

CHILDHOOD CANCER SURVIVOR STUDY

Analysis Concept Proposal – 12/14/01

1. Title: Health Concerns in Survivors of Childhood Cancer

2. Working Group and Investigators: This proposed publication will be within the Epidemiology/Biostatistics Working Group. Proposed investigators (name/e-mail/fax) will include:

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3. Background and Rationale: Significance of the Research:

Childhood cancer and its subsequent treatment predispose survivors of childhood cancer to a higher risk of certain life-threatening and debilitating diseases than most individuals. It is important for long-term survivors to be knowledgeable about their illness, their treatment, and the consequent need for health surveillance and maintenance practices to optimize their future health. Therefore, they must be made aware of these health issues for which they are at a greater than normal risk.

Of interest in determining education strategies, is to know when and how to approach individuals on health issues that may be of concern to them specifically. Previous work suggests that individuals differ in the extent to which they want information about medical treatment. Often brochures or information given to the individual are designed for 'after care' treatment, and may be received at a time when they are not interested in specific issues, such as fertility. In addition, individuals treated at younger ages will need to be informed of possible treatment

consequences once they get older. Therefore it would be important to identify subgroups by clinical and demographic variables to determine how they might respond to information about their future health.

CCSS provides a unique opportunity to study high-risk adults who have already been identified in a larger group of childhood cancer survivors. Available demographic and treatment information on the CCSS cohort will enable us to identify groups of survivors with similar high-risk profile types and health intervention needs. The future development of optimal education and intervention strategies in this study group may benefit the 200,000 individuals who are now childhood cancer survivors, as well as those children diagnosed in the future.

4. Specific Aims/Objectives/Research Hypotheses: This proposal will look at general questions which rates how concerned CCSS participants are regarding issues about their future and their health. This proposal is designed to investigate whether there is an appropriate age or time in the life of a childhood cancer survivor in which they will be concerned and open to information about the possible long-term effects of cancer and its associated therapies.

We have two objectives: (1) to identify and describe those cases who express more concerns about their future and their health according to clinical and demographic characteristics (clinical and demographic), and (2) to compare these concerns with those of siblings.

Hypothesis:

I. Concerns about future health and other health issues will be highest in the age group of 25-29, when survivors are at a stage in their life to take on adult roles and responsibilities, such as parenting and long-term employment. Associated concerns will be highest in survivors who are female, are married, and are interested having in (or already have) children.

ii. Concerns will also be higher in certain diagnosis groups, such as Hodgkin's Disease (due to treatment complications), and Wilms tumor (for genetic reasons).

iii. Concerns about future health and other health issues will be higher in survivors than in siblings.

5. Analysis Framework:

a. Outcome of interest: responses on Section R of baseline questionnaire (R.1-R.6). Question R.6 is an open ended questions regarding 'any other issues'. This question will be evaluated, and depending on responses, will be grouped into other issues described.

b. Subject population: all CCSS participants. Cases who were 18 or older at the time of baseline completion will be analyzed separately from those < 18 where there was a proxy respondents .

c. Explanatory variables: sex, race, income, education, current marital status (L.2), ever tried to become pregnant (M.5), occurrence of second cancer (K.1-K.6), age at diagnosis (0-4, 5-9, 10-14, 15+), age at follow-up (5-9,10-14, 15-18), time since diagnosis, diagnosis type, type of treatment (see categories below), radiation site, dose of radiation, specific chemotherapeutic agents that have been implicated in gonadal dysfunction, subsequent malignancies.

Possible risk factor variables that will also need to be taken into consideration are: history of smoking (N.1), physical activity (N.9), limitations to activities (to determine difficulty with exercise) (N.14).

d. Specific tables:

1) Characteristics of all CCSS participants by 5-scale levels of concern by specific questions in section R. Characteristics will include:

- sex
- age at diagnosis (0-4, 5-9, 10-14, 15+)
- mean age at follow-up (standard deviation)
- mean time since diagnosis (standard deviation)
- diagnosis type
- race (white, black, Hispanic, Am Indian, Asian, other)
- type of treatment

- chemotherapy only
- radiation only
- surgery only
- chemotherapy+surgery
- chemotherapy+radiation
- radiation+chemotherapy
- chemotherapy+radiation+surgery

2) Multivariate analysis tables will be constructed to describe each concern (R.1-6) by diagnosis type, sex, time since diagnosis, radiation exposure, and selected chemotherapy agents. Final models will include correlated data adjustment using generalized estimation equations to account for the lack of independence between cases with matched siblings.

6. Special Consideration: This proposal will be worked on in conjunction with the three analysis concept proposals that were revised and approved by the Publications committee ('Health Status', Barriers to Health Care', Preventative Health Practices'), because of possible overlap in variables and it will contribute to the information in these proposals. This decision was agreed upon by members of the analysis team.

Hegang Chen is a biostatistician at the University of Minnesota, and is currently involved with the three proposals mentioned above. He will be also responsible for this analysis.

Once approved, we will contact CCSS investigators to request the addition of other authors with expertise in health behavior and health services research to be part of this proposed analysis.