Childhood Cancer Survivor Study Analysis Concept Proposal – **Draft 11/19/2010**

Title: Longitudinal changes in health care utilization by survivors of childhood cancer

1. **Working Group Investigators**: This proposed study will be within the Cancer Control Committee. The investigators include:

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2. **Background and Rationale**

The improved survival of children with cancer to almost 80% is one of the major success stories in oncology.[1] Consequently, there are over 328,000 childhood cancer survivors alive in the U.S.[2] This has resulted in an increasing number of adult survivors who require ongoing medical care and surveillance targeted at the chronic health problems that can arise from their cancer treatment (i.e. late effects) as well as ongoing health maintenance.[3] [4] Risk adapted follow-up care is essential for adult survivors of childhood cancer since more than two-thirds will develop a late effect and 25% will develop a severe or life-threatening late effect, such as cardiac or pulmonary disease, or a second malignancy.[5] [6] Since risk for late effects increases as survivors age, an understanding of the factors that influence health care utilization is vital in order to guide the development of interventions that can increase compliance with recommended risk-based care.

Two CCSS publications have examined the medical care reported by adult survivors of childhood cancer. The first presented cross sectional data from the baseline survey.[7] The 9,434 respondents reported on four types of medical care received in the preceding two years. These categories were not mutually exclusive. Eighty-seven percent reported general or non-specific contact with a healthcare provider, 71% reported a general physical examination, 42% reported a cancer-related medical visit, and 19% reported a medical visit to a cancer center. This analysis generated four primary findings: (1) almost 90% of survivors report some contact with the medical system; (2) the likelihood of a general physical examination or a cancer-related medical visit decreases with age and time from diagnosis; (3) less than 20% of survivors are seen regularly in a cancer center; and (4) most survivors do not report care related to their prior cancer. The 2003 survey examined risk-based medical care in greater detail. In the publication arising from this survey, the medical care received by 8,522 survivors over the preceding two years was classified hierarchically into four mutually exclusive categories – 11% reported no medical care, 57% reported general medical care (a medical visit unrelated to their prior cancer), 14% reported general survivor-focused medical care (a medical visit related to their prior cancer) and 18% reported risk-based survivor-focused medical care (a medical visit related to their prior cancer in which screening tests were discussed or ordered or the survivor was counseled on how to reduce his/her specific risks).[8] Consistent with the baseline study, most survivors (89%) reported some contact with the medical system; however, less than one-third reported an encounter related to their prior cancer, and less than one out of five survivors reported a visit in which their health care provider discussed ways to reduce the risks arising from their prior cancer treatment.

The CCSS has not formally examined the changes in healthcare utilization that have occurred longitudinally between the baseline, 2003 and 2007 surveys. Over that period, several factors may have increased compliance with regular cancer-focused medical care. For example, during the period between surveys, there has been a distribution of a biannual newsletter amongst participants in the CCSS.[9] The Children's Oncology Group Survivorship Guidelines were published in 2003 which could also impact on health care utilization for long-term childhood cancer survivors.[10] In addition, since the prevalence of late effects increases as survivors grow older, it is anticipated that the need for medical care focused on detecting or treating these late effects should increase. However, an informal look at data from the two CCSS publications reveals a concerning trend: the frequency of cancer-related medical visits (42% vs. 32%) and of visits to a cancer center (19% vs. 15%) decreased between the baseline and 2003 surveys. In essence, as risk increases, risk-based care appears to decrease. Lastly, during the proposed interval of our longitudinal analysis, Oeffinger and colleagues conducted an intervention study (Project VISION) which tested the feasibility of using a virtual information center to improve mammogram and echocardiographic screening in Hodgkin lymphoma survivors. This group may have improved health care utilization due to the one page treatment summary intervention, however, the sample size for this study was only 69 participants.[11]

In the present analysis, we aim to examine longitudinal changes in cancer-related care utilization patterns since baseline enrollment. We intend to examine the patient- and disease-related factors that are associated with changes in health care patterns over time and identify factors associated with increased or decreased levels of cancer-related care. We are primarily interested in the receipt of "cancer-related care" (defined as a medical visit related to the prior cancer, or one in which the survivor is counseled about how to reduce their risks or has surveillance tests ordered or discussed). We would like to examine: (1) factors that predict an increased utilization cancer-related care (from a lower level, e.g. no health care); and (2) factors that predict a decrease in utilization of cancer-related (no longer receiving cancer-related care as reported at baseline). Although we will assess all predictive factors (i.e. demographic, socio-economic, disease/treatment, co-morbidities, etc), the clinical relevance will come from identifying modifiable predictors of change that we can target for future intervention research.

In summary, the clinical questions to be answered with this analysis are:
(1) What are the factors that predict survivors who received "cancer-related care at baseline and who are no longer receiving this level of care at a later time period (based on 2003, 2007 survey data)?
(2) What are the factors that predict survivors who were not receiving "cancer-related care" at baseline and who are receiving this level of care at a later time period?

3. Specific Aims:

Specific Aim #1: To describe the changes in health care utilization by adult survivors of childhood cancer by comparing the medical care reported at the baseline questionnaire to that reported at follow-up (using 2003 and 2007 survey data) using the definitions of health care utilization described in the two previous CCSS publication on health care utilization.[7 8]
Specifically, we will categorize medical care into one of three mutually exclusive levels.
(1) *No health care*
(2) *General medical care* (one or more visits to a doctor or nurse, none of which were related to their prior cancer)
(3) *Cancer-related care* (defined as a medical visit related to the prior cancer, or one in which the survivor is counseled about how to reduce their risks or has surveillance tests ordered or discussed).

The 4th category, *risk-based survivor focused care*, described in the most recent health care utilization publication by Nathan et al will not be included as it cannot be generated from the data collected in the baseline survey. However, as this publication points out, the hierarchy we are using was "constructed to classify levels of medical care related specifically to the prior cancer and its risks and is not intended to imply a level of quality of care for health issues unrelated to the previous cancer." In addition, "the assigned level of care is independent of who delivered the care (cancer specialist or primary care clinician) or where the care was received (cancer center or community setting)."[8]

We will describe the proportion of survivors who fall within a total of nine combinations of longitudinal care at baseline and at last point of contact (either 2003 or 2007) within 3 categories of change in health care utilization:

Category I = no change in level of health care utilization over time

1. No health care to no health care.
2. General medical care to general medical care.
3. Cancer-related care to cancer-related care.

Category II = increased level of health care utilization over time

4. No health care to general medical care.
5. No health care to cancer-related care.
6. General medical care to cancer-related care.

Category III = decreased level of health care utilization over time

7. General medical care to no health care.
8. Cancer-related care to general medical care.
9. Cancer-related care to no health care.

We will also describe the location of care received for survivors at baseline and at last point in contact (either 2003 or 2007). We will divide the survivors into groups who were seen:

1. At least once at a cancer center (regardless of who else they saw)
2. Seen at a doctor's office (but not a cancer center)
3. Never seen

Specific Aim #2: To determine the predictors of change in those survivors who report a decreased level of health care utilization between the baseline survey and a later time point.

Hypothesis: Socioeconomic variables (age, race/ethnicity, insurance status, income, education, employment status), health status variables, and treatment will be important predictors of having a decreased level of health care utilization between baseline and follow-up. More specifically, we hypothesize that being younger at the follow-up period (18-29 years), being a minority, being uninsured, having a lower income, having a lower educational achievement (< high school), and being unemployed will be predictive of having a decreased level of cancer care. In addition, having a good health status, having no pain, having good emotional health and having a lower chronic disease status burden will also be predictive of having a decreased level of cancer care over time.

Specific Aim #3: To determine the predictors of change in those survivors who report an increased level of health care utilization between the baseline survey and a later time point.

Hypothesis: Socioeconomic variables (age, race/ethnicity, insurance status, income, education, employment status, health status variables, and treatment will be important predictors of having an increased level of cancer care utilization between baseline and of follow-up. More specifically, we hypothesize that being older ($\geq$ 30 years of age), being non-Hispanic white (NHW), being insured, having a higher income, having higher educational achievement (> high school), being employed will be predictive of having an increased level of cancer care. In addition, reporting a poorer health status, having pain, having poor emotional health and *having a higher chronic disease status burden will also be predictive of having an increased level of cancer care.*

4. Methods for each specific aim as outlined below:

Specific Aim #1: We will complete an exploratory, descriptive analysis of the percent of survivors who fall within the 3 different combinations of the 3 major categories of change as described below. We will develop a 3 x 3 table of proportions (based on combinations of responses from baseline and follow-up). The full 9 category grid will be displayed descriptively in a table and will be illustrated in a graph.

Category I = no change in level of health care utilization over time
1. No health care to no health care.
2. General medical care to general medical care.
3. Cancer-related care to cancer-related care.

Category II = increased level of health care utilization over time
4. No health care to general medical care.
5. No health care to cancer-related care.
6. General medical care to cancer-related care.

Category III = decreased level of health care utilization over time
7. General medical care to no health care.
8. Cancer-related care to general medical care.
9. Cancer-related care to no health care.

We will also describe the location of care received for survivors at baseline and at last point in contact (either 2003 or 2007). We will divide the survivors into groups who were seen:
1. At least once at a cancer center (regardless of who else they saw)
2. Seen at a doctor's office (but not a cancer center)
3. Never seen

The data will be displayed descriptively in a table.

Specific Aim #2: To determine the predictors of change in those survivors who report a decreased level of cancer-related care utilization between the baseline survey and follow-up

Subjects included in this analysis: Survivors who received cancer-related care at baseline and have either or both of 2003 and 2007 surveys.

Analysis framework: We will look at whether they are receiving cancer-related care at the most recent follow ups (Yes/No). If the survivor responded to both the 2003 and 2007 questionnaires and their cancer-related care status is discordant between the two follow ups, we will use the 2007 follow up.

Statistical model: We will model the predictors of the change in cancer-related care, among those who were receiving it at baseline but were no longer receiving it at follow-up. Log-binomial models will be used to associate the probability of the change with covariates. Time since diagnosis at baseline will be included as a covariate: this will allow us to characterize change by groups defined by time from diagnosis to baseline (i.e., 10-yr, 15-yr, 20-yr, 25-yr survivors at baseline). In addition, all the covariates hypothesized or targeted due to their clinical relevance/modifiability will be assessed in the modeling.

Result format: We will present relative risk of no longer receiving cancer-related care at follow-up. The relative risk will be modeled by time since diagnosis and other clinically-relevant and/or modifiable characteristics at baseline.

Utility: We will know, among survivors who are receiving cancer-related care, the risk of no longer receiving cancer-related care at the follow-up time point based on the characteristics of the survivors.

Specific Aim #3 To determine the predictors of change in those survivors who report an increased level of cancer-related care utilization between the baseline survey and follow-up.

We will complete the same analysis as 1, but analyze "survivors who were *not* receiving cancer-related care at baseline and report receiving such care at the last point of contact.

Other Statistical Considerations:

1. We will identify those survivors who participated into Project VISION and integrate receipt of the one page treatment summary intervention into the models as this can affect their utilization of care.
2. Inclusion Criteria:
   - All cancer diagnostic groups
   - Complete treatment information from medical record abstraction.
   - Alive at baseline and 2003 or 2007. We have chosen to use either or both the 2003 and 2007 participants as our analysis will be looking at changes from baseline to last point of contact.
3. Exclusion Criteria:

   We will exclude the participants who died between baseline and 2003 or 2007 questionnaire, recognizing that we will need to include in our discussion of the results. We recognize that this analysis will not take into account the most severely affected survivors (those who are deceased) which can impact on the generalizability of our findings. However, we will show this mortality data in flow diagram to provide a clear picture of who is in the sample. Death rates are 1% per year and this is steady rate, i.e. a large number of survivors will not die at all once.

   Data on the deceased reviewed for this concept proposal are (data from Yutaka Yasui): At baseline, there were 6,941 users of cancer care & 6,571 nonusers (definitions based on Oeffinger et al paper).[7]

   Of the 6,941 baseline users, we have:

2258	32.5% non-users at FU2 (i.e. 2003)
1862	26.8% users at FU2
1318	19.0% died before FU2
1503	21.7% LTFU/Refused/missing cancer-care answer

Of the 6,571 baseline non-users, we have:

3532	53.8% non-users at FU2
922	14.0% users at FU2
292	4.4% died before FU2
1825	27.8% LTFU/Refused/missing cancer-care answer

Comment [mmh1]: Other survivor may have a treatment summary, so I assume that this will be considered for all in the model?

Sample Table 1: Demographic, diagnosis and treatment variables:

	Total n (%)	Baseline Questionnaire n (%)	2003 or 2007 Questionnaire n (%)	p-value
Age				
At time of questionnaire				
Age at diagnosis (mean)				
Gender				
Male				
Female				
Race/Ethnicity				
Non-Hispanic White (NHW)				
Black				
Hispanic				
Asian				
Other				
Health Insurance status				
No, U.S.				
Yes, U.S.				
Private				
Public				
Canadian resident				
Annual household income				
< $40,000				
$40-79,000				
$80,000 or greater				
Education				
< high school				
High school				
College graduate				
Employment status				
Employed or caring for home				
Looking for work or unable to work				
Student				
Cancer diagnosis				
Leukemia				
CNS tumor				
Hodgkin lymphoma				
Non-Hodgkin lymphoma				
Wilms tumor				
Neuroblastoma				
Sarcoma				
Bone tumor				
Treatment variables				
Radiation therapy				
Brain				
Chest				
Not brain, not chest				
None				
RT status not known				
Cardiotoxic therapies				
Anthracyclines, no chest RT				
Chest RT, no anthracyclines				
Anthracyclines + chest RT				
No anthracyclines, no chest RT				
Alkylating agent dose				
None				
1st tertile				
2nd tertile				
3rd tertile				

Sample Table 2: Descriptive Statistics of Cancer-Related Care Utilization Changes between Baseline and last follow-up (either 2003, 2007 data):

Health Care Utilization Change	n (%)
Category I = no change in level of health care utilization over time	
No health care to no health care	
General medical care to general medical care	
Cancer-related care to cancer-related care	
Category II = increased level of health care utilization over time	
No health care to general medical care.	
No health care to cancer-related care.	
General medical care to cancer-related care.	
Category III = decreased level of health care utilization over time	
General medical care to no health care.	
Cancer-related care to general medical care.	
Cancer-related care to no health care	

Sample Table 3: Location of Care

	Baseline (Question B2)	**Follow-Up (2003 – Question A2; 2007 - Question B2**
Cancer Center		
Doctor's office, not Cancer Center		
None of the above, not seen		

Table 4: Examples of predictor variables which will be used in the regression analysis for having an increased level of cancer-related care or for having a decreased level of cancer-related care utilization. In the analysis, we will evaluate the effect of the predictor variables as they change from Baseline to the last time point of follow-up using 2003 or 2007 data:

	Baseline	**2003 Questionnaire**	**2007 Questionnaire**
Overall Health Status	**N15** Would you say your health is: - Excellent - Very good - Good - Fair - Poor	**E1** My health is excellent: - Definitely true - Mostly true - Don't know - Mostly false - Definitely false	**L19** In general, would you say your health is: - Excellent - Very good - Good - Fair - Poor
Concern for future health	**J37** Do you currently have anxieties/fears as a result of your cancer, leukemia, tumor or similar illness, or its treatment? - No anxiety/fears - Small amount of anxiety/fears - Medium amount of anxiety/fears - A lot of anxiety/fears - Very many, extreme anxiety/fears **R1** How concerned are you about: Your future health - Very concerned - Somewhat concerned - Concerned - Not very concerned - Not at all concerned	**G20** Do you currently have anxieties/fears as a result of your cancer, leukemia, tumor or similar illness, or its treatment? - No anxiety/fears - Small amount of anxiety/fears - Medium amount of anxiety/fears - A lot of anxiety/fears - Very many, extreme anxiety/fears **F13** I expect my health to get worse: - Definitely true - Mostly true - Don't know - Mostly false - Definitely false	**L20** Do you currently have anxieties/fears as a result of your cancer, leukemia, tumor or similar illness or its treatment? - No anxiety/fears - Small amount of anxiety/fears - Medium amount of anxiety/fears - A lot of anxiety/fears - Very many, extreme anxiety/fears **01** Please rate how concerned you are about the following: Your future health - Very concerned - Somewhat concerned - Concerned - Not very concerned - Not at all concerned
Physical health – **Change in SF-12 summary score from baseline to FU(?) will be quantified.** We will examine means, SD, and standard errors of measurement (SEM). We will use 1.96 SEMs to determine 3 groups: (1) Improved group = Those who improved on their scores; (2) Decline group = Those who declined on their score; (3) No change group = Those with no change in their scores.[12]	**N14** (SF12) Over the last 2 years, how long (if at all) has your health limited you in each of the following activities - Not limited at all - Limited for 3 months or less - Limited for more than 3 months a. The kinds or amounts of vigorous activities you can do, like lifting heavy objects, running or participating in strenuous sports b. The kinds or amounts of moderate activities you can do, like moving a table, carrying groceries or	**G series** Does your physical health now limit you in these activities? If so, how much? - No, not limited - Yes limited a little - Yes limited a lot **G3** Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports **G4** Moderate activities, such as, moving a table, pushing a vacuum cleaner, bowling, or playing golf **G5-12**	**N26** Over the last 2 years, how long (if at all) has your health limited you in each of the following activities? - Not limited at all - Limited for 3 mos or < - Limited for > 3 mos a. The kinds or amounts of vigorous activities you can do, like lifting heavy objects, running or participating in strenuous sports b. The kinds or amounts of moderate activities you can do, like moving a table, carrying groceries or bowling c. Walking uphill or climbing a few flights

	bowling c. Walking uphill or climbing a few flights of stairs d. Bending lifting or stooping e. Walking one block f. Eating, dressing, bathing or using the toilet	Lifting or carrying groceries Climbing several flights of stairs Climbing one flight of stairs Bending, kneeling or stooping Walking more than one mile Walking several blocks Walking one block Bathing or dressing yourself	of stairs d. Bending, lifting, or stooping e. Walking one block f. Eating, dressing, bathing, or using the toilet
Pain	**J36** Do you currently have pain as a result of your cancer, leukemia, tumor or similar illness or its treatment? - No pain - Small amount of pain - Medium amount of pain - A lot of pain - Very bad or excruciating pain ***No general bodily pain question***	**G19** Do you currently have pain as a result of your cancer or similar illness, or its treatment? - No pain - Small amount of pain - Medium amount of pain - A lot of pain - Very bad, excruciating pain Bodily pain = **E21**	**L21** How much bodily pain have you had during the past 4 weeks? - None - Very mild - Mild - Moderate - Severe - Very severe
Emotional health	**J16-J35** BSI-18 Note: Scoring – Presents raw and normalized T scores for each of the three Primary Symptom Dimensions and the Global Severity Index. The plotted T scores are based on your choice of the community or oncology norms	**G1-18** BSI-18 Note: Scoring – Presents raw and normalized T scores for each of the three Primary Symptom Dimensions and the Global Severity Index. The plotted T scores are based on your choice of the community or oncology norms	**L1-18**
Chronic disease status from **baseline** self-report questionnaire data (per Oeffinger's NEJM paper)[2] Grade 0- 2 vs. Grades 3-4 Define Grades 3-4 as: Having at least one grade 3(severe) or grade 4 (life-threatening or disabling) chronic condition			

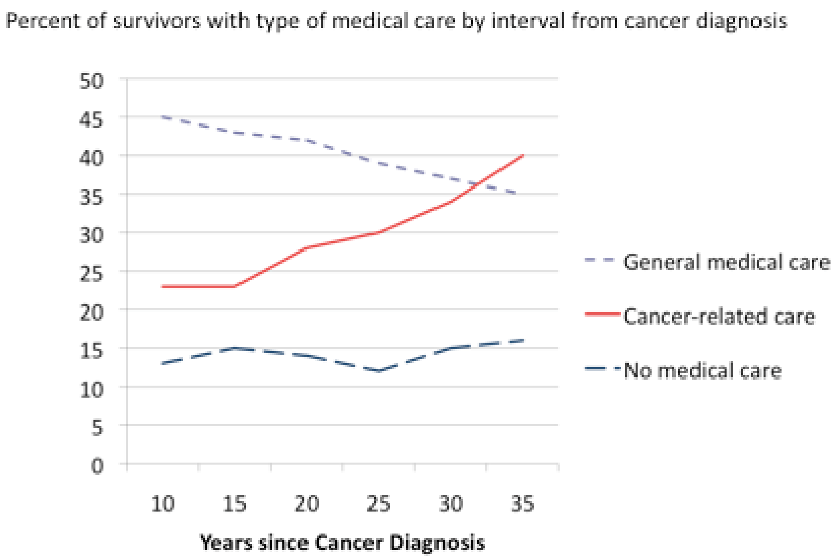
Sample table 5 – Regression analyses:

Predictor Variables	Relative odds of receiving higher level of care from Baseline to last follow-up (using 2003, 2007 data)	Relative odds of receiving a lower level of care from Baseline to last follow-up (using 2003, 2007 data)
Age At time of questionnaire		
Age at diagnosis (mean)		
Gender Male Female		
Race/Ethnicity Non-Hispanic White (NHW) Black Hispanic Asian Other		
Health Insurance Status – Current vs. previous (in the baseline questionnaire may have had insurance with parents) No, U.S. Yes, U.S. Private Public (Medicaid/Medicare) None Canadian resident		
Current Annual household income < $40,000 $40-79,000 $ 80,000 or greater		
Current Education < High school High school College graduate		
Employment status Employed or caring for home Looking for work or unable to work Student		
Overall Health Status		
Concern for future health		
Physical health		
Pain		
Emotional health		
Chronic disease status		
Mortality		

Sample table 6 - Regression analyses:

	Relative odds of receiving higher level of care from Baseline to last follow-up (using 2003, 2007 data)	Relative odds of receiving lower level of care from Baseline to last follow-up (using 2003, 2007 data)
Radiation therapy		
Brain		
Chest		
Not brain, not chest		
None		
RT status not known		
Cardiotoxic therapies		
Anthracyclines, no chest RT		
Chest RT, no anthracyclines		
Anthracyclines + chest RT		
No anthracyclines, no chest RT		
Alkylating agent dose		
None		
1st tertile		
2nd tertile		
3rd tertile		

Sample Figure 1:



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