

## Childhood Cancer Survivor Study Concept Study Proposal

**1. STUDY TITLE:** Predictors of receipt of a treatment summary, its relationship to receipt of risk-based health care, and health status.

### 2. WORKING GROUP AND INVESTIGATORS:

2.1 Working groups: Cancer Control

2.2 Investigators:

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### 3. BACKGROUND AND RATIONALE:

In the 2003 and 2006 Institute of Medicine (IOM) reports on cancer survivors, recommendations were delineated regarding the long-term follow up care of all cancer survivors.<sup>1,2</sup> The IOM specified that survivors need lifelong risk-based health care which integrates the cancer and survivorship experience with the overall health needs of the individual. The cornerstone of these recommendations is to provide patients with a survivorship care plan (SCP) written by their cancer treatment team. An SCP is intended to assist survivors and their health care providers with a roadmap for post-treatment coordination of care. The key SCP elements include a cancer treatment summary, information on possible late effects, identification of providers, and guidelines for follow-up care. Importantly, the IOM reports emphasize that having an SCP is an essential quality indicator of survivorship care.<sup>1-3</sup>

The incidence and severity of many late effects can be substantially reduced through prevention and early detection.<sup>25</sup> Recognizing that potential cancer-related health complications are associated with decreased quality of life and excess early mortality, it is imperative that survivors receive risk-based, lifelong care dedicated to the screening, prevention, and treatment of late effects. Seventy percent of adult survivors of childhood cancer have a chronic health condition, and by age 50 years, the cumulative incidence of a severe or life-threatening condition is 46% as compared to an incidence of 14% in siblings.<sup>1,2</sup> A recent CCSS study reported that only 28% of survivors of childhood and adolescent and young adult (AYA) cancer at risk for cardiomyopathy

received an echocardiogram in the preceding two years.<sup>17</sup> Likewise, Oeffinger and Ford, et al reported that only 36.5% of survivors at risk for breast cancer (BC) had a mammogram in the preceding 2 years.<sup>22</sup> In a Canadian study of HL survivors diagnosed on average at 35 years of age, only 12.9% of women exposed to chest RT had undergone BC surveillance in years 2 through 15 after their HL diagnosis.<sup>23</sup> Despite the high and increasing rates of adverse health conditions with age, less than 20% of adult survivors in the CCSS report having received risk-based, survivor-focused care and only 15% report having a treatment summary.<sup>17,21</sup>

Importantly, our preliminary work has demonstrated that having an SCP does lead survivors to obtain appropriate risk-based surveillance. In one of our pilot studies, we provided high-risk survivors with an SCP and found that among those who were previously non-adherent with recommended surveillance, 41% reported having a mammogram, and 20% reported having an echocardiogram within the subsequent 6 months.<sup>24</sup> However, this data was gathered in a relatively small cohort of survivors. The CCSS has data on treatment summaries for a very large group of childhood cancer survivors. In the 2003 CCSS questionnaire, participants were asked about whether they had received a treatment summary (not an SCP). While the SCP is considered the “gold standard” of care for survivors, a treatment summary would be, at a minimum, important for both survivors and their healthcare providers to have for their records and to inform their long-term health care. However, little is known about the predictors of receipt of a treatment summary among childhood cancer survivors and whether having a treatment summary is related to meaningful and important clinical outcomes in a large cohort (i.e., risk-based care and/or late effects and health status).

#### **4. SPECIFIC AIMS / HYPOTHESES:**

##### **4.1 AIMS**

1. To identify predictors of receipt of a treatment summary among survivors in the CCSS
2. To identify predictors of report of primary care doctor having a treatment summary and/or copies of medical records from cancer treatment center.
3. To determine if sharing treatment summary with primary care health care provider is associated with higher rates of risk-based health care.
4. To determine if receipt of a treatment summary and/or sharing it with primary health care provider is associated with better current and future health status.

Exploratory aim: To examine the concordance between reporting of receipt of treatment summary between CCSS participants on the 2003 survey, mammogram practices survey and health care needs survey.

##### **4.2 HYPOTHESES**

4.2.1. There will be multiple sociodemographic and medical characteristics associated with receipt of a treatment summary including, gender, primary diagnosis, location of care, education, and age at diagnosis.

4.2.2 There will be multiple sociodemographic and medical characteristics associated with primary care doctor having a copy of treatment summary and/or cancer-related medical records, including gender, primary diagnosis, location of care, education and age at diagnosis.

4.2.3. Receipt of a treatment summary will be positively associated with more recent visit to a cancer center, visit to a primary health care provider, greater risk-based health care (e.g., compliance with high risk surveillance (mammogram if radiated, echo if anthracyclines/chest rads, colonoscopy if abdominal rads, DEXA if steroids/MTX, skin exam if radiated), and greater standard risk screening (e.g., mammogram at 40/50; FOB/colonoscopy, PAP)

4.2.4. Receipt of a treatment summary will be positively related to more positive current and future health status (ie, health status on 2007 CCSS questionnaire).

## **5. DATA ANALYSIS** (*Analyses will be conducted by Chaya Moskowitz, PhD at Memorial Sloan-Kettering Cancer Center*):

Study population: All CCSS participants who completed the treatment summary questions (A9 and A10) as reported on the 2003 CCSS questionnaire.

Outcome of Interest: *Receipt of a treatment summary* will be defined by responses to the following questions on the 2003 follow-up questionnaire:

- A9 (Does survivor have a treatment summary or copies of medical records summarizing childhood cancer treatment)
- A10 (Does local/primary care doctor have a treatment summary or medical records summarizing childhood cancer treatment)

### Independent (exploratory variables):

#### A. Disease/treatment variables:

- Cancer diagnosis
- SMN (yes/no) prior to 2003 follow-up questionnaire
- Age at diagnosis
- Chemotherapy versus surgery versus radiation versus SCT versus combination
- Cranial RT
- Chest RT
- Abdominal/pelvic RT
- Treatment era
- Cyclophosphamide equivalent dose
- Anthracycline doxorubicin-equivalent dose

#### B. Sociodemographic variables

- Age at interview (from date of completion of 2003 follow up questionnaire and birth date)
- Gender (Baseline A2)
- Race/ethnicity (Baseline A4, A4a)

- Age at diagnosis
  - Highest level of education (FU 2003 Question1)
  - Household income
  - Marital status (FU 2003 Q2)
  - Employment Status (FU 2003 Q4)
  - Current health insurance coverage FU2003 M1)
- C. Health Status (all asked about in the past 7 days or “current”) from FU 2003 and 2007
- Current smoker (FU 2003 L2; FU 2007 N9)
  - Perceived general health (FU 2003, E1; FU 2007 L19)
  - Mental health (BSI-18; FU 2003, G questions generate global score and depression, anxiety and somatization subdomains; FU 2007 L1-L18) (assessed in past 7 days)
  - Physical impairment/activity limitations (FU 2003 E3-12; FU 2007 N26a-f physical function section of SF-36)
  - Pain as a result of previous cancer (FU 2003 G21; FU 2007 L21)
  - Anxiety as a result of previous cancer (FU 2003 G20; FU 2007 L20)
  - Concern about future health (FU 2003 F13; FU 2007 O1)
  - IES scores and PTSD (from IES + BSI and/or impairment on SF36) (FU 2003 section K) -if available these (only available for subset of subjects who responded to the “long version FU2003”)
- D. Health Care Utilization (2007 Follow-up questionnaire)
- Seen by a physician or nurse in the last 2 years (B1)
  - Location of care (B2)
  - Number of times seen physician (B3)
  - Visit related to prior cancer (B4)
  - Issues discussed during visit (B5)
  - Most recent routine checkup (B6)
  - What recommended at visit (B7)
  - When next visit with Dr (B8)
  - Last time pt had Echocardiogram (C1)
  - Last time pt had DEXA (C2)
  - Last time pt had blood stool test (C3)
  - Last time pt had sigmoidoscopy/colonoscopy (C4)
  - Last time pt had mammogram (C5)
  - Last time pt had breast MRI (C6)
  - Last time pt had pap smear (C7)

### Data Analysis Plan

Aims 1, 2: The proportion of survivors who reported having a treatment summary or a copy of their cancer treatment medical records as reported on the 2003 follow-up will be estimated together with 95% confidence intervals. The proportion of survivors who report their primary care doctor received a treatment summary or a copy of their cancer treatment medical records as

reported on the 2003 follow-up will also be estimated together with 95% confidence intervals. Generalized linear regression models will be used to assess both univariate and multivariate associations between receipt of a treatment summary (separately for both survivors and the primary care physicians) and sex, age at primary diagnosis, race/ethnicity, primary diagnosis, primary cancer treatments, location of care, will be determined. Time varying variables, such as income, education, insurance status, etc. cannot be used to predict receipt of treatment summary since date of receipt of treatment summary is unknown.

Aim 3. The proportion of survivors who report having a treatment summary or a copy of their cancer treatment medical records as reported in the 2003 follow-up will be associated with the following risk-based care outcomes reported on the 2007 questionnaire: a more recent visit to a cancer center, visit to a PCP, greater risk-based health care (e.g., compliance with high risk surveillance (mammogram if radiated, echo if anthracyclines/chest rads, colonoscopy if abdominal rads, DEXA if steroids/MTX, skin exam if radiated – as defined in Nathan, et al 2008<sup>17</sup>), and greater standard risk screening (e.g., mammogram at 40/50; FOB/colonoscopy, Pap). Generalized linear regression models will be used to assess both univariate and multivariate associations between receipt of a treatment summary and risk-based care (as reported after the 2003 follow-up questionnaire). Risk-based care reported prior to 2003 cannot be used as date of receipt of treatment summary is unknown. Surveillance will be assessed and examined among high-risk groups (risk-based care), for example, mammography and/or breast MRI among women who received chest RT.

Aim 4. Receipt of a treatment summary, as reported in the 2003 follow-up will be positively related to higher health (and mental health) status (ie, lower anxiety, pain, etc). We will examine whether having a treatment summary is associated with better health status (in 2003) and/or future health status (2007) using separate generalized linear models for each health status measurement.

Tables

**A. Table 1. Demographic and medical characteristics as of 2003 questionnaire**

<b>Age group at time of questionnaire (Mean=x)</b>	N	%
18-24 years 25-34 years 35+ years		
<b>Gender</b> Female Male		
<b>Race/Ethnicity</b> White Native American Asian Black Hispanic Other		
<b>Highest level of education</b> <HS Completed high school/GED Training after high school, other than college / some college College graduate / Post graduate level		
<b>Household Income</b> ≤\$20,000 >\$20,000		
<b>Current health insurance</b> Yes (or Canadian) No		
<b>Employment Status</b> Working (full-time or part-time) Unemployed and looking for work Unable to work due to illness or disability Retired / Caring for home or family (not seeking paid work)/ Student		
<b>Marital Status</b> Married/ Living as married Single Widowed / Divorced / Separated		
<b>Age at diagnosis</b> 0-4 years 5-9 years 10-14 years 15-19 years		
<b>Treatment era</b> 1970 – 1979 1980 – 1986		

<p><b>Primary cancer diagnosis</b>  Leukemia  CNS  Hodgkin disease  Non-Hodgkin lymphoma  Wilms' tumor  Neuroblastoma  Bone tumor  Sarcoma</p>		
<p><b>Second cancer or recurrence</b>  Yes  No</p> <p><b>Treatment exposures</b>  Chemotherapy  Surgery  Radiation  Cranial RT  Chest RT  Abdominal/pelvic RT  SCT  Chemotherapy+Surgery  Chemotherapy+Radiation  Chemotherapy+Surgery+Radiation</p>		
<p>Cyclophosphamide equivalent dose</p> <p>Anthracycline doxorubicin-equivalent dose</p> <p><b>Cranial radiation therapy</b>  No  &lt;20 Gy  ≥20 Gy</p>		

**Table B. Health Status (2003 and 2007 questionnaires)**

<p><b>Current smoker</b>          Yes          No</p> <p><b>Physical impairment/activity limitations (E3-12; physical function section of SF-36)</b></p> <p><b>Concern about future health (F13)</b></p> <p><b>Health status (perceived general health)</b>          Excellent/good/very good          Fair/poor</p> <p><b>Health status (mental health)</b>          Normal          Abnormal (lowest quartile on BSI)</p> <p>Depression (above clinical cutoff scores)          Somatization (above clinical cutoff scores)          Anxiety (above clinical cutoff scores)</p> <p><b>Health status (physical impairment/activity limitation)</b>          Yes          No (lowest quartile on SF-36 physical fn)</p> <p><b>Health status (pain as a result of previous cancer)</b>          Yes          No</p> <p><b>Health status (anxiety as a result of previous cancer)</b>          Yes          No</p> <p><b>IES scores (section K, p. 12, 2003 f/u questionnaire)</b></p> <p><b>PTSD diagnosis (from IES + BSI or SF36 impairment question)</b>          Yes          No</p>		
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**C. Table 3. Health care utilization 2007 questionnaires**

	<b>N</b>	<b>%</b>
<p><b>Visit to Dr in past 2 years</b>          Yes          No</p> <p><b>Health care providers seen for medical care (over 2 yr period)</b>          Physician          Nurse          Other (chiropractor, physical therapist, other)</p>		



<p><b>Location of health care</b></p> <ul style="list-style-type: none"> <li>Doctor's office</li> <li>Oncology (cancer) center or clinic</li> <li>Other type of clinic</li> <li>Hospital</li> <li>Emergency room or urgent care center</li> <li>Long-term follow-up clinic</li> <li>Other</li> </ul>		
<p><b>Number of times see physician over 2 yr period</b></p> <ul style="list-style-type: none"> <li>None</li> <li>1-2 times</li> <li>3-4 times</li> <li>5-6 times</li> <li>7-10 times</li> <li>11-20 times</li> <li>More than 20 times</li> </ul>		
<p><b>How many of these visits were related to previous cancer</b></p> <ul style="list-style-type: none"> <li>None</li> <li>1-2 times</li> <li>3-4 times</li> <li>5-6 times</li> <li>7-10 times</li> <li>11-20 times</li> <li>More than 20 times</li> </ul>		
<p><b>Did you discuss any of the following issues with your physician or primary health care provider during any of these visits?</b></p> <ul style="list-style-type: none"> <li>None</li> <li>Heart disease</li> <li>Osteoporosis (weak or brittle bones)</li> <li>Risk of developing cancer (breast, skin, other) Hep C</li> <li>Dental problems</li> <li>Fertility issues</li> <li>Mental health</li> <li>Other cancer-related issues</li> </ul>		
<p><b>At check up did doctor</b></p> <ul style="list-style-type: none"> <li>Give you advice about what to do to reduce risks</li> <li>Discuss or order medical screening tests</li> <li>Suggest you see a cancer specialist</li> <li>Suggest you see another type of medical subspecialist(s)</li> <li>Tell you that you had nothing to worry about based on findings at the check-up</li> </ul>		
<p><b>When was your MOST RECENT routine check-up where a doctor examined you and did tests to see if you had any health problems from your cancer or your cancer treatment?</b></p> <ul style="list-style-type: none"> <li>Less than 1 year ago</li> <li>1-2 years ago</li> <li>More than 2 years but less than 5 years ago</li> <li>5 or more years ago</li> <li>Never</li> </ul>		
<p><b>When do you plan to have your NEXT visit with a doctor in order to examine you for any health problems from your cancer or your cancer treatment?</b></p> <ul style="list-style-type: none"> <li>Less than 1 year from now</li> <li>1-2 years from now</li> </ul>		

<p>3-4 years from now 5 or more years from now Never</p>		
<p><b>When was the last time pt had.</b> An echocardiogram (ultrasound of the heart to look at the heart muscle and heart valves)? Never Less than 1 year ago 1-2 years ago More than 2 years but less than 5 years ago 5 or more years ago Don't know</p>		
<p><b>A blood stool test</b> Never Less than 1 year ago 1-2 years ago More than 2 years but less than 5 years ago 5 or more years ago Don't know</p>		
<p><b>A sigmoidoscopy or colonoscopy (a procedure to view your entire colon)?</b> Never Less than 1 year ago 1-2 years ago More than 2 years but less than 5 years ago 5 or more years ago Don't know</p>		
<p><b>A test to measure your bone strength or bone mineral density (such as a DEXA, quantitative CT scan, or ultrasound)?</b> Never Less than 1 year ago 1-2 years ago More than 2 years but less than 5 years ago 5 or more years ago Don't know</p>		
<p><b>A pap smear (test for cancer of the cervix)?</b> Never Less than 1 year ago 1-2 years ago More than 2 years but less than 5 years ago 5 or more years ago Don't know</p> <p><b>When was the last time you had a mammogram?</b> Never Less than 1 year ago 1-2 years ago More than 2 years but less than 5 years ago 5 or more years ago Don't know</p>		

<b>When was the last time pt had breast MRI?</b> Never Less than 1 year ago 1-2 years ago More than 2 years but less than 5 years ago 5 or more years ago Don't know		
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#### D. Table 4. Descriptives of Outcomes

##### *Receipt of a treatment summary*

	N	%
Does survivor have a treatment summary or copies of medical records summarizing cancer treatment? (A9) Yes No		
Does local/primary care doctor have a treatment summary or medical records summarizing childhood cancer treatment (A10) Yes No		

#### E. Tables of univariate and multivariate associations

Univariate associations between receipt of a treatment summary (for both survivors and the primary care physicians) and sex, age at primary diagnosis, race/ethnicity, primary diagnosis, primary cancer treatments, SES, health status and medical care will be determined.

Multivariable logistic regression models will be developed to determine factors associated with survivor and/or physician receipt of a cancer treatment summary.

The impact of potential predictors of receipt of a treatment summary will be examined between these two groups in separate multivariate logistic regression models, adjusting for current age, sex, and race/ethnicity as well as any other *a priori variables*.

**Exploratory aim:** We will examine the concordance between reporting of receipt of treatment summary between CCSS participants on the 2003 survey, mammogram practices survey and health care needs survey.

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