in the 'work and education' domain trigger a social worker visit. NCCH will tailor the map of referral pathways to their institution prior to the onset of data collection such that AYAs' needs are triaged to the appropriate parties at their institution.

Implementation guidance. Based on data collected during AYA NA-SB development, we compiled a list of potential implementation barriers and implementation strategies hypothesized to mitigate them. Participating NCCH providers will be given this information to inform their own deployment of strategies. To enhance the real-world applicability of findings, the implementation strategies will not be explicitly prescribed to NCCH, but the strategies they use will be carefully documented to contextualize findings.

Instruments & procedure (Aims 1,2)

Provider training. Six weeks prior to the onset of data collection, participating NCCH providers will participate in a 3-hour group training to familiarize them with the intervention and pilot protocol. In addition to the implementation leader, additional relevant providers identified by the implementation leader will participate in this training.

During the first hour of the training, I will provide an overview of AYA NA-SB and its development as well as a detailed summary of the pilot protocol. During the second hour of the training, we will collaboratively identify appropriate referral pathway providers for each needs assessment domain, explicitly outlining the

processes needed to initiate these referral pathways. During the third hour, we will brainstorm potential implementation strategies that might be deployed to facilitate AYA NA-SB implementation.

Needs assessment administration. The needs assessment portion of AYA NA-SB will be administered to AYAs through a secure online survey platform, RedCAP, and will take approximately 15 minutes to complete. The survey link will be delivered to AYAs through a patient portal message from the implementation leader. AYAs will receive a $15 incentive for completing the needs assessment.

Referral pathway initiation. Within seven calendar days of AYA NA-SB completion, the implementation leader will review completed needs assessments and, depending on AYAs' preferences indicated at the end of the needs assessment, will either (a) initiate appropriate referral pathways, or (b) provide a list of recommended referrals to AYAs. For each needs assessment reviewed, they will document these actions on a brief fidelity checklist which timestamps their completion of these tasks, documents the referral pathways selected, and gauges their confidence in selecting appropriate referral pathways (**Appendix B**). This process is expected to take less than 10 minutes/ needs assessment.

Postintervention AYA survey. One month following their completion of the needs assessment, I will engage AYA pilot participants in an online postintervention survey (**Appendix C**) assessing their perceptions of AYA NA-SB's feasibility, acceptability, and appropriateness. In addition to items assessing AYAs' perspectives of the needs assessment itself, this survey will solicit information about the follow-up care AYAs received in response to needs they reported in the needs assessment and whether they felt their needs were met (Aim 2). This survey will administered through RedCAP and will take approximately 15 minutes to complete. AYAs will receive a second $15 incentive for completing the postintervention survey.

Postintervention provider interview. I will conduct a semi-structured interview with the implementation leader and other participating providers from NCCH after AYA NA-SB has been administered to a minimum of n=15 AYAs. The purpose of this 1-hour interview is to assess provider perceptions of the feasibility, acceptability, and appropriateness of AYA NA-SB and to elicit information about perceived implementation determinants and strategies deployed. Interviews will be recorded and transcribed for analysis. **Appendix D** contains the interview guide.

Activity	Provider Training	Needs assessment administration	Referral pathway initiation	Postintervention AYA survey	Postintervention provider interview
Time	0	+6 weeks	+7 weeks	+10 weeks	+10-15 weeks

Instruments & procedure (Aims 3)

I will conduct annual semi-structured qualitative interview**s** with AYA providers and program leaders from diverse health systems to proactively address challenges and prepare for future AYA NA-SB scale-up and sustainability.

An interview guide (**Appendix E**) was developed using domains and constructs from the Dynamic Sustainability Framework, which conceptualizes the dynamic relationship among interventions, practice settings, and broader systems over time.[19] During interviews, I will review pilot data with providers and ask them to consider how AYA NA-SB's implementation and outcomes might unfold similarly or differently in their health systems given their practice context (e.g., staffing, informational systems, culture) and broader context (e.g., policy, regulations, market forces).

I will conduct interviews via telephone at a time of participants' choosing. Interviews will last approximately 60 minutes. They will be recorded and transcribed for analysis.

Outcome Measure(s)

Variable	Definition	Measure	Participants	Data source
Demographic/clinical variables (Aim 1, Aim 2)				
Demographics	Age; sex; race/ethnicity; health insurance status		AYAs	Needs assessment
Clinical variables	Cancer diagnosis; stage at diagnosis; time since diagnosis		AYAs	Needs Assessment
Implementation measures (Aim 1)				
Feasibility	extent to which AYA NA-SB can be successfully used	Feasibility of Intervention Measure (FIM)[20]	AYAs	Postintervention AYA survey

	in cancer programs		Providers	Postintervention provider interview
Acceptability	perception of whether AYA-NA-SB is agreeable, palatable, or satisfactory to users	Acceptability of Intervention Measure (AIM)[20]	AYAs	Postintervention AYA survey
			Providers	Postintervention provider interview
Appropriateness	perception of AYA-NA-SB's fit, relevance, or compatibility with the context in which it will be used	Intervention Appropriateness Measure (IAM)[20]	AYAs	Postintervention AYA survey
			Providers	Postintervention provider interviews
Fidelity	the degree to which AYA NA-SB is implemented as intended	Proportion of needs assessment reviewed by provider within one week and referral pathways initiated	Providers	Fidelity checklist
Implementation determinants	Perceived barriers and facilitators to AYA NS-SB implementation	Qualitative analysis of perceived determinants based on CFIR constructs	Providers	Postintervention provider interview
Implementation strategies	Strategies deployed to facilitate AYA NA-SB implementation	Qualitative analysis of strategies used and their perceived level of influence	Providers	Postintervention provider interview
Service and patient outcomes (Aim 2)				
AYA needs	Prevalence of needs by item; crosstab with demographic/clinical variables(?)		AYAs	Needs assessment
	Prevalence of needs by follow-up domain; crosstab with demographic/clinical variables(?)			
Services rendered	Distribution of referral pathways initiated in response to AYAs' reported needs		Providers	Fidelity Checklist
	Distribution of services and resources rendered in response to needs reported by AYAs		AYAs	Postintervention AYA survey
Care coordination	The delivery of multidisciplinary services to address needs reported by AYAs	AYA's receipt of services/ resources from across disciplines to address reported needs within one month of needs assessment completion	AYAs	Postintervention AYA survey
Needs met	Extent to which services and resources received met reported needs	AYAs' perception of the degree to which their needs were adequately addressed during the study period	AYAs	Postintervention AYA survey

Analytical Plan

Aim1. I will report descriptive

statistics on demographic and clinical variables. I will also calculate descriptive statistics on all quantitative implementation outcomes. Index scores will be generated for each measure by calculating an unweighted average of items within each construct. Further, I will conduct bivariate analyses to assess whether implementation outcomes vary by demographic and clinical variables to ensure that AYA NA-SB is feasible, acceptable, and appropriate across patient characteristics.

Qualitative interview data will be analyzed using template analysis[21] based on a priori themes (i.e., Proctor's model and CFIR constructs) but allowing for additional emergent themes. A peer and I will independently abstract data from interview transcriptions per Proctor outcomes and CFIR constructs and discuss discrepancies until consensus is reached. When necessary, a third party will be pulled in to resolve discrepant coding.

Aim 2. I will calculate descriptive statistics on AYAs' identified needs, reporting the prevalence of specific needs and needs within specific domains, as well as on services received. I will also calculate descriptive statistics on quantitative service and patient outcomes. I will conduct bivariate analyses to assess whether service and patient outcomes vary by demographic and clinical variables.

Aim 3. Interview data will be analyzed using template analysis[21] of interview transcriptions based on a priori themes (i.e., domains of the Dynamic Sustainability Framework) but allowing for additional emergent themes. A peer and I will independently abstract data from interview transcriptions and discuss discrepancies until consensus is reached. When necessary, a third party will be pulled in to resolve discrepant coding.

Human Subjects Protection

Subject Recruitment Methods

Aim 1/2: AYAs will be recruited by the implementation leader who, during routine encounters with AYAs, will provide a brief description of the study objectives and a 1-page recruitment flyer with additional details (**Appendix F**). Additionally, they will receive a fact sheet containing all of the relevant information from the consent form template (**Appendix G**). The implementation leader will distribute the needs assessment link to AYAs interested in participating (via a secure patient portal message), following up with non-responders using Dillman's approach for maximizing survey response rates which includes initial contact, then follow-up with non-responders at 1, 3, and 7 weeks.[22]

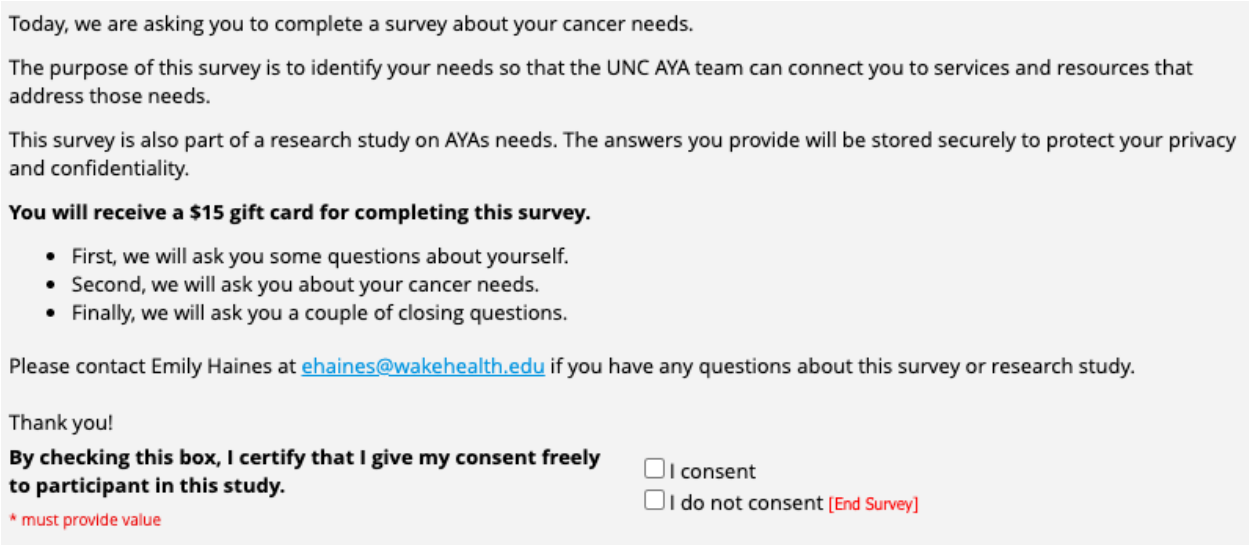
When recruiting AYAs, implementation leaders will prioritize achieving heterogeneity in terms of cancer type, gender/sex, and race/ethnicity. The implementation leader will not share the identity of AYAs interested in participating, even to members of the study team.

Aim 3: Four interviewees have already been identified: (1) Program Manager, Stanford AYA Cancer Program, (2) AYA Nurse Navigator, University Hospitals, (3) Program Coordinator, Bon Secours St. Francis Cancer Center, and (4) Patient Navigator, Fort Worth AYA Oncology Coalition. With expressed support from Teen Cancer America, an advocacy group that consults with AYA programs around the country, I will identify four additional key contacts (i.e., AYA providers) from diverse health systems. I will email these key contacts information about the study, following Dillman's approach for maximizing response rates which includes initial contact, then follow-up with non-responders at 1, 3, and 7 weeks.[22] Key contacts will identify individuals within their institution who are best equipped to participate in these annual interviews.

Informed Consent

Aim 1/2: During recruitment, AYAs will receive from their provider a study fact sheet with all relevant consent form information (**Appendix G**). This will give them time to review and process this information prior to receiving the online link to the first survey. Additionally, this will remove any pressure they may feel to agree to participate as a result of their provider being present. Informed consent will then be obtained from AYAs on the first page of the web-based needs assessment and postintervention AYA survey (see screenshot, below). This waiver of documentation of consent is appropriate because (1) this research presents no more than minimal risk of harm to participants, and (2) this research involves no procedures for which written consent is normally required outside the research context. Additionally, we believe that this 2-stage consent process will alleviate any undue pressure that AYAs feel to participate. Finally, this 2-stage consent process provides some measure of privacy

protection to potential participants because, although their provider will be aware of the identity of potential participants during recruitment, this information will not be shared with the study team.



Today, we are asking you to complete a survey about your cancer needs.

The purpose of this survey is to identify your needs so that the UNC AYA team can connect you to services and resources that address those needs.

This survey is also part of a research study on AYAs needs. The answers you provide will be stored securely to protect your privacy and confidentiality.

You will receive a $15 gift card for completing this survey.

- First, we will ask you some questions about yourself.
- Second, we will ask you about your cancer needs.
- Finally, we will ask you a couple of closing questions.

Please contact Emily Haines at ehaines@wakehealth.edu if you have any questions about this survey or research study.

Thank you!

By checking this box, I certify that I give my consent freely to participant in this study.

* must provide value

☐ I consent
☐ I do not consent [End Survey]

Aim 3: Prior to interviews, Aim 3 participants will receive a fact sheet containing consent information (Appendix H). Verbal consent will be obtained at the beginning of telephone interviews with providers.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Subject-identifying information will be destroyed one year after closure of the study by permanently deleting all files, leaving only an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

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Appendix A: AYA NA-SB

AYA NA-SB

AYA NEEDS ASSESSMENT &
SERVICE BRIDGE

Needs Assessment

1. INFORMATION

	I want more information about:	Agree	Somewhat agree	I have enough information about this concern	Not sure
1	My cancer diagnosis				
2	The short-term side effects of treatment				
3	The long-term side effects of treatment				
4	What will happen when treatment finishes				
5	My disease status				
6	My test results				
7	What to do if I have side effects from my treatment				
8	How my genetics may or may not have impacted my diagnosis and treatment				

2. CANCER CARE TEAM

	I want my cancer treatment team to do a better job of:	Agree	Somewhat agree	My cancer treatment team is doing this already	Not sure
9	Respecting me as an individual, not just a cancer patient				
10	Offering to talk to me in private, without my family or friends				
11	Explaining what they were doing in a way I can understand				
12	Encouraging me to ask questions				
13	Engaging me in decision-making about my treatment and respecting my decisions				
14	Asking me about my treatment concerns				

3. PHYSICAL HEALTH

	I want more help with:	Agree	Somewhat agree	I have enough help with this concern	Not sure
15	Managing pain				
16	Managing my medications				
17	Managing physical side effects of treatment				
18	Managing feeling tired/ fatigued				

19	Managing loss of walking ability				

4. EMOTIONAL HEALTH

	I want more help with:	Agree	Somewhat agree	I have enough help with this concern	Not sure
20	Feeling anxious or scared				
21	Feeling depressed				
22	Having what I need to cope with my diagnosis				
23	Worrying about my cancer spreading				
24	Worrying about my cancer returning or getting another type of cancer				
25	Worrying about how my family is coping				
26	Coping with changes in my dating or romantic life				
27	Coping with changes in my relationships with my family members				
28	Coping with changes in my relationships with friends				
29	Feeling independent				
30	Coping with changes in my physical ability				
31	Coping with changes in my appearance				
32	Coping with not being able to do the same things as other people my age				
33	Managing the emotional side effects of treatment				
34	Being able to make plans or think about the future				

5. SEXUAL & REPRODUCTIVE HEALTH

	I want more information about:	Agree	Somewhat agree	I have enough information about this concern	Not sure
35	My risk of infertility and my fertility preservation options				
36	Treating infertility and other options for having children in the future (i.e., sperm/egg freezing, artificial insemination, in vitro fertilization, surrogacy, adoption, etc.)				
37	Sexuality and intimacy during cancer treatment				
38	Sexual side effects of my treatment (e.g., sexual dysfunction)				
39	The effects of treatment on long-term hormone changes				

6. HEALTH BEHAVIORS & WELLNESS

I want more information about:	Agree	Somewhat agree	I have enough	Not sure

					information about this concern	
40	Nutrition					
41	Exercise or physical activity					
42	Getting enough or better-quality sleep					
43	Smoking or vaping during cancer treatment					
44	Drug or alcohol use during cancer treatment					
45	Spiritual support or resources					
46	Alternative therapies (herbal treatment, acupuncture, massage therapy, meditation, etc.)					

7. WORK & EDUCATION

	I want more help with:	Agree	Somewhat agree	I have enough help with this concern	Not sure
47	Managing my school life while going through cancer treatment				
48	Managing my work life while going through cancer treatment				

8. PEER SUPPORT & PROGRAMMING

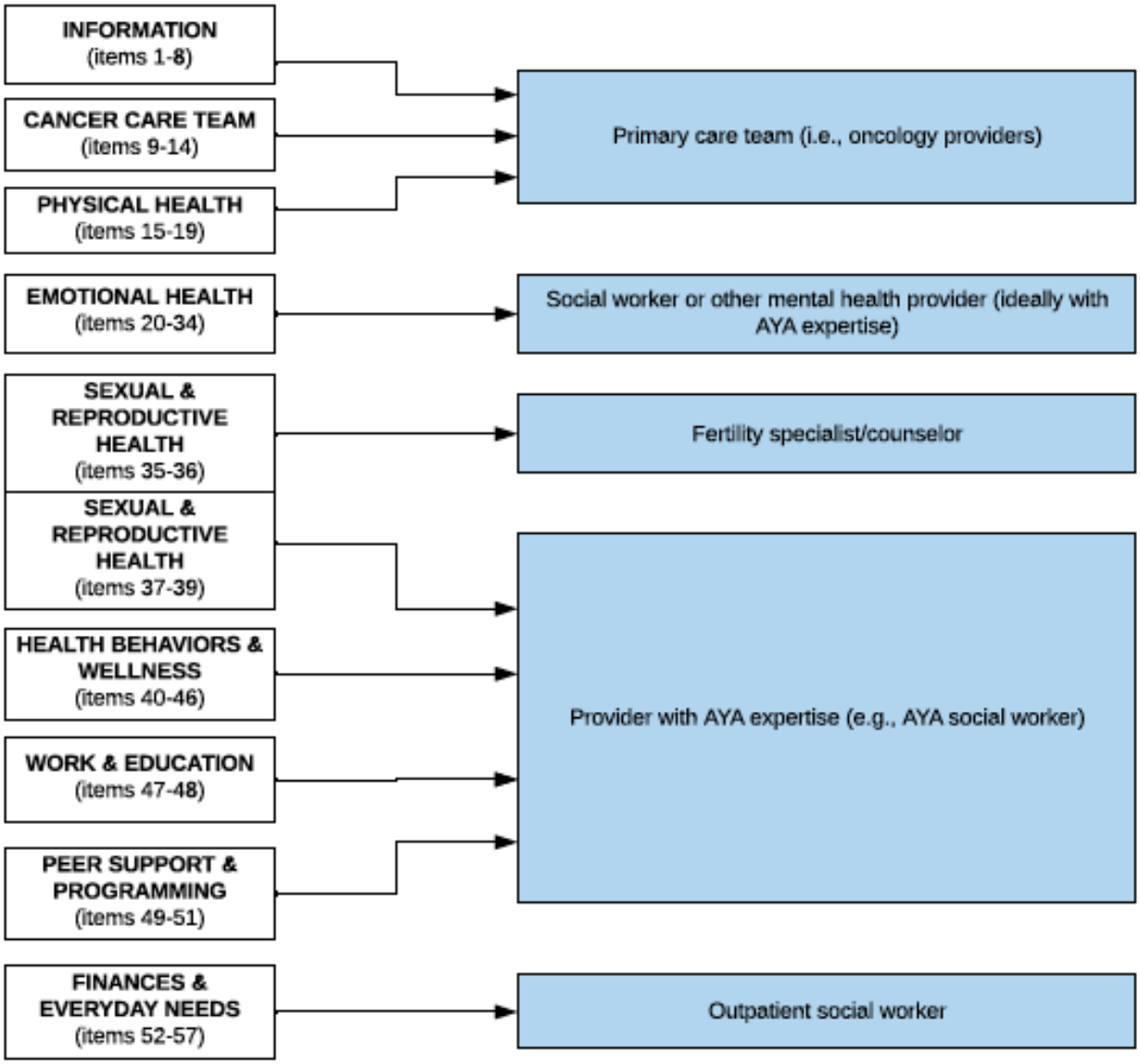
	I want more help with:	Agree	Somewhat agree	I have enough help with this concern	Not sure
49	Being able to spend time with people my own age				
50	Being able to talk to people my own age who have been through a similar cancer treatment experience				
51	Participating in social activities				

9. FINANCES & EVERYDAY NEEDS

	I want more help with:	Agree	Somewhat agree	I have enough help with this concern	Not sure
52	Paying my bills				
53	Scholarship or loan repayment options				
54	My health insurance (e.g., access/eligibility, coverage, cost)				
55	Getting to and from my cancer care appointments				
56	Having childcare during my cancer care appointments				
57	Having stable housing				

Please indicate anything else you want help with, below:

Map of referral pathways



Implementation Guidance

1	Consider a phased-in approach to implementation, for example, by implementing within one disease group and expanding outwards
2	Build buy-in by engaging in implementation planning any provider groups who will interface with AYA NA-SB in practice
3	Build buy-in among leadership, emphasizing the potential benefits of AYA NA-SB for patient care, patient-provider communication, provider-provider communication, and program development
4	Provide education across disease groups and identify champions within each disease group to facilitate referrals of AYAs to AYA program
5	Obtain a thorough understanding of services and resources available at your institution prior to implementation, identifying gaps that may hinder follow-up on needs reported by AYAs on the needs assessment. For identified gaps, bolster existing services or tailor the needs assessment to address the subset of needs that your institution has the capacity to address.
6	Explicitly outline referral pathways for each follow-up domain, identifying primary contacts, current workflow, and best method of communication for service/resource providers.
7	Where possible, leverage existing communication and documentation channels in AYA NA-SB delivery. Modify communication and documentation processes as needed to allow for, at a minimum, traceable documentation of follow-up on needs.
8	Leverage staff who are currently assessing and addressing the needs of AYA patients at your institution and thus, have the necessary expertise and time allocated towards these tasks.
9	Identify approach for ensuring that services and resources are provided in a timely manner once needs are identified.
10	Use pilot testing to tailor AYA NA-SB to your institution, for example, to: • Make additional refinements to the needs assessment tool to tailor it to your institution • Determine frequency of needs assessment administration that makes sense in your institution (e.g., 1 month versus 3 months) • Map out changes needed to your institution's EHR to facilitate systematic documentation

Appendix B: Fidelity checklist

Assessment ID (see top of assessment)	_ _ _ _ _ _				
Assessment Date (see timestamp at top of assessment)	_ _ / _ _ / _ _ _ _				
Date I reviewed assessment	_ _ / _ _ / _ _ _ _				
Date in which I initiated referral pathways	_ _ / _ _ / _ _ _ _				
Referral pathways initiated	**Need #**	**Referral Pathway**			
For needs indicated by this AYA, I was confident about which referral pathways to initiate	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
	①	②	③	④	⑤

Appendix C: Postintervention AYA survey

Acceptability of Intervention Measure (AIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The needs assessment meets my approval.	①	②	③	④	⑤
2. The needs assessment is appealing to me.	①	②	③	④	⑤
3. I like the needs assessment.	①	②	③	④	⑤
4. I welcome the needs assessment.	①	②	③	④	⑤

Intervention Appropriateness Measure (IAM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The needs assessment seems fitting.	①	②	③	④	⑤
2. The needs assessment seems suitable.	①	②	③	④	⑤
3. The needs assessment seems applicable.	①	②	③	④	⑤
4. The needs assessment seems like a good match.	①	②	③	④	⑤

Feasibility of Intervention Measure (FIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The needs assessment seems implementable.	①	②	③	④	⑤
2. The needs assessment seems possible.	①	②	③	④	⑤
3. The needs assessment seems doable.	①	②	③	④	⑤
4. The needs assessment seems easy to use.	①	②	③	④	⑤

Face validity/ content validity

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The needs assessment helped me to communicate my needs.	①	②	③	④	⑤
2. The needs assessment was relevant to me.	①	②	③	④	⑤
3. The needs assessment included all needs that I was concerned about.	①	②	③	④	⑤

Usability

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree

1. I think that I would like to complete the needs assessment again.	①	②	③	④	⑤
2. I found the needs assessment too complicated.	①	②	③	④	⑤
3. I think the needs assessment was easy to complete.	①	②	③	④	⑤
4. I think I would need help to complete the needs assessment.	①	②	③	④	⑤
5. I felt very confident completing the needs assessment.	①	②	③	④	⑤

Usefulness

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The needs assessment provided a helpful way for me to tell my doctors what I need.	①	②	③	④	⑤
2. I did use or would use services and resources offered to me by my doctors based on the needs I checked in the needs assessment.	①	②	③	④	⑤

Care coordination/Needs met

	Yes	No
1. I reported no needs on the needs assessment	① (skip to end)	②
2. I received follow-up care for the needs I reported (e.g., referrals, counseling, other services or resources)	①	② (skip to end)

3. Please indicate the type of follow-up care that you received. *(check all that apply)*	(1) communication from my primary oncology team (2) a phone call or visit from a social worker (3) a phone call or visit from a nurse navigator (4) A referral to a specialist (e.g., fertility counselor, nutritionist, physical therapist, etc.) (5) educational materials (6) other

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
4. The follow-up care I received addressed my needs.	①	②	③	④	⑤

Appendix D: Postintervention provider interview guide

Introduction:

Thank you for your interest in this study. The aim of the interview is to help us understand your experiences implementing the AYA Needs Assessment and Service Bridge (NA-SB). During the interview, I will ask questions about NA-SB implementation including barriers you encountered and strategies you used.

Our discussion should last approximately one hour. All of your responses will remain confidential and will only be reported in aggregate. You may choose to stop the interview at any time, and there is no penalty to you or your organization for not completing the interview. Before we begin, we would like to ask your permission to audio record our discussion for the purposes of future analysis. Would it be OK with you if I record this interview? (*If participant refuses to be audio-recorded, the RA will take notes instead.*) The interview will be transcribed; however, your name or any personal identifiers will not be associated with any of the notes. The audio recordings will be deleted once the project is complete.

Do you have any questions before we begin?

Intervention Characteristics

Evidence Strength & Quality

1. *In a healthcare setting, influential stakeholders may include influential and well-respected clinicians, where as in an education setting, this may include influential and well-respected teachers or educators.*
   What do influential stakeholders think of the intervention?
   - What do administrative or other leaders think of the intervention?

Adaptability

1. What kinds of changes or alterations do you think you will need to make to the intervention so it will work effectively in your setting?
   - Do you think you will be able to make these changes? Why or why not?

Complexity

1. How complicated is the intervention?
   - Please consider the following aspects of the intervention: duration, scope, intricacy and number of steps involved and whether the intervention reflects a clear departure from previous practices.

Design Quality & Packaging

1. What is your perception of the quality of the supporting materials, packaging, and bundling of the intervention for implementation?
   - Why?

Cost

1. What costs will be incurred to implement the intervention?

Outer Setting

Patient Needs & Resources

1. How well do you think the intervention will meet the needs of the individuals served by your organization?
   - In what ways will the intervention meet their needs? E.g. improved access to services? Reduced wait times? Help with self-management? Reduced travel time and expense?
2. How do you think the individuals served by your organization will respond to the intervention?
3. What barriers will the individuals served by your organization face to participating in the intervention?
4. Have you heard stories about the experiences of participants with the intervention?
   - Can you describe a specific story?

Inner Setting

Structural Characteristics

1. How will the infrastructure of your organization (social architecture, age, maturity, size, or physical layout) affect the implementation of the intervention?
   - How will the infrastructure facilitate/hinder implementation of the intervention?
   - How will you work around structural challenges?
2. What kinds of infrastructure changes will be needed to accommodate the intervention?
   - Changes in scope of practice? Changes in formal policies? Changes in information systems or electronic records systems? Other?
   - What kind of approvals will be needed? Who will need to be involved?

- Can you describe the process that will be needed to make these changes?

Culture

1. How do you think your organization's culture (general beliefs, values, assumptions that people embrace) will affect the implementation of the intervention?
    - Can you describe an example that highlights this?

Implementation Climate

1. *This question is likely to uncover topics to explore more within other sub-constructs, but be attentive to other themes that may not be included in your assessment.*
   What is the general level of receptivity in your organization to implementing the intervention?
    - Why?

Compatibility

1. How well does the intervention fit with your values and norms and the values and norms within the organization?
    - Values relating to interacting with individuals served by your organization, e.g. shared-decision making vs. being more directive?
    - Values related to referring to outside vendor-based programs vs. providing services by in-house staff?
2. How well does the intervention fit with existing work processes and practices in your setting?
    - What are likely issues or complications that may arise?
3. Can you describe how the intervention will be integrated into current processes?
    - How will it interact or conflict with current programs or processes?

Goals & Feedback

1. *This question can be framed in terms of the intervention. For example, in a healthcare setting: How does implementation of the intervention align with organizational goals related to preventing*
   How does implementation of the intervention align with other organizational goals?

Readiness for Implementation

Leadership Engagement

1. What level of involvement has leadership at your organization had so far with the intervention?
    - Do they know about the intention to implement the intervention?
    - Who are these leaders? How do attitudes of different leaders vary?
    - What kind of support have they given you? Can you provide specific examples?
2. What kind of support or actions can you expect from leaders in your organization to help make implementation successful?
    - Who are these leaders? How do attitudes of different leaders vary?
    - Do they know about the intention to implement the intervention?
    - What kind of support can you expect going forward? Can you provide specific examples?
    - What types of barriers might they create?

Available Resources

1. Do you expect to have sufficient resources to implement and administer the intervention?
    - [If Yes] What resources are you counting on? Are there any other resources that you received, or would have liked to receive?
    - What resources will be easy to procure?
    - [If no] What resources will not be available?
2. How do you expect to procure necessary resources?
    - Who will be involved in helping you get what is needed?
    - What challenges do you expect to encounter?

Characteristics of Individuals

Knowledge & Beliefs about the Intervention

1. What do you know about the intervention or its implementation?

Self-efficacy

1. How confident are you that you will be able to successfully implement the intervention?
    - What gives you that level of confidence (or lack of confidence)?
2. How confident do you think your colleagues feel about implementing the intervention?
    - What gives them that level of confidence (or lack of confidence)?

Process

Planning

1. What have you done (or what do you plan to do) to get a plan in place to implement the intervention?

Engaging

Opinion Leaders

1. Who are the key influential individuals to get on board with this implementation?

Key Stakeholders

1. Who are the key individuals to get on board with the intervention?
    - To encourage individuals to use the intervention? To help with implementation?

Intervention Participants

1. How will you or your colleagues communicate to the individuals that are served by your organization about the intervention?
    - How will they participate in the intervention?
    - How will they access the intervention?

Reflecting & Evaluating

1. What kind of information do you plan to collect as you implement the intervention?
    - Which measures will you track? How will you track them?
    - How will this information be used?
2. How will you assess progress towards implementation or intervention goals?
    - How will results of the evaluation be distributed to stakeholders?

Appendix E: Aim 3 Interview guide

Introduction:

Thank you for your interest in this study. The aim of the interview is to help us prepare for the future scale-up and sustainability of the AYA Needs Assessment and Service Bridge (NA-SB), and intervention that we developed to assess and address the needs of AYAs with cancer. During the interview, I will ask questions about how NA-SB might be implemented and sustained in your health system.

Our discussion should last approximately 30 minutes. Your responses will help us understand how NA-SB components or its implementation might need to be modified to address the needs of diverse health systems. All of your responses will remain confidential and will only be reported in aggregate. You may choose to stop the interview at any time, and there is no penalty to you or your organization for not completing the interview. Before we begin, we would like to ask your permission to audio record our discussion for the purposes of future analysis. Would it be OK with you if I record this interview? (*If participant refuses to be audio-recorded, the RA will take notes instead.*) The interview will be transcribed; however, your name or any personal identifiers will not be associated with any of the notes. The audio recordings will be deleted once the project is complete.

Do you have any questions before we begin?

YEAR ONE: Exploration

[Summarize progress of NA-SB implementation and outcomes in the North Carolina Cancer Hospital (NCCH), as it relates to the Exploration stage.]

I'd like to begin by discussing how AYAs' needs are assessed and addressed at your institution.

1. What happens when an AYA is diagnosed at your institution?

   Prompts: How are new AYA patients identified? How are their needs identified and addressed? Are any formalized needs assessments or other tools used? Is a referral to a provider with AYA expertise automatically triggered?

2. Considering what I've told you about NA-SB's implementation and outcomes so far at NCCH,
   What are your thoughts on the appropriateness (&acceptability & feasibility) of NA-SB in the context of your health system? How do you see this as an opportunity? If not, what are the challenges in your health system that might influence the implementation of this intervention?

YEAR TWO: Preparation & Implementation

[Summarize progress of NA-SB implementation and outcomes at NCCH to date, as it relates to the Preparation & Implementation stage.]

I'd like to start by talking about the potential barriers/facilitators as you consider what preparing for the implementation of NA-SB might involve in your health system.

1. What activities might be pursued in your health system in preparation to implement NA-SB?

   - Examples: Training, financing, hiring, reorganizing, obtaining other resources, de-implementing previous approaches
   - Other prompts: whether these activities relate to different patient population / care setting and delivery / policy context / external environment associated with their health system

2. Are there particular barriers or facilitators that you have in mind as you think through how you would prepare to implement NA-SB?

   - Probe on why the participants perceive them as barriers or facilitators
   - Other prompts: patient population / care setting and delivery / policy context / external environment
   - E.g., how did your health system respond to changes (new practices or interventions), if any?

3. As you consider the experience of NCCH as I've described it, how do you think implementation might compare in your health system?

   Prompts: Previous experience of implementing a new practice/intervention into the system?

4. How would the organization/health system proceed if they were to implement this new intervention?

   Prompts: What are some next immediate steps? How would the organization determine who is in charge of what task? How does this differ from NCCH's experience? How? Why?

YEAR THREE: Sustainment
[Summarize progress of NA-SB implementation and outcomes at NCCH to date, as it relates to the Sustainment stage.]

1. How would your health system approach sustaining NA-SB?

2. What do you think the organization could do prior to implementation and/or during implementation to make it sustainable?

   Prompts: When should the organization start thinking about sustainment? What process do you think is necessary? What resources do you think are needed to make this intervention sustainable?

Those are all of the questions that I had planned for today. Is there anything else that you want to share regarding the intervention or its scalability?

Thank you so much for your time!

Appendix F: Recruitment flyer

AYA EXPERTISE NEEDED FOR RESEARCH STUDY!

Improving Care Coordination for AYAs with Cancer: Implementing a Bridge Between Needs and Services

What is the study?
We developed a tool to help connect adolescents and young adults (AYAs) with cancer to the services and resources they need. We need input from AYAs to make sure we created a tool that works for you.

What would you have to do?
If you agree to participate in this research effort:

1. An AYA social worker will send you a MyChart message with a link to a survey that assesses your needs. The survey will take approximately 15 minutes and you will receive a $15 Amazon gift card for completing it.
2. Based on the needs you report in the survey, an AYA social worker will reach out to you about services and resources that might help meet your needs.
3. One month later, you will receive a link to a 2nd survey asking you about your experience with the first survey, and the follow-care you received. The survey will take approximately 15 minutes and you will receive a $15 Amazon gift card for completing it.

If you choose to participate, you can opt out of the study at any time. Everything you say will be kept confidential; protecting your privacy is our priority!

How do you sign up?
Tell your AYA social worker (Lauren Lux or Catherine Swift) that you are interested in participating and they will send you the survey link.

Please do not hesitate to reach out to me with any questions or concerns you have!

Emily Haines, PhD
ehaines@wakehealth.edu
(336) 906-3395
Wake Forest School of Medicine

Social Sciences and Health Policy

Improving care coordination for adolescents and young adults with cancer: implementing a bridge between needs and services

Informed Consent Form to Participate in Research
Sarah Birken, PhD, Principal Investigator

Summary

You are invited to participate in a research study. The purpose of this research is to test an intervention designed to identify your cancer needs and connect you with services that address those needs. You are invited to be in this study because you are between the ages of 18-39 and have been diagnosed with cancer. Your participation in this research will involve completing 2 online surveys over the course of 1 month; each should take about 15 minutes to complete.

Participation in this study will involve identifying your cancer needs so that your providers can connect you with services that might address them. All research studies involve some risks. A risk to this study that you should be aware of is potential distress related to answering questions about your cancer needs. You may benefit from participation in this study through being connected to services that are aligned with your needs.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Sarah Birken, PhD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: sbirken@wakehealth.edu .

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at 336-716-4542 or the Research Subject Advocate at Wake Forest at 336-716-8372.

Introduction

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are an adolescent or young adult with cancer. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

Why Is This Study Being Done?

The purpose of this research study is to get feedback from adolescents and young adults on a new intervention to assess and address their cancer needs.

How Many People Will Take Part in the Study?

25-50 people will take part in this study.

What Is Involved in the Study?

1. You will receive a link via a MyChart message to complete an online survey (needs assessment). This needs assessment will ask you about your cancer needs and will take approximately 15 minutes to complete.
2. Your social worker will review your needs assessment with you during your next visit and ask you if you would like to be referred to services to address your needs.
3. One month later, you will receive a link to complete a second, follow-up survey. This survey will ask you about your experience completing the needs assessment and reviewing it with your social worker and will take approximately 15 minutes to complete.

How Long Will I Be in the Study?

You will be in the study for about *one month.*

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Are There Benefits to Taking Part in the Study?

Your participation may result in you being more efficiently connected to services that address your needs. We hope the information learned from this study will benefit other people in the future.

What Other Choices Are There?

You do not have to be in this study to receive referrals to address your cancer needs. You should talk to your social worker about all the choices you have.

What Are the Costs?

All study costs, related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

Will You Be Paid for Participating?

You will be paid *$15* for each of two surveys you complete (for a total of $30).

Who is Sponsoring this Study?

This study is being sponsored by an institutional training grant from the National Cancer Institute. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

What About My Health Information?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes **information about your physical, psychosocial, and practical needs.**

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research

Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Emily Haines that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Emily Haines
377 McGowan Lane
Chapel Hill, NC, 27516

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

What Are My Rights as a Research Study Participant?

You may choose not to take part or you may leave the study at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest or

because the entire study has been stopped. Information about you may be removed from the study data and could be used for future research or shared with other researchers without additional consent from you.

By continuing, I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. I have had a chance to ask questions about being in this study and have those questions answered. By taking part in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, *Name* at *telephone number (also include after hours number)*.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at (336) 716-4542 or the Research Subject Advocate at (336) 716-8372.

Social Sciences and Health Policy

Improving care coordination for adolescents and young adults with cancer: implementing a bridge between needs and services

Informed Consent Form to Participate in Research
Sarah Birken, PhD, Principal Investigator
Emily Haines, PhD, Co-investigator

Summary

You are invited to participate in a research study. The purpose of this research is to seek feedback on an intervention designed to assess and address the needs of adolescents and young adults (AYAs) with cancer: the AYA Needs Assessment & Service Bridge (NA-SB). You are invited to be in this study because you a provider serving AYAs with cancer. Your participation in this research will involve participating in a 60-minute telephone interview.

Participation in this study will asking you questions about how NA-SB might be implemented at your institution. All research studies involve some risks. A risk to this study that you should be aware of is a slight risk of breach in confidentiality, although we will take measures to protect your privacy. You will not directly benefit from your participation in this study, but your feedback on NA-SB will help us to refine it so that it better addresses the needs of AYAs and cancer care providers.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Sarah Birken, PhD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: sbirken@wakehealth.edu.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at 336-716-4542 or the Research Subject Advocate at Wake Forest at 336-716-8372.

Introduction

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are an adolescent or young adult with cancer. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask the study staff to explain any words or information contained in

this informed consent document that you do not understand. You may also discuss the study with your friends and family.

Why Is This Study Being Done?

The purpose of this research study is to get feedback from providers on a new intervention to assess and address the needs of AYAs with cancer.

How Many People Will Take Part in the Study?

8 people will take part in this study.

What Is Involved in the Study?

You will participate in a 60-minute telephone interview. During this interview, we will ask you questions about your thoughts on NA-SB and how it might be implemented at you institution.

As part of this research study, you will be audiotaped. This is being for the purposes of transcription. You understand that you may request the recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the audiotape before it is used. You should also understand that you will not be able to inspect, review, or approve the audiotapes before they are used in this study.

Please choose one of the following regarding the use and disclosure of the audiotape used in this research study:

_____ I would like the audiotapes of me to be destroyed once their use in this study is finished.

____ The audiotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

How Long Will I Be in the Study?

You will be in the study for about *one day* (i.e., the time it takes to participate in 60-minute interview).

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Are There Benefits to Taking Part in the Study?

There are no expected direct benefits from taking part in the study.

What Other Choices Are There?

You do not have to be in this study to use NA-SB at your institution.

What Are the Costs?

All study costs, related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Interview recordings from this study will be stored securely and only shared among members of the study team. They will be stored for approximately 6 months to allow for transcription and then permanently deleted. Note that, during interviews, participants can choose to stop the recording at any time.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

Will You Be Paid for Participating?

You will not be paid for participating.

Who is Sponsoring this Study?

This study is being sponsored by Wake Forest School of Medicine. The sponsor is providing money or other support to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

What About My Health Information?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes **information about your physical, psychosocial, and practical needs.**

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Emily Haines that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Emily Haines
377 McGowan Lane
Chapel Hill, NC, 27516

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

What Are My Rights as a Research Study Participant?

You may choose not to take part or you may leave the study at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest or because the entire study has been stopped. Information about you may be removed from the study data and could be used for future research or shared with other researchers without additional consent from you.

By continuing, I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. I have had a chance to ask questions about being in this study and have those questions answered. By taking part in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, *Sarah Birken, PhD* at (919) 357-2662 or after-hours at (336)906-3395.

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The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at (336) 716-4542 or the Research Subject Advocate at (336) 716-8372.

You will be given a copy of this consent form.