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PGY2
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**Project Title:** Examining Long-Term Outcomes and Trends Following Cardiac Transplant in Pediatric Patients

## Study Purpose and Rationale

The first human cardiac transplant was performed in December of 1967. Outcomes of those initial transplant patients were poor due to high rates of infection and graft rejection. However, with our deeper understanding of cardiac physiology, infectious disease, and the immune system, as well as improvements in medical technology (such as the widespread use of ventricular assist devices), outcomes of these patients have drastically improved. In particular, the use of cyclosporine-based immunosuppression starting in the 1980s brought about a significant improvement in survival rates of cardiac transplant patients and led to the use of transplant as the standard of care for children with end stage heart failure. Although overall survival of these patient has improved significantly, there are still major limitations in improving the outcomes of these patients, many of them stemming from the immunosuppressive agents used to prevent graft rejection. These complications include end-stage renal disease (ESRD) requiring renal transplant and the development of post-transplant lymphoproliferative disease (PTLD).

Columbia Children's Hospital performed its first successful orthotopic cardiac transplant in June of 1984, and has since become a high-volume cardiac transplant center. We aim to use the data collected from the past 20 years of cardiac transplants to examine long-term outcomes and trends of these patients post-transplant to help identify ways to improve future outcomes

## Study Design and Statistical Analysis

This is a retrospective epidemiologic chart review. We will identify all patients who have received a cardiac transplant at the age of 0-18 years from January 1, 2000 to January 1, 2020 and perform a chart review to collect demographic information as well as outcomes of these patients. Kaplan-Meier (KM) survival analysis will be use to compare outcomes of patients transplanted from 2000 – 2009 and 2010 – 2019. These curves may be compared to the data registry published by the International Society of Heart and Lung Transplant to identify gaps in outcomes between patients at our institution and patients across other institutions.

<u>The demographic information we will collect includes</u>:

1. Ageß
2. Gender
3. Date of transplant
4. Reason for transplant:
    a. Dilated cardiomyopathy (DCM)
    b. Hypertrophic cardiomyopathy (HCM)
    c. Restrictive cardiomyopathy (RCM)

    d. Single-ventricle physiology
    e. Other
5. Cardio-pulmonary support required pre-transplant
    a. Extra-corporeal mechanical oxygenation (ECMO)
    b. Left ventricular assist device (LVAD)
    c. Biventricular assist device (BiVAD)
    d. Intra-aortic balloon pump (IABP)
6. Patient disposition:
    a. Followed at Columbia Children's Hospital
    b. Transitioned to adult care at Columbia Irving Medical Center
    c. Transferred care to another institution
    d. Death

The outcomes that we plan to examine are:

1. Time to survival
2. Time to graft rejection
3. Development of and time to ESRD
4. Development of and time to diagnosis of PTLD

**Study Subjects**

All patients who received a cardiac transplant at ages 0 – 18 at Columbia Children's Hospital will be included in our study. As this is a retrospective study, no subjects will be recruited.

**Informed Consent of Study Subjects**

This study may be considered for a waiver of consent as it fulfills the following criteria:

1. The research involves no more than minimal risk to the subjects: there is no medical risk involved with this retrospective study, the only risk is loss of confidentiality of the data for which we will use encryption methods to ensure secure storage of the data
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects: this is a retrospective study and will not affect the rights or welfare of the study subjects
3. The research could not practicably be carried out without the waiver or alteration: a significant number of our subjects may be deceased, therefore it would not be possible to obtain consent from all subjects
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation: given that this is a retrospective study that will not affect the treatment or potential outcomes of study subjects, they will not be notified of pertinent information or results of the study.

**Confidentiality of Study Data**

All data will be obtained from the Columbia University Irving Medical Center electronic records and saved in an encrypted Excel spreadsheet. Data storage and analysis will be performed on an encrypted machine.

## Potential Conflict of Interest

No potential conflicts of interest.

## Location of the Study

This is a single-center study. All data will be obtained from the Columbia University Irving Medical Center electronic medical records.

## Potential Risks

This is a minimum risk study, with loss of confidentiality of data being the only risk. Measures to reduce this risk is noted above.

## Potential Benefits

As this is a retrospective study, there is no direct potential benefit to study subjects. However this study may help us to improve outcomes for future cardiac transplant patients.

## Compensation of Subjects

No compensation will be provided to study subjects.

## References


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