SHARE-S Aim 3: Shared Healthcare Actions & Reflections Electronic systems in Survivorship

Wake Forest Baptist Comprehensive Cancer Center (WFBCCC)
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1.0 Summary

Nationally, there is a recognized gap in *implementing* guideline-concordant cancer survivorship care planning (SCP). Initial SCP guideline implementation efforts focused on document/information delivery and demonstrated limited efficacy for improving patient health outcomes. The proposed SHARE-S Implementation Program builds upon successful SCP studies based on the Chronic Care Model and aims to enhance SCP implementation, leveraging technology. SHARE-S will enhance SCP with self-management coaching and text/coaching support for adherence to the SCP guidelines that require self-management. We will conduct a single-arm pragmatic pilot study of SHARE-S implemented in clinical care (n=40). We will test the study protocols, implementation program, and complete mixed-methods data collection to guide future study planning. The primary goal of this study is to assess how successfully SHARE-S can be implemented in a clinical setting that already consistently provides survivorship care planning documents to improve guideline concordant survivorship care. We will also collect data on the feasibility of assessing the impact of SHARE-S on service outcomes and patient outcomes. The primary goal of the future larger study will be to assess SHARE-S in multiple clinical settings to improve implementation of guideline concordant survivorship care and thus patient health outcomes. SHARE-S is a novel approach to supporting patient self-management that is integrated with clinical care and may generalize to improving care for other chronic illnesses such as cardiovascular disease.

2.0 Introduction and Background

The transition from active cancer treatment to survivorship is a particularly challenging time with an opportunity to improve upon guidance for how patients can take a more active role to optimize their health outcomes.[3] Survivorship care planning (SCP) supports the transition from active cancer care to survivorship care by enhancing communication among clinical teams and empowering patients and families. Nationally, there is a recognized gap in *implementing* guideline-concordant cancer SCP. The Commission on Cancer (CoC) quality program for survivorship care initially required that at least 75% of eligible patients receive a formal survivorship care plan document. Yet, cancer care providers found this standard difficult to achieve, which is illustrated by the subsequent change in the survivorship care standard to providing care plan documents to 50% of eligible participants in 2017.[4,5] A publically available draft of the newly updated survivorship quality standard includes a *recommendation* for a formal care plan document, although has removed the requirement for a care plan document with an *increased emphasis on the SCP delivery model and activities*.[6] Care plan documents in this new standard are considered one of the potential services offered as a component of meeting SCP requirements.[6] Recommended components of a comprehensive care plan document include: (1) a treatment summary and (2) outline of follow-up care needs including support for ongoing concerns and recommended healthy behaviors.[3,7,8]

While care plan documents were initially the focus of implementing SCP clinical guidelines, there is also an evidence gap in this approach.[9,10] SCP guideline implementation focused on document/information delivery and demonstrated limited efficacy for improving patient health outcomes.[9,11] In this document-focused model, when care plans were developed, they were infrequently delivered to survivors or other healthcare providers.[12,13] Concerns for limited adoption of care plan documents included the perceived lack of evidence that documents improved outcomes.[9] Evidence supports that care plan documents may benefit providers and health care systems, but the benefits to patients has remained unclear.[14] Some document-focused SCP trials have been negative, with limited evidence of improved care coordination,[15] and suggestions that care plans may even increase patient anxiety in patients experiencing more threatening illness.[16] Recommended next steps for SCP research include enhancing information technology support for developing and optimizing the use of care plan documents,[17] viewing SCP as an opportunity to facilitate patient engagement and support of self-management (e.g., health behaviors), and assessing care plans using hybrid implementation-effectiveness studies that consider context.[1,9,11,17–20]

Recent evidence supports that cancer care plan documents are more efficacious when derived from shared decision making (e.g., patient-centered or preference-sensitive) versus provider-driven processes.[1] A particularly strong SCP study that resulted in improved self-reported health outcomes (i.e., improvements in social, emotional, and physical role functioning, self-reported health, bodily pain) included one intervention session with a mental health professional focused on creating a patient-owned care plan through the process of goal setting, action planning, and other motivational interviewing techniques to engage survivors in self-managment.[1] Another similar one in-person or telephone session with an advanced practice nurse that included goal setting and regular assessments of progress to foster survivors' confidence in their ability to perform self-management showed preliminary support for improving patient-reported health outcomes (e.g., depression, anxiety, self-efficacy, physical functioning, role limitations, pain, general health, quality of life).[2] Both of these SCP studies were based on the Chronic Care Model (CCM) in the context of transitioning from acute active cancer treatment to survivorship chronic condition management.[1,2] Limitations of these studies were that the delivery model did not include follow-up contact, which is typically part of the CCM.[1]

The CCM posits that self-management support is a key component of a health system that delivers high-quality chronic illness care.[21] Self-management support includes collaborating with patients to ensure they have the information and skills they need to be actively engaged in the process of their care and leads to improved health outcomes.[21] An eHealth enhanced version of the CCM proposes that electronic tools can support productive patient-provider interactions and improve health outcomes.[22] Self-determination Theory[23] provides more in depth guidance for the self-management support component of the CCM needed to result in the activated patient and productive interactions.

Self-determination Theory emphasizes that supporting patients' partnership in healthcare decisions will enhance patients' autonomous engagement in their care and ultimately lead to more sustainable improvement in health outcomes.[24] Patient-driven goals are more likely to be achieved than goals that are extrinsically motivated.[25] One method for supporting patients' engagement in their care and to support shared decision making is to use a patient-centered communication style and behavioral change strategies (i.e., self-management coaching).[23] The CCM and Self-determination Theory fit within a comprehensive conceptual framework for implementing and assessing survivorship care planning that will be integrated with Proctor's implementation outcomes framework.[2,20,26]

The proposed SCP implementation program (SHARE-S) builds upon the above described successful SCP studies based on the CCM model[1,2] and **aims to enhance SCP implementation through self-management coaching and supportive text messages to increase engagement with the care plan and support SCP goals**. Completing the complex process of SCP within the context of single clinical visit presents challenges (time constraints; healthcare provider may have limited knowledge of effective shared goal-setting techniques; and patient's ability and willingness to commit to goals within the same time context).[27] As providers and patients have increasingly compressed time during an in-person clinical visit, several visioning reports, including *Crossing the Quality Chasm*[28] call for transforming medicine from episodic, in-person care to the provision of continuous, coordinated care delivery. Using Technology-Facilitated Implementation Science concepts, we will *offload* some of the implementation effort of guideline-concordant cancer SCP from clinical teams, and at the same time give patients *more time* to carefully engage in and consider their healthcare goals. Adding more robust follow-up contact may further enhance and sustain positive results found in the previously effective SCP delivery model. **Shaping knowledge about SCP, identity (valued self-standards), regulation (reduce negative emotion [mindfulness] - skill), goals and planning, feedback and monitoring, comparison of outcomes, and social support (emotional) are the behavioral change techniques[29–31] that will be adopted as implementation strategies to (1) prepare patients to be active participants and (2) enhance survivors uptake and adherence to the SCP guidelines (self-management)**.[32]

Preliminary Data

Provider Identified Local Setting Quality Gap. WFBCCC recently opened a Survivorship Clinic in Winston-Salem directed by Dr. Stacy Wentworth (Co-Investigator) in June of 2019. The WFBCCC Survivorship Clinic has seen approximately 61 new cancer survivors from July – December 2019 (approximately 10 per month). It is a high priority for WFBCCC to follow the CoC quality standard.[6] Quality standard requirements are evaluated annually by reporting: (1) the estimated number of patients impacted by each of the chosen services; (2) the cancer sites impacted by each of the chosen services; and (3)

resources/processes utilized to enhance each of the chosen services.[6] The updated CoC quality standard also includes a designated director of the survivorship care program, an identified team responsible for development of survivorship care delivery models and activities, and a survivorship program that addresses needs of cancer survivors.[6] *Dr. Wentworth has identified a local need such that 64% of the166 survivorship clinic patients seen in the past year who completed feedback surveys would also be interested in seeing a "counselor."* The flyer for the Cancer Survivorship Clinic also lists “lifestyle” coaching as a component of the existing clinic visit with an advanced practice practitioner, a service, which Dr. Wentworth believes has room for improvement. Although different terms have been used, we will adopt the term “health” coaching as a more colloquial term for self-management coaching specific to the health context as the term we use to present this intervention to participants. Health coaching is an emerging field such that the American Medical Association Current Procedural Terminology (CPT) panel launched a relevant new level 3 CPT© for health coaching[33] and using another term could lead to confusion if implemented more broadly. Therefore, providing coach and texting support in the proposed study may fill the unspecified gap identified by participants who would like additional counseling support and enhance (not replace) the intention of the clinic visit to provide coaching. Dr. Wentworth is thus interested in piloting the proposed enhanced survivorship visit that will pilot use of health coaching and supportive text messages . We will design this study so it will support the CoC quality standard requirement to provide an in-depth evaluation/review of this new service that aims to address survivors’ identified needs. Dr. Wentworth also directs SCP at WFBCCC Hayworth Cancer Center and is interested in extending evaluation of the enhanced survivorship visit to include this site.

Patient Stakeholder Feedback (PI: Dr. Sohl). Our team has experience recruiting and implementing a one-session self-management intervention with colorectal cancer survivors through our pilot study entitled, Use of Systems Support Mapping to Guide Patient-Driven Self-Management in Rural and Urban Cancer Survivors in the same two clinics. We recruited 24 colorectal cancer survivors (36% of the 66 potentially eligible participants approached agreed to participate). Preliminary analyses revealed that a majority of participants (58.8%) indicated in a follow-up survey that they would find it helpful to meet with someone to discuss their goals *monthly* and preferred discussing these goals *by telephone*. Self-determination Theory guided the intervention and assessments selected in this study. Goals that emerged after holistically considering how to prioritize self-management within one’s life context included topics such as engaging in physical activity (walking, swimming), eating wisely, scheduling follow up care, finding quiet time (to pray, read, meditate), enhancing social connections (friends, family) and other personal development (e.g., cognitive, financial).

Technology-assisted implementation experience (PI: Dr. Houston). We have experience with technology-assisted implementation to enhance engagement between clinical teams and patients. In a prior NCI trial, we

randomized 174 community-based practices; half of the practices were provided brochures (paper-referrals) to encourage patient access to a web-assisted tobacco intervention (WATI); and the other half of practices received an implementation program to support use of an "e-referral" tool, an online portal where registered clinical teams could, with patient permission, enter the patient's email. These patients who were then e-referred received up to 10 automated emails, encouraging patients to use the WATI.[34] Each practice adapted the automated messages for their own clinical setting. During the trial, a total of 4,789 smokers were referred. Eighty-one of the eighty-seven practices randomized to e-referral referred at least one smoker. Mean smokers referred per practice was not statistically different by group (eRefer (24.9 (SD 22.3)) vs. comparison (30.1 (SD 25.5), $p = 0.15$), suggesting that the additional step of e-referring was not excessively burdensome, compared to the brochure. The e-referral portal implementation program resulted in nearly triple the rate of patient engagement (31% of all smokers e-referred used the WATI versus 11% in the brochure arm, $p < 0.001$) among smokers who were not highly motivated to quit.[34]

3.0 Objectives

Shared SCP is more likely to be adopted, adhered to, and monitored. Yet, shared planning is challenging to integrate into brief clinical visits. Considering this translational gap, we propose the SHARE-S Implementation Program pilot. SHARE-S uses a clinical team-initiated, technology-facilitated shared survivorship planning system, engaging patients *before and/or after survivorship care planning visits* using a centralized, automated "meta-composite" tool. We will conduct a single-arm pragmatic pilot study of SHARE-S implemented in clinical care. We will test the study protocols, implementation program, and complete mixed-methods data collection to guide future study planning. The primary goal of this study is to assess how successfully SHARE-S can be implemented in a clinical setting that already consistently provides survivorship care planning documents to improve guideline concordant survivorship care. We will also collect data on the feasibility of assessing the impact of SHARE-S on service outcomes and patient outcomes. We will further document our overall progress through the Stages of Implementation Completion (pilot of Implementation Stages.[35]

3.1 Primary Objective

3.1.1. To evaluate how successfully SHARE-S can be implemented into clinical care as characterized by rates of enrollment.

We hypothesize >30% of patients e-referred to SHARE-S will enroll.

3.2 Secondary Objective

3.2.1 To assess additional implementation outcomes that evaluate preliminary implementation success (i.e., further assessment of adoption, acceptability, appropriateness, further assessment of feasibility, and fidelity).

3.2.2 To describe service outcome variability to inform future studies. We will assess service outcomes relevant to CoC requirements[6] by reporting annual estimates for: (1) the estimated number of patients impacted by SHARE-S; (2) the cancer sites impacted by SHARE-S; and the (3) resources/processes utilized to enhance each of the chosen services if barriers were encountered. We will also assess safety and perceived patient-centeredness of care.

3.2.3 To describe patient health outcome variability to inform future studies (i.e., social role, physical functioning, anxiety, depression, fatigue, sleep disturbance, pain, cancer-specific quality of life, health behaviors, patient autonomy, self-efficacy for managing cancer, engagement with the survivorship care plan document, and satisfaction with care).

3.2.4 To evaluate the Implementation Program we will assess key Stages of Implementation Completion (SIC) milestones and processes for this pilot study of the Implementation Stage,[35] measured at the clinic level.

3.2.5 To qualitatively assess implementation barriers and facilitators using semi-structured interviews that will be audio-recorded.

3.2.6 To examine how study results vary by cancer type.

4.0 Patient Selection

We aim to enroll 40 participants over 16 months. All participants will be recruited from Wake Forest Baptist Comprehensive Cancer Center (WFBCCC) survivorship programs. We will ask clinic staff to use an e-referral tool to notify our study team of patients with an upcoming or recently completed survivorship visit. The eRefer portal developed by the University of Massachusetts Center for Clinical and Translational Science Informatics Core is a recruitment tool that allows potential participants to verbally agree to provide their email and/or cell phone number and be sent only one email and/or text message with information about a research opportunity they are interested in. Clinical staff, the “Referrer” in the eRefer portal, enter his/her email address on the eRefer home page, select

the study name from the project list and enter the potential participant's email address and/or cell phone number as preferred by the patient (for this study we will use cell phone number only). By providing their email address or cell phone number, the patients verbally agree to be sent the study invitation messages and contacted for recruitment. After the referral has been executed, the eRefer portal provides study staff with the participant's contact information, allowing the study team to contact the participant.

The study team will then communicate with eligible patients either in person or remotely (e.g., telephone, myWakeHealth, mail) regarding their interest in study participation. The study coordinator will provide study information and answer questions to determine willingness to participate. After making sure the patient clearly understands the study procedures and agrees to follow them, the consent will be signed remotely or in person. If signed remotely, patients will be asked to send the form back to us by a secure means (e.g., REDCap, mail). In the case that the patient is consented remotely, either a hard copy or email attachment of the informed consent document will be provided to the participant. We will compensate participants up to $100 based on level of assessment completion ($25 for each assessment, $25 for the interview). Study compensation will not be mentioned by the "Referrer".

4.1 Inclusion Criteria

4.1.1 Adults ≥18 years of age
4.1.2 Documented or planned cancer survivorship visit
4.1.3 Have a texting enabled telephone
4.1.4 Cognitively able to complete study procedures as judged by the study team
4.1.5 Able to understand, read and write English

Children under the age of 18 with cancer will be excluded due to the potentially different self-management support intervention needs of this population that will likely include parental involvement. Results from this research may inform future studies in children with cancer under 18 who should be researched separately.

4.2 Exclusion Criteria

4.2.1 Declined participation in the study

4.3 Inclusion of Women and minorities

The target population for this study is adult men and women who have a documented or planned cancer survivorship visit. We are drawing directly from patients seen by the clinic and thus expect that women and

minorities will be represented as is consistent with the proportion seen in the past five years at the Wake Forest Baptist Comprehensive Cancer Center. For this pilot study, non-English speaking patients will be excluded because the intervention content (text messages, coach calls) will be in English. Pending results of the pilot, a future study to determine the efficacy of translating the intervention will be proposed. Referrals will be implemented within the clinical workflow and the intervention is designed reduce barriers to participation with the goal of reaching all patients.

5.0 Methods

5.1 Registration Procedures

This protocol utilizes Reduced Review registration which means that eligibility and other review are not performed by the CRM registrar.

5.2 Study-Related Activities

The SHARE-S workflow supports a survivorship visit. The clinic scheduler or other staff will initiate a brief discussion about the opportunity for an enhanced survivorship visit with patients who have a documented or planned upcoming visit. Then the clinic staff will enter an e-referral to an automated computer-tailored health communication system that shifts parts of the discussion to the time before and/or after a clinic visit and document this referral in the electronic health record (Epic/Wake One).

Overview of Study-Related Activities

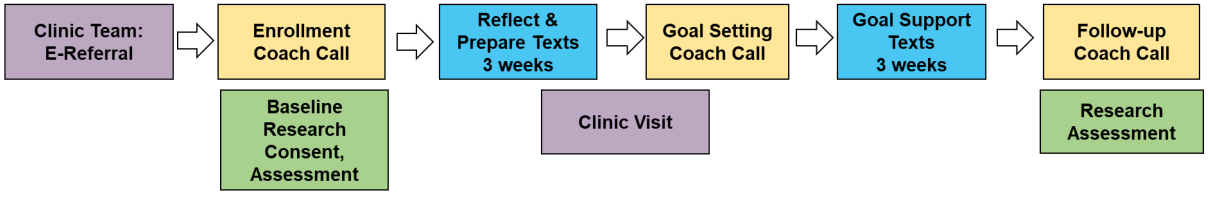
	Pre-Study[a]	Baseline	SHARE-S[b]	Follow-up[c]
E-referral	X			
Informed consent	X			
Demographic/ Clinical Factors		X		
Self-Reported Measures		X		X
Intervention Adherence			X	
Acceptability Ratings				X
Semi-structured Interview				X
Adverse event evaluation			X	X

[a] Pre-study requirements listed in table must be completed within 60 days prior to registration.
[b] SHARE-S = study intervention, must be completed within one-year of registration.
[c] Follow-up visit to be completed the same day or within 30 days of the final intervention session.

5.3 Intervention Description

The proposed SCP implementation program (SHARE-S) has three components (please see Figure 1). First, we will use an *electronic referral (e-referral)* to enhance care coordination and communication among clinical teams and the patient/family. We developed this tool and demonstrated the ability to implement an e-referral in our preliminary studies (at the University of Massachusetts Medical School). The e-referral *provider-level* component of the implementation program supports adaptation such that multiple clinical team members can complete the process, and it can be completed using the mobile app, on a desktop (e.g., when scheduling a clinic visit), or even expandable into the community. To execute a referral, the referring clinician goes to www.erefer.umassmed.edu, selects the messaging program they are referring to, and, with patient verbal permission, enters their cell phone number, and clicks submit. The patient then gets a welcome message with information about what they are receiving, and the clinic/study's designated staff receive a notification of patient engagement, along with the patient's contact information. The e-referral and text messaging systems will not be branded to participants as coming from any specific Institution. Patients can cancel the service with each message sent. To facilitate implementation of SHARE-S, facilitators will train clinical teams in the use of the SHARE-S technology enhancements. Each clinic will be asked to identify two implementation coordinators (physicians, nurses, or other staff). These two implementation coordinators act as points of contact and clinic champions. They will be trained in the e-referral tool *and* train-the trainer guidance, so they can act as an internal facilitator, engaging the rest of the practice and encouraging adoption. Training includes experiential learning (hands-on demonstrations of the eRefer tool, including initial registration; practice e-referring a "test" patient; and discussing what the patient will receive after eReferral) and materials that will support this initial conversation. As reminders, a series of motivational booster emails will be sent to clinic staff during the 6-week initiation period. The emails will be sent by the study team from the Wake Forest internal email system. For ongoing facilitation, our external facilitator will complete a total of four proactive booster facilitation calls (approximately 10-20 minutes) assessing perceived barriers, strategizing solutions, and reinforcing success. *Note that we found that registration in e-refer was a barrier* for patients and providers, and we now have a method to remove this barrier. For SHARE-S, if a patient agrees to enroll, then they are automatically registered with the system and begin to receive the messages. *This new eRefer process is adaptable, and we will monitor adaptations*. Each clinic will be allowed to consider how to best integrate the referrals into their workflow, allowing for adaptation in implementation (who completes the referral, when in the workflow to bring up referral, etc.).

Figure 1. Example of Possible SHARE-S Study Flow



Second, we will support patient engagement with SCP guidelines[7] through self-management/health coaching. The first coaching call/videoconference will be 60 minutes and two subsequent coaching calls/videoconferences will be 30 minutes each. These sessions will be digitally recorded to review for treatment fidelity. Recordings will be made on a handheld device and saved to a Wake Forest server in a folder only accessible by the study team. Coaches will engage patients in a similar behavior change techniques described in the above mentioned exemplar one-session survivorship care planning intervention and other interventions that have informed recommendations included in survivorship clinical guidelines (i.e., goals and planning, feedback and monitoring, motivational interviewing).[1,7] Coaches will emphasize supporting the autonomy of the patient in facilitating behavior change consistent with the principles of behavior changed outlined by Self-determination Theory.[23] Other theoretical models for health behavior change generally choose the behavior of study and do not focus on peoples' motivation to engage in a particular behavior within their broader life context of other behaviors and how they contribute to broader goals.[36] In this study, coaches will support participants in selecting personalized health goals to be consistent with our conceptual framework that is grounded in promoting patient choice. This approach was successfully implemented in another telephone lifestyle coaching study that provided participants with a range of topics for health goals that we adapted for use in this study: (1) Eat Wisely; (2) Be Physically Active; (3) Be Tobacco Free/Limit Alcohol; (4) Strengthen Social Connections; (5) Restore (e.g., manage Stress); (6) Get adequate Rest; (7) Engage in preventive Care; (8) Other Personal Development (e.g., spiritual, work, finance).[37] Goals that emerged when considering life context from cancer survivors in our preliminary data informed adapted and added topics. The health coaching model adopted in this study includes training in mindfulness to enhance autonomy support.[23]

Third, the patient receives a set of automated, tailored text messages (daily for 3 weeks after the first and second coach calls for a total of 6 weeks). SHARE-S offloads some communication about SCP, and enhances patient understanding and activation through the concept of spaced education,[38–40] providing small pieces of information over time, and through brief assessments that can guide shared decision-making. Although evidence for these approaches exist, they have rarely been used in the context of cancer, and have not been applied to SCP. We adapted this text messaging intervention content with stakeholder input for use with cancer survivors. The system can send messages with a request for patient response (a two-way message) and store that information as an additional tailoring variable and as patient-generated data to be reviewed by the clinical teams. Messages can sent by text and will be based on the key components of SCP. We will also mail participants a packet of materials summarizing SCP and each of the topics introduced in coaching and text messages.

6.0 Outcome Measures

We will collect patient-reported data either remotely or in person at baseline (before the first coaching call) and follow-up (after the last coaching call).

6.1 Primary Outcome

6.1.1. Feasibility as defined by the # participants enrolled/those e-referred.

6.2 Secondary Outcomes

6.2.1. Other implementation outcomes

6.2.1.1. Adoption (e.g., #e-referred patients e-referred/those possible [based on chart review])
6.2.1.2. Acceptability (e.g., Acceptability of Intervention Measure[41], qualitative feedback from cancer survivors)
6.2.1.3. Appropriateness (e.g., Intervention Appropriateness Measure[41])
6.2.1.4. Other indicators of feasibility (e.g., number of participants enrolled per month, Feasibility of Intervention Measure,[41] adherence rates, retention rates)
6.2.1.5. Fidelity (e.g., patient adherence to text responses, adherence to coaching sessions, length of coaching sessions, observational checklist completed for a subset of coaching sessions)

6.2.2 Service outcomes

6.2.2.1. Number of patients enrolled
6.2.2.2. Cancer types
6.2.2.3. Qualitative feedback on resources/processes utilized to enhance each of the chosen services
6.2.2.4. Adverse events related to the intervention will be described
6.2.2.5. Patient-reported measure of patient-centered communication[42] and relatedness completed only at follow-up [HEAL Patient-Provider Connection][43]

6.2.3 Patient health outcomes (Self-reported)

6.2.3.1.1 Social role, physical functioning, anxiety, depression, fatigue, sleep disturbance, pain [PROMIS Profile 29; also used in clinical practice][44]. We will also assess the feasibility of pulling these data from the electronic health record.

6.2.3.1.2 General health [one-item assessing perceived health].[45]

6.2.3.1.3 Cancer-specific quality of life [Cancer-specific subscale of the QLACS][46,47]

6.2.3.1.4 Health behaviors [tobacco use, alcohol use,[48] physical activity, nutrition, stress reduction]

6.2.3.1.5 Patient autonomy [Index of Autonomous Functioning][49] Self-efficacy for managing cancer [Self-efficacy to Manage Chronic Disease Scale][50,51] Mindfulness[52]

6.2.3.1.6 Engagement with the survivorship care plan document (Self-reported reference to the care plan since it was given to them)

6.2.3.1.7 Satisfaction with care

6.2.4 Implementation Program

6.2.4.1 Time from opening the study to first patient e-referred, time to 10th patient e-referred

6.2.4.2 When the survivor was e-referred (indicating whether it was when scheduling an appointment or required review of upcoming appointments). We will use a combination of field notes, electronic medical record notes, and direct observation to measures these milestones.

6.2.5 We will also adopt mixed-methods to assess select implementation outcomes as guided by the Consolidated Framework for Implementation Research (CFIR).[53] We chose to incorporate CFIR because it will facilitate assessment of potential barriers and facilitators at multiple levels to help us prepare for implementing SHARE-S more widely.

6.2.6 Clinical factors (cancer type, time since diagnosis, prior treatments, comorbidities) abstracted from medical charts or self-reported.

We will also collect demographic characteristics for descriptive purposes (age, sex, rural-urban residence [classified by the Federal Office of Rural Health Policy definition of rural],[54] race/ethnicity, marital status, education level, health literacy).[55]

7.0 Analytic Plan

7.1 Sample Size and Power

This pilot study has an accrual goal of 40 cancer survivors. The primary objective is to evaluate the feasibility of implementing SHARE-S into clinical care, where feasibility is defined based on the rate of enrollment. Assuming a negative binomial distribution and true enrollment rate of 30%, the probability that we would have to approach 164 or more people to recruit 40 is <0.05. Therefore, if we approach ≥164 participants to enroll 40, it is unlikely the true probability is above 30%, and we will conclude the study may not be feasible. Assuming we are able to enroll 40 survivors, with this sample size we will be able to estimate rates of interest within +/- 16% using exact 95% binomial confidence intervals. A sample size of 40 will also allow for reasonable estimates of SDs to be used to plan future studies.

The number of participants interviewed (12-24) will be determined when data saturation is reached. As is conventional for thematic analysis, we will conduct interviews until we think there is enough qualitative data to address issues related to the acceptability of study procedures.[56] The study team's experience leads us to believe that 12-15 interviews from cancer survivors will be sufficient to achieve this objective. Our analyses of differences between cancer type will be for exploratory purposes and therefore data saturation using those variables is not the goal. If unexpected information emerges and our timeline allows, we will consider amending the protocol to recruit additional participants.

7.2 Data Analyses

This study will provide quantitative data on implementation outcomes, service outcomes, patient health outcomes, implementation program information, and qualitative feedback on barriers and facilitators to guide future study planning. We will calculate 95% confidence intervals for each of the measures to determine the range of estimates that are consistent with our data. We will track the number of patients seen in the Survivorship Clinic, the number e-referred, and the percent who agree to enroll in SHARE-S. For those not enrolled, reasons will be summarized. The proportion of participants and corresponding exact 95% CI for participants who participated in SHARE-S and those who completed all assessments will be computed; we will also calculate the frequency of any adverse events and percent of participants who complete the follow-up visit to assess retention. We will use one-sample tests of binomial proportions to compare the recruitment rate to the hypothesized value of 30%. In exploratory analyses, we will compare participants who enroll versus decline, are non-adherent or who drop out by demographic characteristics and baseline scores of the measures (when applicable) using fisher's exact tests or Wilcoxon rank sum tests as appropriate. We will also investigate any differences in these analyses by cancer type.

Baseline analyses will include descriptive statistics of quantitative data on implementation outcomes, service outcomes, patient health outcomes, and background characteristics (i.e., clinical, demographic). The distributions of continuous variables will be examined to determine the presence of outliers and whether transformations are necessary for analysis. The primary goal of the statistical analysis of these measures will be to estimate standard deviations (SD) for use in future studies. Additional analyses will include fitting mixed ANCOVA models (adjustment for baseline) to model the trajectory of patient health outcomes by time and group accounting for the repeated measures on a subject. The purpose of all of these models will be to obtain estimates of the SD of change adjusted for covariates of interest and the within-person correlation of the repeated measures, not to perform formal hypothesis testing. We will consider the different recall time frame for the quality of life measures when interpreting the results. In exploratory models we will examine the impact of adherence to SHARE-S on changes in the measures, subgroup analysis by cancer type, and we will examine the role of patient autonomy and self-efficacy as potential mechanisms. The purpose of these analyses will be to estimate SD and within-person correlation by subgroup and with adjustment for mechanisms; no formal hypothesis testing will be done.

Interview transcripts will be coded independently by the QPRO shared resource staff at WFBH. Twenty-five percent of the transcripts will be coded by two separate coders to ensure consistency of code application. Unresolved discrepancies reconciled by a third person. Using thematic analysis, the coded text will be iteratively reviewed and interpreted.[56] The qualitative and quantitative analyses will be evaluated in a mixed-methods framework for consistency and discrepancies to refine the protocol for future studies. In particular, we will analyze the feasibility, acceptability and appropriateness data using a mixed-methods since these measures have not been validated in a similar sample. For example, if the qualitative interviews indicate that a particular subgroup of patients (e.g., by cancer type) perceive greater benefit from SHARE-S, then we will perform exploratory subgroup analysis of the quantitative data.

7.3 Accrual Rate

The WFBCCC Survivorship Clinic has seen approximately 61 new cancer survivors (multiple cancer types) from July – December 2019 (approximately 10 per month). In addition, our team has experience recruiting and implementing a one-session self-management intervention with colorectal cancer survivors. We recruited 24 exclusively colorectal cancer survivors (36% of the 66 potentially eligible participants approached agreed to participate). Therefore, we conservatively expect to

enroll 2-3 participants per month over 16 months to reach our accrual goal of 40.

7.4 Length of Study

We estimate that we will complete study enrollment in 16 months, follow-up in 18 months, and analyses in 24 months.

8.0 Data Management

Informed consent document	EPIC
E-referral documented, decline reasons	EPIC
Protocol Registration Form	WISER/OnCore
Demographic Factors	WISER/OnCore
Patient-reported Measures	REDCap
Intervention Fidelity Form	REDCap
Chart review: Clinical Factors	REDCap
Intervention Materials	Files on a local Secure Server in a folder accessible only by the study team
Process measures	Files on a local Secure Server in a folder accessible only by the study team
Patient adherence and text responses	Files on a Secure Server (tech system hosted at University of Massachusetts)
Qualitative feedback	Files on a local Secure Server in a folder accessible only by the study team
Adverse Events Log	WISER/OnCore

9.0 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. Following data collection, subject identifying information will be destroyed consistent with data validation and study design, producing 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 collected in the eRefer portal (patient contact information) will be stored by the University of Massachusetts in a regulated environment until completion of the project or upon the request of the potential participant. The regulated environment provides applications to a secure network for collecting and storing confidential data. The regulated environment has been securely configured to allow application access via the secure socket layer (HTTPS) protocol. The regulated environment is secured using hardware and software firewalls, along with access restrictions to provide the needed security protocols for the regulatory and Federal standards required. Access is restricted through a Virtual Private Network, a secure RSA token, and only restricted personnel are allowed access to the regulated environment. The software program will use a secure Application Programmable Interface to send and receive the text messages. These text messages will be sent from toll-free number (1-844-276-4493).

The texting service, also developed by the University of Massachusetts, will be responsible for sending the texts and receiving the text responses. The software program will use a secure Application Programmable Interface to the service to send and receive the texts. To minimize risks, text messages will not contain any personal health information. The software program will read the texting service servers to extract the data and enter the regulated environment. As soon as this is complete, the program will then delete the data from the texting service servers. The texting service does not store the phone numbers. It will only use the phone number to send and receive messages. During the informed consent process, participants will be informed of this potential risk to confidentiality through their sending and receiving text messages.

All data will be stored in a HIPAA compliant regulated environment and access will be only through a secure VPN network. All patient related identifiers are encrypted in the database. The regulated environment provides applications a secure network for collecting and storing confidential data. The regulated environment has been securely configured to allow application access via the secure socket layer (HTTPS) protocol. The regulated environment is secured using hardware and software firewalls, along with access restrictions to provide the needed security protocols for the regulatory and Federal standards required. Access is restricted through a Virtual Private Network, a secure RSA token, and only restricted personnel are allowed access to the regulated environment.

10.0 Data Safety and 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.

11.0 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 – Subject Eligibility Checklist

IRB Protocol No. 000064683	**WFBCCC 99420**
Study Title: SHARE-S Aim 3: Shared Healthcare Actions & Reflections Electronic systems in Survivorship	
Principal Investigator: Stephanie Sohl, PhD	

Inclusion Criteria (as outlined in study protocol)	**Criteria is met**	**Criteria is NOT met**	**Source Used to Confirm * (Please document dates and lab results)**
Adults ≥18 years of age	☐	☐	
Documented or planned cancer survivorship visit	☐	☐	
Have a texting enabled telephone	☐	☐	
Cognitively able to complete study procedures as judged by the study team	☐	☐	
Able to understand, read and write English	☐	☐	
Exclusion Criteria (as outlined in study protocol)	**Criteria NOT present**	**Criteria is present**	**Source Used to Confirm * (Please document dates and lab results)**
Declined participation in the study	☐	☐	

This subject is ☐ eligible / ☐ ineligible for participation in this study.

ORIS Assigned PID: _____

Signature of research professional confirming eligibility: _____
Date: _____

* Examples of source documents include clinic note, pathology report, laboratory results, etc. When listing the source, specifically state which document in the medical record was used to assess eligibility. Also include the date on the document. Example: “Pathology report, 01/01/14” or “Clinic note, 01/01/14”

SHARE-S Aim 3: Shared Healthcare Actions & Reflections Electronic systems in Survivorship

Wake Forest Baptist Comprehensive Cancer Center (WFBCCC)

WFBCCC # 99420

Appendix B – Protocol Reduced Review Registration Form

DEMOGRAPHICS

Last Name: _____ First Name: _____

MRN: ___ ___ ___ ___ ___ ___ ___ ___ ZIPCODE: ___ ___ ___ ___ ___

*SEX: ☐ Male ☐ Female

*Ethnicity (choose one): ☐ Hispanic ☐Non-Hispanic

*Race (choose all that apply): ☐ WHITE ☐African American ☐ ASIAN ☐ PACIFIC ISLANDER ☐ NATIVE AMERICAN (Alaskan)

*Diagnosis: _____

DOB (mm/dd/yy): ___ ___ / ___ ___ / ___ ___ (include if no MRN is provided)

*MD Name (Last, First) : _____, _____

*Date of Consent: ___ ___ / ___ ___ / ___ ___

Date of Registration: (if different than consent) ___ ___ / ___ ___ / ___ ___

PID # (OnCore): ___ ___ ___ ___ ___ ___ ___ ___ (to be completed by registrar)

Comprehensive Cancer Center requires that all registrations be sent to the CCCWFU Centralized Registrar the day the patient is consented; if this is not possible we require that all registration be communicated to the Centralized Registrar within 72 hours by the CRM registrar.

***Reduced Review means eligibility and other review are not performed by CRM registrar.*

For questions, the Protocol Registrar can be contact by calling 336-713-6767 between 8:30 AM and 4:00 PM, Monday – Friday.

Completed Eligibility Checklist and Protocol Registration Form must be hand delivered, faxed or e-mailed to the registrar at 336-713-6772 or registra@wakehealth.edu.

**** if not using the full wakehealth.edu outlook client (full outlook, not web outlook) save this file and attach to an email to registra@wakehealth.edu.*