Research Project Narrative: Primary Care Physicians Attitudes and Knowledge Regarding the Care of Childhood Cancer Survivors

Principal Investigator: Tara Henderson, MD, MPH
Co-Investigators: Christopher K. Daugherty, MD and Fay Hlubocky PhD, MA

BACKGROUND

One of the great successes in medicine in the past several decades has been the dramatic strides made in the treatment of childhood cancers. Currently, almost 80% of childhood cancers can be cured, with rates higher than 80% in childhood lymphoblastic leukemia, Hodgkin’s disease and Wilms’ tumor. With this success comes cost associated with the childhood cure, and the literature is ever expanding in the studies examining the late effects and mortality affecting childhood cancer survivors. Virtually all organ systems can be affected by radiation, chemotherapy, or surgery administered at a young age, leading to a wide array of potential late effects, including second malignant neoplasms (SMN), organ dysfunction, early death, endocrine abnormalities and neuropsychological dysfunction. Guidelines have been developed by organizations such as the Children’s Oncology Group to highlight potential late-effects and provide screening guidelines to identify and minimize potential morbidities. As discussed by Kadan-Lottick et al, there are important knowledge deficits among survivors of childhood cancer regarding basic aspects of their diagnosis and treatment. No studies have examined the physician’s knowledge base regarding the risks for these patients. Elucidating physician understanding of late effects across specialties is essential to
streamlining education interventions such that appropriate care is delivered to survivors.

For the purpose of this study, “primary care physicians” may describe, but are not limited to, pediatricians, internists, family physicians, pediatric oncologists, adult oncologists, and/or any physicians that may care for childhood cancer survivors and are in the position to routinely refer these patients to childhood cancer survivorship programs.

AIMS

Primary Aim: To describe the attitudes and knowledge of primary care physicians, including pediatricians, internists and family physicians, regarding the health care of childhood cancer survivors, including their understanding of the primary cancer diagnosis, its associated therapies and late effects, and appropriate screening for these individuals.

METHODS

1. Survey Instrument

We developed a survey-based study to examine physician knowledge regarding the health of childhood cancer survivors to be mailed to subjects. The survey will be based on prior surveys regarding physician knowledge, communication, and attitudes of cancer patients. Specifically, the survey will consist of demographic questions, vignettes, and multiple survey questions with primarily quantitative but also qualitative items. (Please see the Appendix for the survey instrument). The survey questions seek physician (pediatricians, internists and family practitioners) self-reports regarding knowledge of health risks due to pediatric cancers, their understanding of appropriate surveillance for...
these health risks, and their attitudes regarding caring for these patients. The survey instrument will be modified for pediatricians as appropriate for different physician specialties. The survey will be pilot ed in order to examine the clarity and validity of the instrument.

The survey questions will be printed on two sides of a sheet of cardstock and will be mailed with a cover letter explaining the purpose of the study and soliciting responses. Each survey form can be folded in thirds, sealed with an adhesive strip, and is self-addressed and stamped for easy return mailing to the study investigators.

For modified versions of the survey that do not fit in to the tri-fold format, surveys will be printed on white paper and mailed flat in 9x11 envelopes with the cover letter and post-paid return envelope.

Demographic questions in the survey may include, but are not limited to, a description of the subject’s gender, primary specialty, type of practice (such as HMO, private or academic), years in practice, and information regarding prior training with childhood cancer survivors. Quantitative survey items may include, but are not limited to, their familiarity with childhood cancer treatment sequelae and monitoring guidelines, their familiarity with several specific pediatric cancer diagnoses, how many childhood cancer survivors they have cared for in the last five years, and whether their practice is affiliated with a long-term follow up program for cancer survivors. One clinical vignette that may be used is given with four follow-up questions regarding approaching the specific clinical scenario. Finally, subjects will be asked to give a qualitative written example about caring for
2. Subject Selection

Subjects will be selected from the recent professional membership directories that are expected to include physicians whom are likely to care for childhood cancer survivors and/or are in the position to routinely refer these patients to childhood cancer survivorship programs. These directories may include: the Children’s Oncology Group (COG), the American Society of Clinical Oncology (ASCO), of the American Academy of Pediatrics (AAP), the American College of Physicians (ACP), and the American Academy of Family Physicians (AAFP), and physicians affiliated with the Hospital for Sick Children (SickKids).

For non-responders, non-responding subjects will be contacted by email/fax. In previous work by Daugherty and colleagues, subjects have reported that they would like to respond electronically to the survey electronically by email only (not by website). As well, given this response from subjects in previous survey projects, surveys will also be sent for this project. We would like to request a slight modification of the subject enrollment by sending the survey by email/fax. This change is necessary given several subjects reported they would like to respond to the survey by email. Confidentiality will be maintained with no identification of survey subjects by the use of subject identifiers. All data received from subjects will not be labeled with subject identifiers. All data will be stored in password protected computer databases within the locked offices of The
3. Enrollment Procedures

Surveys will be mailed in sets corresponding to targeted membership directories (ie, one set to COG physicians, one set to ASCO physicians, etc). As previously noted, surveys may or may not be modified for each group to appropriately address various physician specialties. Surveys will either be sent from, or mailings will be coordinated by, study staff at the University of Chicago.

Once subjects are selected for each set of mailings, a total of three mailings will be completed. A total of three mailings will be sent out. The first mailing will be a pre-notification letter to potential subjects introducing the study and announcing the subsequent arrival of the survey. The second mailing will include another letter re-emphasizing the goals of the study, a pre-addressed and stamped investigational survey, and a $5 Barnes & Noble gift card. A third mailing will follow specifically to non-responders including another letter soliciting responses and an additional copy of the survey.

A pre-notification letter to potential subjects will be followed by the first survey mailing with the self-addressed stamped survey. A third mailing will be planned with the survey being sent for a second time to non-responders.

4. Informed Consent
A written description of the research purpose of the questions will be attached to the survey. (See Appendix for survey cover letter). This will involve no oral contact with the survey subjects. The pre-notification letter will describe involves all of the pertinent information regarding consent and confidentiality. The letter accompanying the survey will describe the research purpose(s) of the survey questions. This method will involve no oral contact with the survey subjects. Refusal to participate will be apparent when a survey is not be returned. All surveys will be anonymously collected.

Participation in this study is voluntary, and the confidentiality of subject responses has been and will be maintained.

5. Participant characteristics

- Study participants are both physicians who have had either significant clinical experience caring for pediatric cancer patients and the general population of pediatric oncologists, physicians, or who are in the position to routinely refer childhood cancer survivors to childhood cancer survivorship programs, will be approached for study participation. As previously noted, this may includes pediatricians, internists, family physicians, pediatric oncologists, adult oncologists, and/or physicians that are involved in the care of those with pediatric cancer, both oncologists and physicians involved in the care of those with childhood cancer.

6. Duration of protocol

- Data collection, analysis, and manuscript preparation for this study is expected to take approximately one year, but may take longer to achieve target enrollment and data saturation, one year.
7. Location of protocol -

The University of Chicago Medical Center (UCMC) will coordinate the distribution of surveys either locally or through participating agencies and sites. All raw survey data will be collected at UCMC for analysis.

8. Location where research has been conducted -

This is a mailed survey. Survey data will be stored in behind locked offices and file cabinets. Data will be entered into statistical computer databases which will be password protected. Analysis will be conducted at the desks of Dr. Tara Henderson, Dr. Chris Daugherty, and Fay Hlubocky.

9. Precautions required - None

10. Controls/placebos - None

11. Number of subjects - 6000 subjects

12. Statistical Analyses--

All data will be coded and entered into a database using standard statistical software (STATA Release 9.0. College Station, Texas 2005). Missing responses, responses that
did not fit into one of the specific item responses, and items in which subjects provided more than one response to a survey item will be all considered missing. Descriptive statistics will be calculated as proportions. To test for an association between demographic variables (e.g., gender and affiliation) with continuous responses, two-sample t-tests will be performed. To test for an association between demographic variables and the ordinal responses, Mann-Whitney tests will be completed. To test for an association between years since completing formal training and continuous variables, Pearson’s correlation coefficient will be calculated and tested for equivalence to zero. Spearman’s correlation coefficient will be calculated and tested for equivalence to zero to test for an association between years since completing formal training and the ordinal variables.

**Informed consent and safety**

**INFORMED CONSENT AND SAFETY**

1. Risks and benefits-

   There are no physical risks to the subjects by being in this study. The possible non-physical risks of the study include loss of time in completing the survey and loss of confidentiality. There are no significant benefits of the study for subjects. Possible minor benefits include greater physician understanding, improved patient-physician communication and better-informed participants. In addition, we hope the study will provide insight into how physicians’ views may impact on the
doctor-patient relationship and how this in effect influences patient decision making for treatment.

2. Payment

A $5 (five) dollar Barnes & Noble gift card incentive will be enclosed with the survey.

3. Informed consent-

As previously described above, please see above. This is a mailed survey. If physicians agree to consent, subjects consent to participation, they will respond to the survey and return it by mail. Potential perceived risks or benefits to the study are described above. Refusal to participate in the study will be apparent when the survey is not returned. Again, participation is voluntary. Confidentiality of subject responses will be maintained (please see below).

4. Confidentiality-

Unique study-specific identifiers will be assigned to each individual survey subject’s survey data allowing the tabulated data to be anonymized. Manipulation and analysis of the data and reporting of the results will be preformed in aggregate fashion and in no way will identify individual subjects. In addition, all data and any information that has specific subject identifying information on returned surveys (prior to
anonymization) will be maintained in a secure location, within a locked office in a password protected computer. Only study personnel will have access to this information.

8. **Location of Protocol** – The University of Chicago Medical Center.

9. **Location of Research** – This is a mailed survey. Survey data will be stored behind locked offices and file cabinets. Data will be entered into statistical computer databases which will be password protected and analysis will be conducted at the desks of Tara Henderson, Christopher Daugherty and Fay Hlubocky.

10. **Precautions required** – None.

11. **Controls/Placebos** – None.

12. **Number of subjects** – 15

5. **Participant Characteristics**

6. **Duration of Protocol**

7. **Location of Protocol**

8. **Location of Research**

9. **Precautions**
10. Controls/Placebos

11. Number of subjects

12. Statistical Analyses

INFORMED CONSENT AND SAFETY