Hyundai Hope On Wheels™
Helping kids fight cancer

10 YEARS OF FIGHTING PEDIATRIC CANCER

# Hyundai Hope on Wheels
# Hyundai Scholar Research


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***Background – Cancer Survivorship Research***

Therapeutic strategies in pediatric oncology today are increasingly using "risk-based" therapy that seeks to deliver effective anti-neoplastic therapy with reduced toxicity to the patient. While the number of survivors has grown, untoward health outcomes known as 'late effects' are often recognized in survivors of cancer therapy. Some of these issues affect the developing child while others may not surface until adulthood. Research focused on long-term survivors of childhood cancer has allowed us to anticipate certain organ-specific complications, including learning impairment, abnormal growth and development, gonadal and reproductive abnormalities, and the development of secondary malignancies. Although research to identify chemotherapy regimens that minimize late effects without compromising survival rates is ongoing, interventions that identify and manage late effects continue to be important components of the treatment of childhood cancer survivors.

Cancer survivorship research requires a systematic approach to identify and characterize the late complications of childhood cancer. Whether the focus of a specific research study is a physical, psychosocial, or care-delivery issue, the overall objective of this field of research is to improve medical outcomes and enhance quality of life in cancer survivors. Although cancer survivorship research is collaborative in nature, the research questions often arise from smaller descriptive studies conducted at a single institution.

***Study Objective***

The objective of the research program that we will conduct with funds from the Hyundai Hope on Wheels Program is to develop and refine a Long-Term Follow-Up (LFTU) Program that is

uniquely designed to meet the needs of childhood, adolescent, and young adult cancer survivors treated at the USA Children's and Women's Hospital. We seek to develop a comprehensive, multidisciplinary team approach modeled after the LFTU guidelines provided by the Children's Oncology Group (COG) that will allow us to promptly identify and efficiently manage multiple health and psychosocial issues in the children treated for cancer at our facility. The team will coordinate medical management, patient and family education, and referrals to appropriate specialties and resources. Data will be collected using a newly-developed database that will allow us to monitor for late effects and to perform targeted studies that evaluate the effects of different therapeutic regimens and subsequent organ function.

***Study Design***

LTFU Electronic Database

To collect and analyze data in a longitudinal fashion, we will develop and refine an electronic LTFU database for our institution's pediatric oncology program. The basic data elements that will be included in this clinical database for use in our cancer survivorship research will include:

1. Demographic data
2. Disease-related data
3. Treatment-related data
4. Clinical outcomes
5. Toxicity criteria

Collecting data is a labor-intensive process and maintaining quality data input requires the expertise of a well-trained CRA. The funds donated by the Hyundai Hope on Wheels Program will be utilized to train and support the data entry functions of a full time CRA.

Who will be included in the database?

We will enroll all pediatric cancer patients at our institution when they complete active therapy. This will allow analyses of our entire population of cancer survivors.

How will the data be collected?

Medical record abstraction and data entry may take place in advance of the patient's visit, with review and update of the information (specifically the patient's contact information and

information about actual late effects and severity) completed at the clinic visit. For young adult survivors whose care has been transferred to a primary care provider, changes in demographic information and other data elements may be updated at the start of the annual clinic visit or by phone or mail on an annual basis.

Clinicians and clinical research assistants (CRAs) will record information during the clinical interview using standardized data collection forms. Data may also be collected by mail or telephone conducted outside of the standard LTFU clinical encounter.

Who will provide information?

Survivors age 18 and over can generally respond for themselves, unless they are cognitively impaired or developmentally delayed. Younger survivors may complete age-appropriate forms with parental consent. Family members can be proxy respondents for children too young to complete the forms and for those survivors with cognitive impairment or developmental delay.
How can quality data collection be assured?

Rigorous training in medical record abstracting, patient interviewing and data entry for personnel who will be engaged in these activities is fundamental to the development of a complete and accurate clinical database that can be useful for research.

Institutional review board (IRB) approval

Since we plan to use the clinical database to answer research questions that arise over time, IRB approval will be sought. We will submit an IRB application for general data collection upon completion of the clinical database for the LTFU program. IRB application would request survivor's consent to store de-identified information; demographics, disease characteristics, treatment received and late effects, making it available for future analyses.

***Timetable***

We anticipate that the LTFU database can be developed and that data entry can commence within the first four months of this project. Thereafter, data entry will continue indefinitely. Our initial study objectives are to complete data entry for one year, at which time specific analyses focused on improving our understanding of the late effects seen and the care that is indicated for our at-risk population will be developed.

**Bio – Aarati Rao, M.D.**

Dr. Aarati Rao is an Assistant Professor in the Division of Pediatric Hematology/Oncology, Department of Pediatrics, at University of South Alabama College of Medicine, a position she has held since July, 2006. She also serves as an Attending Physician at the USA Children's and Women's Hospital in Mobile. A native of India, Dr. Rao completed a Pediatric Residency at the SUNY Upstate Medical University, Syracuse, NY, in 2003. She received fellowship training in Pediatric Hematology/Oncology at Louisiana State University, New Orleans, from 1999 to 2001, and at Washington University School of Medicine, St. Louis, MO., from 2003-2006, with a research emphasis on familial cancer predisposition syndromes. Dr. Rao is certified by the American Board of Pediatrics and is board-eligible in Pediatric Hematology/Oncology. She has authored 14 papers and 14 abstracts.