Quality of Life in Adult Survivors of Pediatric Heart Transplant
Nicole Stanford PGY3

A. Study Purpose and Rationale

Many children who undergo heart transplantation are having longer survival and more of the population is living well into adulthood. Many QOL studies have looked at adult heart transplant patients, but only a few have looked at the population who receive a transplant as a child. Previous studies have shown that adult survivors of pediatric heart transplant report a good QOL even one comparable to general population of same age range (Hollander et al, 2015) (Petroski et all, 2009). It is important to examine how this chronic illness affects children's development and eventual transition to becoming an adult so that we may be better at counseling future patients.

Aim:
To perform a single point in time assessment of quality of life and psychosocial factors of adults patients who received a pediatric heart transplant and compare their quality of life to that of the adult general population

Main hypothesis:
Our hypothesis is that adult survivors of pediatric transplant have a comparable quality of life to the general population of similar age range.

B. Study Design and Statistical Analysis

The study design is mainly a descriptive study (single point in time assessment). Our study cohort will be patients who received a heart transplant at Columbia University Medical Center between 1984 and through August 1, 2007 who have now survived over 10 years since transplant and are now > 18 years old. Eligibility will be determined by chart review. Patients will be contacted either in person or by phone to determine participation in the study. Once verbally consented, we will ask patients to complete two surveys that will be completed in person or sent in the mail: QLI by Ferrans and Powers and a survey of our own design that will examine psychosocial factors and lifetime achievements including education, relationships, and financial independence. Baseline demographics including age, sex, and indication for transplant, will be obtained from the medical record. This data will already be collected on patients under an existing protocol (IRB AAAC8183: Risk Factors in Pediatric Cardiac Transplantation)

Survey results will be analyzed to look at mean QOL scores of the population with corresponding frequencies and measures of central tendencies well as percentage of population that report certain psychosocial factors and lifetime achievements. Another possible statistical analysis will be using the results of the Ferrans and Powers QLI survey scores and comparing via an unpaired t tests or one sample t test based on published scores of the general population.

C. Study Procedure:

Eligible participants will be determined from the list of patients who received a heart transplant at Columbia University Medical Center between 1984 and August 1, 2007, and were under the age of 18 at the time of transplant, and who are now above age 18 and still alive today. A member of the research team who is also a member of the Pediatric Heart Transplant team will reach out to the patient either by phone or at an upcoming clinic visit to ask if they are willing to hear about the research study. If the patient is interested, verbal consent will be obtained and the patient will be asked to complete 2 surveys, the QLI Ferrans and Powers survey and a survey created by the investigators to look at socioeconomic factors. This will be done either in person at a clinic visit, or the study will be described during a phone call and after verbal consent is obtained, the patient will be mailed the surveys with an information sheet. Finally, for patients who are no longer patients at CUMC, a letter will be mailed from Dr. Addonizio, the director of the Pediatric Heart Transplant Program since its inception in 1984. The letter will mimic the phone script and the mailing will also include the information sheet and surveys. Consent will be implied by return of the surveys.

D. Study Drugs: None
E. Medical Device: None
F. Study Questionnaires: Ferrans and Powers Quality of Life Index- Cardiac Version and CHONY Pediatric Heart Transplant Life Achievement Survey

G. Study Subjects

Patients who received a heart transplant at Columbia University Medical Center between 1984 and August 1, 2007, and were under the age of 18 at the time of transplant, who are now the age of 18 or older and at least 10 years out from the date of their transplant.

H. Recruitment of subjects:

Eligible participants will be determined from the list of patients who received a heart transplant at Columbia University Medical Center between 1984 and August 1, 2007, and were under the age of 18 at the time of transplant, and who are still alive today. A subset of these patients are still cared for in the Pediatric program and for these patients, a member of the research team who is also a member of the Pediatric Heart Transplant team (WZ) will reach out to the patient either by phone or at an upcoming clinic visit to ask if they are willing to hear about the research study. A subset of these patients are now cared for in the Adult program and for these patients, a member of the research team who is also a member of the Adult Heart Transplant team (MF) will reach out to the patient either by phone or at an upcoming clinic visit to ask if they are willing to hear about the research study. If the patient is approached in person at a clinic visit and is interested in participating,

written consent will be obtained and the patient will be asked to complete 2 surveys, the QLI Ferrans and Powers survey and a survey created by the investigators to look at socioeconomic factors. If the patient is being reached over the phone, the study will be described during a phone call and after verbal consent is obtained, the patient will be mailed the surveys with an information sheet. Finally, for patients who are no longer patients at CUMC, a letter will be mailed from Dr. Addonizio, the director of the Pediatric Heart Transplant Program since its inception in 1984. The letter will mimic the phone script and the mailing will also include the information sheet and surveys. Verbal consent for those participants who cannot provide written consent will be implied by return of the surveys.

I. Confidentiality of Study Data:

Data on hardcopy (including survey results) will be stored in a binder, which will be maintained in a locked cabinet in the office of the PI. All patient identifiers will be removed from the electronic data set prior to analysis, and each patient will be assigned a unique study ID number. A separate file correlating this study number with patient identifiers will be kept in a secure database encrypted with password protection, and only the study personnel will have access to the file, which will be kept on encrypted endpoint devices.

During patient enrollment, subjects will be given a signed copy of the informed consent form, which outlines all confidentiality expectations and disclosure of personal health information. All study specific activities, such as the completion of surveys, will be conducted in private rooms (if these activities occur here at the hospital/clinic).

J. Potential Conflict of Interest: None
K. Location of the Study: Columbia/CUMC-Pediatric Cardiology
L. Potential Risks:
The only potential risk to the patient is the very minimal risk of loss of confidentiality. Every precaution will be taken to protect the patients' information as outlined in the Privacy and Data Security section and in the consent and HIPAA forms.

M. Potential Benefits:
There may be no direct benefit to the participant. The aggregate data collected in this registry has the potential to benefit society by providing a better understanding of the quality of life and socioeconomic effects on pediatric patients receiving heart transplantation.

N. Alternative Therapies: Not Applicable
O. Compensation to Subjects: None
P. Costs to Subjects: Not Applicable
Q. Minors as Research Subjects: Not Applicable
R. Radiation or Radioactive Substances: Not Applicable

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