A. SPECIFIC AIMS:

Cancer survivorship care represents a distinct phase of the cancer care trajectory and includes four components of care[1]:

> (1) prevention and detection of new cancers; (2) surveillance for cancer spread, recurrence, or new cancers intervention for consequences of cancer and its treatment (e.g., medical problems such as lymphedema and sexual dysfunction; symptoms, including pain and fatigue; psychological distress experienced by cancer survivors and their caregivers; and concerns related to employment and insurance); and (4) coordination between specialists and primary care providers to ensure that all of the survivor's health needs are met (e.g., health promotion, immunizations, screening for both cancer and noncancerous conditions, and the care of concurrent conditions). ([1]p. 188)

Providing cancer survivors and their primary care provider with a document (a Survivor Care Plan) that includes a treatment summary and care plan is one component of survivorship care. The 2007 IOM report *Implementing Cancer Survivorship Care Planning* [2] recommended that this record of care include, at a minimum: diagnostic tests and results; treatment names, start/stop dates, total drug and/or radiation dose, tumor response, and toxicity experiences; support services provided; contact information of institution/providers; return plans and a coordinator of continuing care. Since that time, clinicians have struggled to develop and implement these recommendations due to time, reimbursement, and informatics issues.[3, 4] Because knowledge regarding the development, implementation and outcomes about survivor care plans is nascent, evaluation is needed on both system and patient level processes and outcomes. [5]

Individuals diagnosed with colon cancer comprise the third largest group of cancer survivors in the U.S. and currently number over one million; African Americans (AA) have disproportionally higher rates of morbidity and mortality.[6] In 2010, approximately 4800 North Carolinians will be diagnosed with colon cancer; 22% of those will be in AA.[7] While early diagnosis through screening can be curative for many (90% 5-year survival), only 40% are diagnosed at this localized stage. [6]. For regional cancer (involving lymph nodes), the 5-year survival is 68% whereas metastatic disease has an 11% 5-year survival rate. Both treatment and surveillance are critical in improving outcomes in this high risk population. [8] Survivorship efforts should not only address surveillance and the physical and psychosocial sequelae of the colon cancer and treatment, but should also focus on health promotion to reduce the risk for recurrence and the development of new cancers and other chronic diseases.

Colon cancer survivors would be an ideal group to systematically implement and evaluate the impact of survivor care plans (SCP) on evidence-based surveillance and health promotion guidelines. [1, 2, 9] *JourneyForward* SCP have templates for treatment summaries and surveillance, with a version specifically adapted for colon cancer survivors. Therefore, the overall aim of this pilot study is to address the objectives outlined in CDC SIP RFA 10-029 to develop, implement, and evaluate the feasibility, acceptability and satisfaction of the *JourneyForward* SCP for 120 stage I-III colon cancer survivors at the University of North Carolina from both the survivor and provider perspectives. The specific aims of this project are to:

1. Evaluate the optimum timing to deliver the SCP during the first 12 months from diagnosis from both survivor and provider perspectives.
2. Describe the level of distress, unmet needs, and symptom profile, and quality of life of colon cancer survivors at the time of SCP delivery by treatment type (surgery alone or surgery + chemotherapy) to inform future SCP development in this population.
3. Using data from this project, begin integration of SCP into practice as a standard of quality cancer care in colon cancer survivors at UNC.
4. Disseminate knowledge gained from this intervention through the *Cancer Prevention and Control Research Network (CPCRN).*

B. RESEARCH STRATEGY:

SIGNIFICANCE. While survivorship should be celebrated, cancer has a significant impact on survivors and has several long-term health and psychosocial sequelae. [10-14] In addition to recurrences, cancer survivors are at greater risk for developing second malignancies and other diseases, such as cardiovascular disease (CVD), diabetes, and osteoporosis. Hewitt et al.[11] report that cancer survivors have almost a two-fold likelihood of having at least one functional limitation, and when the survivor has another co-morbid condition, the odds of functional impairment further increases. The likelihood of having other co-morbid conditions is high which, in turn, affects physical and psychological functioning. [15, 16] Clearly, cancer survivors have distinct healthcare needs and are high healthcare utilizers. [17, 18] Survivorship care plans (SCP) are a tool that may be helpful in addressing these issues and to promote communication between providers and survivors; *JourneyForward* SCP is web-based template created for this purpose. The following proposal meets the objectives outlined in CDC SIP RFA 10-029.

Transition from Acute Treatment to Extended Survivorship Can Cause Distress. Many cancer patients find the transition from acute treatment to extended survival difficult. [1] Many treatment-related symptoms resolve over time but some leave long lasting after-effects; other problems may appear over time as late effects. Survivors may not know what tests need to be done, whom to see, or how often to go for follow-up visits once treatment is over, nor the significance of such surveillance. This is particularly important since many do not receive the recommended follow-up care for colon cancer. [19, 20] As the number of survivors and their length of survival increase, long-term health issues specific to cancer survival are fast emerging as a public health concern. However, survivors report that their physicians are often unable to assist with many of the issues they face, and few receive counseling or guidance about lifestyle issues.[21] The Institute of Medicine and National Research Council issued a report on cancer survivors [1] identifying the need to develop strategies to address survivorship as a distinct phase in the cancer trajectory. Efforts during this phase of care should not only address the physical and psychosocial sequelae of the disease and treatment, but should also focus on health promotion to reduce risk for cancer recurrence, new cancers, and other chronic diseases. *JourneyForward* Survivorship Care Plans can include content on these topics.

Colon Cancer Survivors are an Ideal Group Needing Transition Support. [22] In the U.S., colon cancer survivors are the third largest group of cancer survivors, surpassed only by breast and prostate cancer survivors and currently number over one million. Unfortunately, African Americans (AA) have disproportionally higher rates of morbidity and mortality.[6] In 2010, approximately 4800 North Carolinians will be diagnosed with colon cancer and 22% will be in AA.[7] While most reports on incidence, mortality, and prevalence are for 'colorectal' cancer, the majority (>70%) have colon cancer and will be the focus of this pilot study. While early

diagnosis through screening can be curative for many (90% 5-year survival), only 40% are diagnosed at this localized stage. [6] For regional cancers (involving lymph nodes), the 5-year survival is 68% whereas metastatic disease has an 11% 5-year survival rate. To improve on these outcomes, survivors need to learn about surveillance, health maintenance, and health promotion recommendations to decrease the risk of recurrence and to facilitate early detection, should one occur. [23]

Colon cancer is usually treated with surgery alone (Stage I and some Stage II); adjuvant chemotherapy is recommended for some high risk Stage II and most Stage III colon cancers to prevent or delay recurrence. [24] Chemotherapy usually consists of 6 months of chemotherapy. Regimens usually include a fluoropyrimidine (5FU or capecitabine) with or without oxaliplatin. Rarely, radiation may be added for tumors that penetrate and are fixed to another structure. [24] Both treatment and surveillance are critical in improving outcomes in this high risk population. [8] Following recommended surveillance after the completion of treatment has been shown to decrease mortality from colon cancer, yet adherence to this evidence-based schedule is low. [9, 22, 25, 26] Both the cancer and its treatment can cause permanent body changes (e.g. need for temporary or permanent colostomy) and symptoms that can last for years or be permanent (e.g. peripheral neuropathies, diarrhea or frequent bowel movements), along with other physical and psychosocial sequelae that may also need to be addressed.[27-29]

To monitor for recurrence and for the occurrence of new colon cancers, ASCO guidelines [9] recommend the following: a history and physical exam every 3 to 6 months for the first 3 years and then every 6 months for the next 2 years; carcinoembryonic antigen (CEA) blood test every 3 months for 3 years once chemotherapy is completed; annual chest/abdominal CT scan for the first 3 years and a colonoscopy within the first three years and then every 5 years or as directed by the results. Other cancer screening should occur such as mammography, Pap smear, and possibly PSA. Management of late or long term disease or treatment sequelae and routine health monitoring and screening, immunizations, and health promotion should also be included in survivorship care whether provided by the oncologist, primary care provider, or shared by both. [5, 20, 30-33] Shared care has been demonstrated to provide better care to colon cancer survivors with improved delivery of cancer surveillance and routine health monitoring. [20, 25, 26, 34]

Changing lifestyle behaviors (e.g. smoking cessation, weight loss, and regular physical activity) reduces risk, prevents or delays recurrences, and improves the health and well-being of cancer survivors. [35-37]For the cancer survivor who experiences discomfort due to pain, fatigue, or changes in body composition (e.g. losses in bone and muscle mass, weight gain, temporary or permanent colostomy), increasing physical activity has been found to improve sense of control over one's body. Furthermore, increasing physical activity can reduce psychological distress, including anxiety and depression, and enhance self-esteem in cancer survivors. [38, 39] Despite the importance of these healthy lifestyle behaviors, few cancer survivors report being counseled regarding such behavior change in the year following their diagnosis.[21] Literature suggests that a significant proportion (30-70%) of colon cancer survivors engage in less than optimal levels of physical activity. [18, 35, 40] Yet only 10% of colon cancer survivors identified exercising more as a behavior they would like to change. [40]

Survivorship Care Plans (SCP) Provide A Communication Tool for Providers and Patients. A number of surveys have been conducted asking primary care providers, oncologists, and patients about the use of SCP. While all endorse the concept of a survivorship care plan [41, 42], there is less consensus as to who should prepare and deliver it or when that should be delivered along the cancer continuum. The optimal timing of SCP delivery from survivors or providers' perspective has yet to be determined. In particular, we don't know if it be delivered within the first 6 or 12 weeks after the end of treatment (surgery or chemotherapy) or sometime later during the first 12 months after treatment ends.

Given the discordant views of who should deliver what aspects of care to survivors [30], delivering a copy of the SCP to both the patient and the primary care provider may foster communication with the survivor and oncologist and promote shared care. This is particularly important as the projected growth in cancers survivors and shortage of oncologists will most likely shift care back to the primary care providers. In recent analyses of an online survivorship care plan, most participants reported follow-up care from only their oncologist (53%), 13% from only their primary care provider, and 32% from both; few had received survivorship information. [43, 44]. Evaluating the process of delivering SCP to the survivor and primary care provider is needed.

Quality of Survivorship Care. Quality of cancer care includes evaluation of structure, process, and outcomes. [45] Patient centered outcomes include satisfaction [5, 31, 46] and quality of life indicators [47] and have been positively associated with meeting patients' information needs [48]. Key areas to be evaluated with survivorship care plans are identified in figure 1.

INNOVATION. Implementing and evaluating survivorship care plans in colon cancer survivors will potentially enhance recommended surveillance, screening, management of side effects, and health promotion in this high risk population. Studying survivors who have had surgery alone and those who received surgery and chemotherapy at different time points in the first year may provide insight into the different needs and preferences for SCP content and delivery. Identifying a process for implementation and evaluating the optimum time for implementation will lay the groundwork for further studies on the efficacy of survivorship care plans in this and other populations. This proposal evaluates both the survivor and provider perspective and addresses the objectives outlined in the CDC RFA 10-029 in the colon cancer population in both medical and surgical oncology practices.

Figure 1. Measuring Quality Cancer Care: Survivor Care Plan

Hewitt, M, Simone, J. (1999). Ensuring Quality Cancer Care. Washington, DC: National Academies Press.

APPROACH.

Design: This is a prospective cohort study of colon cancer survivors treated in an academic medical center.

Setting and Rationale for Selection: The N.C. Cancer Hospital, opened in 2009, is the clinical home of the UNC Lineberger Comprehensive Cancer Center, one of 40 institutions designated as a Comprehensive Cancer Center by the National Cancer Institute. There are multi-disciplinary and other clinic spaces, including 101 examination, treatment, consultation, and procedure rooms. The UNC Gastrointestinal (GI) Oncology Program established a Multi-disciplinary approach to diagnosing and treating patients with GI cancer in 1979. The program provides and coordinates the expertise of oncology nurse navigators and nurse practitioners, physicians from medical oncology, surgical oncology, radiation oncology, thoracic surgery, transplant surgery, GI surgery, GI medicine, diagnostic radiology, and surgical pathology. The overall goal of the program is to ensure that patients receive cutting-edge, integrated specialty care for their GI cancer. The program is supportive of this study to implement the SCP in the colon cancer population (see letter of support from Dr. Goldberg).

Since 2004, UNC is one of 5 National Cancer Institute designated Specialized Programs of Research Excellence (SPORE) that focuses on translational research in gastrointestinal system. Members of the UNC GI Tumor Program also are active in the SPORE and consist of 5 surgeons, 4 medical oncologists, 2 radiation oncologists, 2 nurse practitioners, 3 patient navigators, and 2 schedulers. All new patients are booked by one of the 2 schedulers. Dr. Mayer, the PI of this study, is a mentor and champion for the nurse practitioners in the GI program and has an active study within this group. Dr. Davies, a co-investigator, is a medical oncologist within the GI program and will be an internal champion for this project.[49] Both Dr. Mayer and Davies are well-positioned to work with the clinicians to develop and implement SCP.

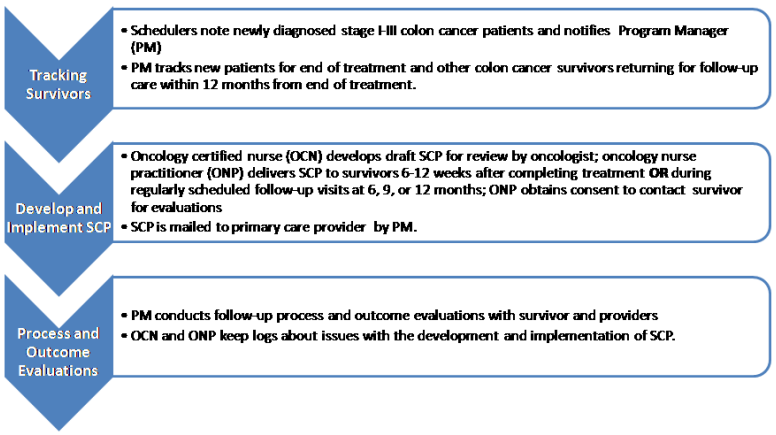
Sample: Based on reviews of weekly clinic schedules in the GI program, approximately 10 Stage I-III colon cancer survivors are seen each week in follow-up within the 12 month window after surgery or surgery and chemotherapy. It is anticipated that approximately 120 care plans (20/month x 8 months; see timeline) could be developed with patients agreeing to participate in the evaluation of the SCP. A minimum of 20% being African American will be recruited; if at least 20% have not been completed with African Americans by the time 96 SCP have been developed, accrual will continue solely in AA until at least 24 have been completed in AA survivors. Eligibility includes being 21 years of age or older, being able to read and speak English, and treated at UNC within the 12 months of treatment ending once IRB approval for the study has been obtained. Stage IV colon cancer survivors are not included in this study as there is no clear endpoint of their treatment and living with advanced cancer requires different clinical care.

Newly diagnosed Stage I-III colon cancer patients will be identified weekly by the schedulers. The Study Program Manager (PM), in consultation with the GI patient navigators, will then follow them online on WebCIS, UNC-CH Hospital's electronic medical record system and maintain a confidential and secure database to track these patients to anticipate the end of their treatment. In addition, to capture other colon cancer survivors within 12 months of treatment ending, the

Table 1. New Colon Cancers Diagnosed at UNC (%)

	2008 % (n= 117)	2009 (n = 77, %) (1st 6 months)
Age (mean, range)	62.2 (26-95)	58.7 (30-87)
Gender		
Female	59 (50.4%)	32 (68.1%)
Male	58 (49.6%)	15 (31.9%)
Race		
Caucasian	77 (65.8%)	36 (76.6%)
AA	33 (28.2%)	11 (23.4%)
Hispanic	4 (3.4%)	0 (0.0%)
Other	3 (2.6%)	0 (0.0%)
Stage		
0	7 (6.0%)	1 (2.1%)
1	17 (14.5%)	12 (25.5%)
2	25 (21.4%)	14 (29.8%)
3	32 (27.3%)	11 (23.4%)
4	35 (29.9%)	14 (18.2%)
Treatment		
Surgery only	52 (44.4%)	24 (51.1%)
Surgery + chemotherapy	51 (43.7%)	18 (38.3%)
Chemotherapy only	8 (6.8%)	2 (4.2%)
No surgery or chemotherapy	6 (5.1%)	3 (6.4%)
Also received radiation	6 (5.1%)	3 (6.4%)

Figure 2. SCP Process



Study Program Manager will review weekly schedules of the GI oncology providers. At least 1 week prior to a scheduled visit, the oncology certified nurse (OCN) will be informed by the Study Program Manager to develop a draft of the SCP for the provider to deliver at that visit. The draft will be reviewed and finalized by the provider scheduled to see the survivor at the next visit. The OCN will keep a log of how long it takes to complete a SCP and any issues that arose in preparing them.

SCP Intervention (content and process)(figure 2): *JourneyForward* is an evidence-based software tool to create Survivor Care Plans in English and Spanish (www.journeyforward.org). We will adapt the colon cancer template to

include the hospital logo and provide local resources. Other information needs identified colon cancer survivors such as life after treatment, nutrition and healthy eating, fitness and exercise, and complementary therapies such as aspirin and calcium supplements will be included (see preliminary data).

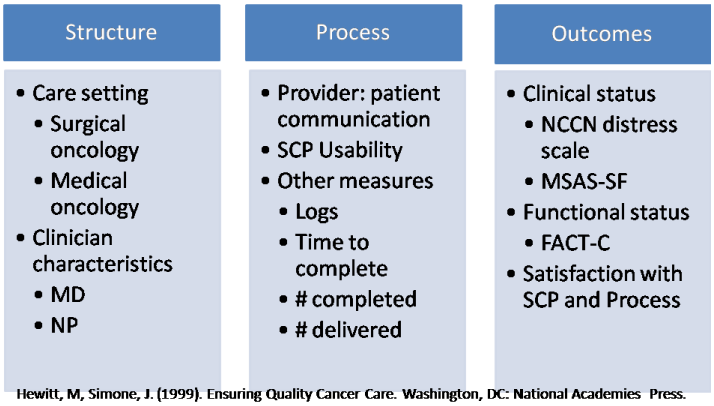
As treatment nears completion, the Study Program Manager will notify the oncology nurse to develop a draft of the survivor's treatment summary and careplan using the *JourneyForward template* which will then be reviewed for accuracy and finalized by the provider scheduled to see the patient at the next scheduled visit. Once it is finalized, it will be given to Surgical or Medical Oncology NP to be reviewed with the patient at a visit scheduled 6-12 weeks after the completion of their treatment (surgery alone or surgery + 6 months of chemotherapy for the majority of patients) or by the oncologist of record on any scheduled return visit for colon cancer survivors from 3-12 months after treatment ends (for those diagnosed prior to the start of the study). In addition, a copy of the SCP will be sent by mail to the primary care provider along with a cover letter and a review article by Ganz on the care of adult cancer survivors [50]. The pdf of the survivor care plan will be uploaded into WebCIS[a] and become a permanent part of the record along with a clinic note documenting the visit referring to the SCP. This visit will be billed for based on length of time using a level four or five evaluation and management code. [3] The ONP will keep a log of the SCP delivered, including length of time to deliver it and any issues that came up regarding the tool or visit.

At the end of the clinical visit, the ONP will ask the patient for permission to contact later for an evaluation of the tool and process. If the patient agrees, the Study Program Manager will be notified. Within 2 weeks of the visit, the Study Program Manager will schedule and conduct a computer assisted telephone interview to collect the measures outlined in table 2. Once completed, the survivor will receive a $20 gift card and a copy of NCI's *Facing Forward: Life After Cancer Treatment.* At three months, the survivor will then be contact to repeat the measures and another $20 gift card will be sent to the survivor.

Being mentored by the Study Program Manager over the course of the project, the GI nurse navigators will work with the schedulers and assume responsibility for developing the SCP draft and working with the oncology nurse practitioners or oncologists to deliver them by the end of the study period.

Variables and their Measurement: Data collection measures are described in Figure 3 and Table 2 and can be found in Appendix A. They will be reviewed and pilot tested by a panel of 3-5 colon survivors and 3 providers before finalizing. Survivors will be interviewed within 2 weeks of the SCP visit and again 3 months later while providers will be interviewed within 2-3 weeks of SCP delivery.

Figure 3. Measuring Quality Cancer Care: Survivor Care Plan



Hewitt, M, Simone, J. (1999). Ensuring Quality Cancer Care. Washington, DC: National Academies Press.

Table 2. Study Measures Description

Structure
Site of care: Surgical or Medical oncology practice at UNC
Care provider: MD or NP
Process
new Stage I-III colon cancer patients # completing treatment # follow-up visits for colon cancer patients 3-12 months from end of treatment # SCP completed/# SCP delivered # Survivors willing to be contacted for evaluation Time completing each SCP Time delivering each SCP Log tracking SCP issues by OCN and ONP
Usability of SCP: A modified System Usability Scale (SUS) [51], a subjective assessment of usability to evaluate the SCP tool from the provider's and survivor's perspective.
Outcomes
NCCN Distress Tool. This measure has one 0-10 rating that measures overall distress and five categories of distress (practical, family, emotional, and physical problems and spiritual/religious concerns) with 35 items (yes/no) experienced over the past week. [52, 53].

[a] Note: while the ability to upload .pdf documents into a patient record does not currently exist within WebCIS, it is expected to be available by 9/10.

Table 2. Study Measures Description

Memorial Symptom Assessment Scale SF (MSAS-SF) is an abbreviated version of the MSAS [54], is a 32-item checklist that measures the frequency, severity, and level of distress of 32 commonly experienced symptoms (28 physical and 4 psychological) with oncology patients. [55] There are three subscales (global distress, physical symptoms, and psychological symptoms); the total score is an average of the scores for all 32 symptoms. All items use a 5-point Likert response (0=absent to 4= present and causes distress). Chang [55] reported Cronbach's alpha coefficients ranging from 0.76 to 0.87 for the subscales, and convergent validity with the FACT-G, performance status, inpatient status, and extent of disease. The instrument takes less than 5 minutes to complete. The time period assessed is over the past week
Functional Assessment of Cancer Therapy-Colon (FACT-C, version 4) is 27-item compilation of general questions in four primary QOL domains: Physical Well-Being, Social/Family Well-Being, Emotional Well-Being, and Functional Well-Being with10 additional items that are colon cancer specific. Acceptable levels of reliability and validity have been established in adults with cancer. [56, 57] Responses are on a five point Likert scale from 'not at all' to 'very much' over the last week.
Satisfaction: A modified adapted version of ARHQ's Consumer Assessment of Healthcare Providers and Systems (CAHPS) Adult Specialty Care Clinician Questionnaire including care received from provider, provider communication, health promotion, education, help with problems or concerns and demographics.

Preliminary Work:
Dr. Deborah Mayer, Principal Investigator, is the Project Leader for an NCI-funded study (P50 CA 095817) 'Interactive cancer communication systems (ICCS) Directed Physical Activity Enhancement for Colon Cancer Survivors' (SurvivorCHESS). This is a randomized controlled trial using a smart phone to increase physical activity, decrease distress, and improve quality of life for 294 colon cancer survivors (stage I-III) in a randomized controlled trial at three National Cancer Institute-designated cancer centers (University of Wisconsin, University of North Carolina at Chapel Hill, and MD Anderson Cancer Center). This intervention incorporates the ASCO recommended surveillance guidelines and care plan recommendations. Stage I-III colon cancer survivors are randomized to SurvivorCHESS versus usual care, The primary aims of the study are to determine whether the SurvivorCHESS intervention survivors demonstrate significantly greater increases in levels of physical activity and improvements in secondary outcomes, such as improved weight status, decreased distress, and improved quality of life. In addition, Dr. Mayer served as a consultant to the South Atlantic Division of the American Cancer Society in the development of a Tool for Cancer Survivors (http://www.southatlantic-cancer.org/survivortool/ACS_Survivor_Tool.pdf). This basic SCP was developed for use by cancer survivors. As a Member of the UNC Comprehensive Cancer Support Program and the Carolina Well, the UNC-Lineberger Cancer Survivorship Program and a member of the LIVSTRONG Survivorship Center of Excellence Network, Dr. Mayer has been involved in implementing SCP within the cancer program and within the breast cancer population and as mentor to the UNC Oncology Nurse Practitioners in delivering survivorship care. The Comprehensive Cancer Support Program team has experience using the *JourneyForward* tool with 34 breast cancer survivors as part of our clinical efforts to implement SCP. Currently it requires adaptation to be able to us it within our electronic health record, WebCIS.

Dr. Janine Davies, co-investigator, is a Medical Oncologist in the Gastrointestinal Tumor Group at UNC. She is actively involved in gastrointestinal cancer and phase I clinical trial research. Additionally, she remains actively involved in a CRC surveillance study at the Tom Baker Cancer Centre in Calgary, Canada. During her medical oncology fellowship in Calgary, she developed and was granted funding for a cohort study to assess CRC surveillance in the Calgary Health Region. The purpose of this cohort study is to assess the impact of the 2005 ASCO CRC surveillance guidelines following treatment of stage II and III CRC before and after the implementation of a computer generated, personalized Discharge Letter. Cohort 1 patients (no intervention) were retrospectively identified from the Alberta Cancer Registry, defined as those that completed adjuvant chemotherapy and/or radiotherapy for stage II and III CRC in a 15 month period prior to implementation of the discharge letter. Prospectively, cohort 2 patients were identified in a similar period; Discharge Letters were sent to those patients that were discharged from the cancer centre at treatment completion. Registry data is collated with clinical, laboratory, and diagnostic imaging data; collection is ongoing. Comparison of adherence rates to recommended surveillance testing between the two cohorts at 1 and 3 years will be reported. To date we have learned that in cohort 1, adherence to CEA testing is suboptimal (38%). Data for the one year follow-up for cohort 2 is anticipated in the summer 2010.

In 2009, a Survivor's Needs Assessment was conducted at UNC; results for colorectal cancer survivors can be found in Appendix A. Of the 24 colorectal survivor respondents, almost half identified understanding treatment follow-up guidelines and instructions for moving from oncologist to primary care physician as unmet needs. Information needs identified by at least half of the respondents will be included in the SCP such as life after treatment (66.7%), nutrition and healthy eating (60.9%), fitness and exercise (58.3%), and complementary therapies (54.2%).

Dissemination Plan: After completion of the pilot study, a workshop to share our experiences will be held at the next annual. As the core center for CPCRN, we will receive support to develop materials and processes leading up to the dissemination of our findings through the CPCRN suite of services supporting investigators in our network, including the annual meeting (see letter of support from Dr. C. Melvin). With the Cancer Prevention and Control Research Network meeting; a representative from each of the 10 participating institutions will be invited to attend the workshop to learn about our experiences and to explore evidence-based approaches (such as reminders, audit and feedback and education [58]) for implementation of the SCP at their institution. Teleconferences will also be held before and after the workshop to work with the group to identify and respond to SCP opportunities within their institutions. We will monitor progress on uptake and use of SCP at each institution, the number of follow-on proposals and publications related to our work and provide updates to the CPCRN at each of its annual meetings and through periodic postings on its website (www.cpcrn.org).

Sample size and power calculations

For this study, we expect to have approximately 120 colon cancer survivors who agree to participate at one of approximately four time points (3, 6, 9 and 12 months) during scheduled surveillance visits after their treatment has ended. We expect to recruit 30 colon cancer survivors at each time point. We present power and sample size considerations for our primary outcome of changes in QOL scores (measured using FACT-C at the beginning and end of 3 month SCP intervention) for these different sets of cancer survivors at 4 points to determine optimum timing to deliver the SCP. Our primary hypothesis is that the SCP delivered as early as at 3 months will have greater improvement in QOL than those who receive it more than three months after treatment ends (at 6, 9, or 12 months).

For the primary hypothesis, we will compare the difference in mean QOL score changes at the end of the SCP intervention between the survivors at 3 months after their treatments and those after 6, 9, and 12 months combined using a simple t-test. We expect the intervention will be more effective for those at 3 months after their treatments compared to the later time periods and expect a mean difference in QOL score change of approximately 7.0 units (standard deviation of change of 11 units) [59] however, we present power calculations for various clinically meaningful differences in mean QOL score changes between these two sets of survivors. [57] Though we expect the QOL score to be higher for the early delivery, we have calculated power conservatively, based on a two-sided test of significance, using the following formula, as follows[60]:

$$Power(1-\beta) = \Phi(Z_{\alpha/2} + |\delta_c - \delta_t|/(\sigma_d\sqrt{1/n_1 + 1/n_2}))$$

where,

- *n1 and n2* are numbers of participants in group 1 and 2
- $\Phi(\cdot)$ is the cumulative density function for the standard normal distribution
- α is the significance level
- $Z_{\alpha/2}$ is the ($\alpha/2$) *x100*-percentile from the standard normal distribution
- σ_d^2 is the variance of the QOL Score change.
- δ_c is the true value of the mean change in QOL Score for the cancer survivors at 3 months.
- δ_t is the corresponding value for the cancer survivors at the other three times combined.

The table below illustrates various power calculations for two-sided tests of significance at α=0.05 and sample sizes of 28 for 3 months and 84 for the three time points combined (after 5% attrition), considering different expected values for the mean differences in QOL Score.

Difference in Mean Changes in QOL Score (δ_c - δ_t)	**Standard Deviation of QOL Score Changes between Baseline and at the End of SCP** σ_d	**Number of Colon Cancer Survivors at 3 months of Their Treatment**	**Number of Colon Cancer Survivors at 6,9, or 12 months of Their Treatment**	**Actual Power** (1-β)
5.0	11	28	84	0.54
5.5	11	28	84	0.62
6.0	11	28	84	0.70
6.5	11	28	84	0.77
7.0	11	28	84	0.82
7.5	11	28	84	0.87
8.0	11	28	84	0.91

We expect attrition to be less than 5% based on our previous experiences and by the interest expressed by colon cancer survivors. Thus, we estimate that having enrolled 120 colon cancer survivors (30 for 3 months and 90 for the three time points after the treatment) provides at least 80% power to detect 7 unit difference in mean QOL scores changes at the end of SCOP intervention between those received SCP intervention at 3 months after treatment and those that received the SCP 6, 9, and 12 months after the treatment together (see shaded row). In addition, we calculated power for the same outcome (change in SQL scores at each time point) to detect various non-zero slopes (expect to be negative) in order to test the hypothesis that the earlier delivery of SCP intervention is better than later delivery (i.e. changes in QOL scores become smaller and smaller with successive time points). The same sample size (30 colon survivors at each time point) provided approximately 80% power to detect a slope of 0.9 unit change in QOL score per month (i.e. 2.7 units between any two time points).

Statistical Analysis

Descriptive statistics will be computed for all variables for each participant. Continuous variables will be summarized using means, standard deviations, medians, minima, and maxima. Categorical variables will be summarized with frequencies and percents. Reliability coefficients will be computed for all scales at each time point. Each data set will now be in a form that will permit us to link them to address the study aims.

Assess usability and acceptability of the survivorship care plan among patients and providers.

Describe the level of distress, unmet needs, and symptom profile, and quality of life of colon cancer survivors at the time of SCP delivery by treatment type (surgery alone or surgery + chemotherapy).

For these outcomes, we will use the same approach as outlined below. We will use Likelihood Ratio and/or Fisher's Exact tests to compare proportions.

To determine the optimum timing to deliver the SCP during the first 12 months from end of treatment at four different time periods after receiving either surgery or surgery + chemotherapy (at 3, 6, 9, or 12 months) on quality of life (QOL).

Hypothesis: Patients who receive the SCP within 3 months after treatment end will have the greatest improvement in QOL scores than survivors who receive it between 3-12 months afterwards.

Compared to the survivors receiving SCP beyond 3 months, we expect that the survivors receiving SCP up to 3 months after treatment ends will have a greater improvement in their QOL Score at follow-up 3 months later. [57] However, we will test our hypothesis using a two-sided t-test with α level of 0.05 under the intent to treat principle and will include data on all survivors initially recruited. Furthermore, we will also estimate slope using linear regression approach to test the linear trend. We may also include a quadratic term in the model to examine the change over time in the quality of life in addition plotting estimated changes in QOL score from 4 time points. Due to small numbers at each time point (n =30), we will not have sufficient power to detect any difference smaller than 8.5 QOL score between any two time points, however, in an exploratory fashion, we will use an overall F test to determine if mean QOL scores changes differed between the survivors received SCP at any two time points and proceed with comparisons of changes at different time points, if the overall F-test is significant at 0.05 probability level.

To explore if the survivors with and without chemotherapy have different QOL scores, we will use multiple regression analysis under the intent-to-treat (ITT) principle as well accounted and unaccounted for the timing of SCP intervention and also may include the interaction term, timing x receiving chemotherapy. Our primary model with main effects is as follows:

$$Changes\ in\ QOL\ Score = \beta_0 + \beta_1 Time + \beta_2 Chemotherapy\ .$$

From this model, we will be able to compare the mean QOL scores changes between those who received chemotherapy and those who did not adjusted for the timing of SCP. Analyses will be conducted using SAS version 9.2.

We will try to minimize attrition and expect less than 5% of participants to be lost to attrition. If attrition exceeds our expectations, for participants who drop out or have incomplete data, we will first examine whether the corresponding data are missing at random (MAR) or non-ignorable missingness. We will then consider imputing data using multiple imputation techniques.

To further explore the effect of the SCP intervention, we will fit multiple regression models that (1) adjust for covariates of interest, considered *a priori* such as age, gender, stage of disease and treatment type that are relevant to QOL Score change [61, 62]; (2) adjust for variables distributed differently among 4 time points and also between those received chemotherapy and those did not; [9] possibly test interaction terms between timing and other covariates; and (4) possibly test interaction terms between chemotherapy and other covariates (moderators).

Timeline

Project Month	1	2	3	4	5	6	7	8	9	10	11	12
Hire program manager	X											
Develop recruitment materials	X											
Obtain IRB approval	X	X										
Pilot test measures		X										
Recruit participants		X	X	X	X	X	X	X	X	X		
Process and Outcome Evaluations			X	X	X	X	X	X	X	X	X	
Prepare data										X	X	
Analyze data											X	X
CPCRN workshop, calls											X	X
Reports/publications												X
Develop proposal to follow patient adherence to recommendations												X

1. Hire program manager (months 1)
2. Develop recruitment materials (months 1)
3. Obtain IRB approval (months 1-2)
4. Review and pilot test measures (month 2)
5. Recruit participants (months 2-10). Once IRB approval has been obtained, we will begin to recruit colon cancer survivors, develop and implement survivor care plans, conduct assessments, and begin data collection.
6. Process and Outcome Evaluations (months 3-11)
7. Prepare data (months 10-11). Submitted study measures data will be examined for completeness and clarity and entered into the study database.
8. Analyze data (months 11-12). Once all the survivors have been recruited, we will begin analyses of each data type.
9. Share with Cancer Prevention and Control Research Network in Workshop at annual meeting (months 11-12). Will develop dissemination materials and hold conference calls with members regarding implementation at CPCRN centers.
10. Reports/publications (months 11-12). The final report will be written in the last 2 months of the project as soon as adequate data are available.

11. Develop research proposal to follow patients' adherence to SCP recommendations, distress and quality of life outcomes (month 12). Begin developing proposal to follow participants' adherence to recommendations.

PROTECTION OF HUMAN SUBJECTS

Eligibility
To be eligible for the study, men and women must, be English-speaking and have stage I-III colon cancer completing treatment at UNC within 12 months prior to the study opening.

Adequacy of Protection against Risks
Recruitment and Informed Consent. After delivering the SCP**, t**he oncology nurse practitioner will explain the study's purpose and seek permission to be contacted by the Study Program Manager. Once received, the PM will contact the survivor, discuss benefits and risks, and ways in which we will protect the individual's privacy and obtain informed consent. Each participant will receive a $20 honorarium and a copy of the National Cancer Institute's 2007 *Facing Forward: Life After Cancer Treatment* for completing the first evaluation process and another $20 gift card after completing the 2nd evaluation at 3 months.

Protection Against Risk. All staff and students involved in our studies sign a confidentiality agreement stating that they are aware that any data they come in contact with is strictly confidential and is not to be discussed outside of the research project. In a study of this type, principal risks include the potential that the confidentiality of subjects' records might be breached. All subjects will be assigned a blind code number. The lists will be kept in a locked file in the PM's office, and will not be shown to any clinic staff. Data collected from participants will have the name removed and the code number attached or entered by the PM. Project staff that has access to the data will have access to a blind code number to all documents rather than the participant's name. Clinic staff with direct contact with the subjects will not have access to the data until the names are removed and the data are labeled with the blind code number.

Data and Hardware Protection. All participant identifying information will be stored in locked file cabinets as paper-based files in the PM's office. The coding system will be kept in a locked cabinet or drawer separate from the actual data and the research team will not have access to it. Any data collected can be directly entered via the tablet pc on a secured, password protected server. The tablet pc screen saver will be password protected. Correspondence that must be faxed will be stripped of survivor identifiers. Before receiving a fax containing sensitive data, the sender must call the receiver to ensure that the receiver is available to pick up the data.

Potential Benefits of the Proposed Research To The Subjects And Others
The colon cancer survivors may benefit substantially from receiving the *JourneyForward* SCP and the opportunity to talk about their experiences. They may also derive a sense of satisfaction by participating in research aimed to improve cancer care for other cancer survivors.[63, 64] Participants will benefit from receiving compensation for completing the interviews ($20 for each of 2 interviews and receive a copy of an NCI Booklet *Facing Forward*.).

Importance of the Knowledge to Be Gained
This study will address implementing survivor care plans to a group of colon cancer survivors. Results of this study will inform optimal timing of SCP delivery in this population. It will provide knowledge about the process to develop and implement SCP, satisfaction of the survivor and health care providers, and measure quality of life changes over time. These findings will be also be used to further study adherence to recommendations made in the SCP regarding surveillance in this population. Lessons learned about implementation of the SCP will be used within other cancer types within UNC. The dissemination of the findings will be targeted to the *Cancer Prevention and Control Research Network (CPCRN)* institutions as well as oncology organizations and advocacy groups interested in survivorship care plans through publications and presentations.

Data and Safety Monitoring Plan
According to NIH, the establishment of a data and safety monitoring board (DSMB) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. The proposed study is not considered a clinical trial, so a DSMB will not be necessary. In accordance with the Health Insurance Portability and Accountability Act (HIPPA), we have adopted the procedures used in the Comprehensive Cancer Support Program in the event a participant is distressed or develops a physical problem warranting medical attention, including referral for psychological counseling and notifying the physician on call.

Training. Prior to gaining access to our data, our students, faculty and staff involved in this study must provide our Data Security Officer with copies of their certificates of completion of Human Subjects online training and online HIPAA Privacy Rule training.

Workstation Policy. All workstations will require login with a unique user name and password. Users will log-out from or lock workstations when leaving them unattended. Screen savers will be configured to require a password to activate after 10 minutes of workstation inactivity. Users will require a password to access any computer containing data for the study.

Policy for Storage, Retrieval, and Disposal of Protected Information. We will take several steps to ensure that subject data are protected.

INCLUSION OF WOMEN AND MINORITIES.
Colon cancer is a disease of adult men and women. The ethnic and racial distribution will be representative of the combined caseloads in the participating institution (see Enrollment Table for details). Every effort will be made to and recruit women and men with diverse racial and ethnic backgrounds. For example, recruitment materials will be developed and reviewed for cultural sensitivity. The GI clinical teams will be alerted to our desire to recruit women and men with diverse racial and ethnic backgrounds. Careful monitoring will occur regarding our minority recruitment. If the planned recruitment reaches 96 without any minorities, only

minorities will be recruited from that point on.

INCLUSION OF CHILDREN
This is a study of colon cancer, which is a disease that primarily affects adults and not a condition usually diagnosed in children. We will, therefore, limit our study to individuals who are 21 and older.

F. Vertebrate Animals
N/A

G. Select Agent Research
N/A

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