Analyzing Outside Influences Leading to High Donor Organ Discard Rates in Pediatric Heart Transplantation

A Research Paper submitted to the Department of Engineering and Society

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

Connor Scott Hyldahl

Spring 2023

On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

Advisor

MC Forelle, Department of Engineering and Society

Introduction

Despite vast advancements in medical procedures and medications over past decades, over 8% of children on the pediatric heart transplant waitlist die each year before a surgery can be performed to replace their heart with a healthy donor organ (Zafar et al., 2015). Many of these children were only a few years old when they were originally listed as needing a transplant and spent months waiting for a suitable donor before succumbing to their heart problems. While it may be unrealistic to expect that every child will survive on a transplant waitlist, what makes this statistic even more startling is that up to 44% of potential donor hearts are discarded before being used in the United States (Gossett et al., 2020). Coupled together, these issues represent a serious problem within the pediatric heart transplant field that have left many medical professionals scrambling to find strategies to connect sick children with new hearts.

The issues present within pediatric heart transplantation are not a new phenomenon, but rather lingering problems in a medical sector that has otherwise seen a wide variety of improvements since the first surgeries were performed several decades ago (Javier et al., 2021). In 1967, the first pediatric heart transplant was conducted on a 17-day old infant by a team of specialist doctors in Brooklyn, New York (Morales et al., 2007). While the infant only survived for a short period of time following the surgery, the operation was seen as a breakthrough in medical science that represented a culmination of years of research and innovation. The operation, which is a transplantation conducted on pediatric patients with end-stage heart failure to replace a struggling heart with a donor heart, has now become an accepted and efficient method that is performed approximately 600-700 times worldwide each year (Bock, 2022). The high discard rate of heart organs within the United States presents a major problem for both

medical specialists and patients across the country, especially considering that waitlist mortality rates can reach as high as 30% at small volume centers (Denfield et al., 2020).

In this paper, I will argue that cardiologists face a complex network of pressures and considerations from outside influences which are leading to the unnecessary discard of donor hearts. To conduct this argument, I will first provide an overview of the literature surrounding pediatric heart transplantation, with emphasis on current processes used in heart transplantation, regulatory agencies used for evaluating transplant centers, and the lack of uniform criteria for assessing a donor heart. From there, I will analyze published medical journal articles, news reports, and transcripts from interviews to construct the network of actors involved in pediatric donor assessment and the various influences that these actors have on donor discard rates. Throughout this analysis, I use Latour's Actor Network Theory to find that influences from these actors are playing a large role in the decision-making of cardiologists and ultimately leading to increased discard rates. Finally, I end my argument with a brief discussion of how regulations and policies need to be changed to ensure cardiologists are making the best decision possible. Examples and policies from other countries or organ systems can be used as references for what changes can be made.

Literature review

Pediatric heart transplantation started off as a risky, breakthrough surgery but has advanced over time with new techniques and decision factors. Since the first surgeries were conducted decades ago, advances in medications, donor procurement and preservation techniques, and post-surgery management tools have allowed patients to continue to experience many years of quality life following a surgery (Norman, 2022). Recent literature has shown that survival rates of pediatric heart transplant patients have been steadily increasing. The median

survival for a transplant patient is now greater than 15 years in all age groups for those who survive past the first year (Dipchand & Laks, 2019).

Current practices within the field require cardiologists at designated transplant centers to assess data on potential donor hearts and make a decision on whether to approve the donor organ for surgery on their patient. During their assessment, cardiologists typically have to review a high volume of data regarding a potential donor heart, including information on the donor organ, donor candidate, and factors such as distance to procure the organs (Dipchand et al., 2020). This leaves these individuals with the difficult challenge of assessing the data to determine whether a potential donor heart is suitable for a patient on the waitlist, with the decision often needing to be made in early hours of the morning within a short time period of about 30 minutes.

This method of donor assessment is accompanied by a complex system of regulatory agencies and governing boards that assess transplant centers and oversee the donor allocation system. Currently, the Scientific Registry of Transplant Recipients (SRTR) is the primary organization responsible for collecting and organizing data on transplant patient outcomes and generating outcome reports for each transplant center which are made available on the SRTR website (Butler et al., 2019). The SRTR also sends these performance reports to the other organizations involved in regulatory oversight. The Organ Procurement and Transplantation Network (OPTN) is another program under contract by the federal government which uses the reports sent by SRTR to monitor transplant center performance. This program is also responsible for setting policies that transplant centers must abide by to avoid being flagged, which are created by a collaborative effort of committees, board of directors, and the public (*OPTN: Organ Procurement and Transplantation Network - OPTN*). Finally, the United Network for Organ Sharing (UNOS) is the primary organization responsible for managing the national transplant

waiting list and matching donor organs to recipients (*What is UNOS?: About United Network for Organ Sharing* 2022). This private, non-profit organization is also responsible for reviewing transplant center performances and investigating centers that fail to meet OTPN obligations.

Despite these various programs created to ensure that the transplant process is occurring effectively, many studies have found that donor hearts are being discarded at rates of up to 45% in the United States and Europe (Gosset et al., 2020). While there is no clear answer as to what is causing such high discard rates, some pediatric professionals have argued that a lack of agreement among cardiologists as to which donor and organ criteria are important for predicting transplant success may be a leading cause. Donor characteristics including size matching, donor age, donor comorbidities (multiple diseases/conditions existing at the same time), infections, and cause of death have all been examined to determine their impact on transplant survival. Despite these studies, the known impact of such data remains limited due to global challenges in studying donor characteristics (Conway et al., 2020). The lack of clear criteria to guide cardiologists in donor assessment has forced many of these specialists to rely on experience and subjective analysis when assessing a donor, which may lead to potentially useful donor hearts being discarded. In one interview conducted with a pediatric heart specialist working at a Children's Heart Center in New York City, the doctor concluded that reliance on a subjective analysis significantly impacted her decision making: "Depending on my mood and the time of the day sometimes a donor gets accepted and sometimes it gets rejected, which is really not acceptable" (Bansal, 2023).

In addition to a lack of clear guidelines on what donor criteria will influence the success of a heart transplant, other publications have argued that behavioral influences have played a factor in discard rates. Recent literature has suggested that cardiologists are often concerned with

finding the “perfect” donor, rather than taking the first acceptable offer that is presented to them. In addition, a lack of transparency has been shown in decision-making, as accepting a donor creates additional work and thus individuals may have a tendency to find a reason to refuse an offer (Baez Hernandez et al., 2020). Similarly, omission bias, which is the principle stating that negative outcomes resulting from commission are viewed more harshly than identical outcomes resulting from omission, may play a role in the psychology of donor assessment. One study found that omission bias has shown to be a potential factor in decision-making, including the fact that cardiologists may view declining a heart as a foregone gain, whereas accepting a heart that leads to a transplant death corresponds to a more heavily-weighted loss (Butler et al., 2019).

In conducting my analysis, I focus on implementing Latour’s Actor-Network Theory, which emphasizes that a series of actors, both human and non-human, interact with each other to influence larger technological systems (Latour, 1992). The use of this framework was suitable for this analysis given the large range of outside agencies and individuals that play a role in the transplantation process and can have an impact on decision-making. This framework has been used to analyze other aspects of the healthcare system, including the network of actors involved in the implementation of information technology (Cresswell, Worth, & Sheikh, 2010). The publication used Actor-Network Theory to show how technology plays a role in shaping social processes within the healthcare setting.

Methods

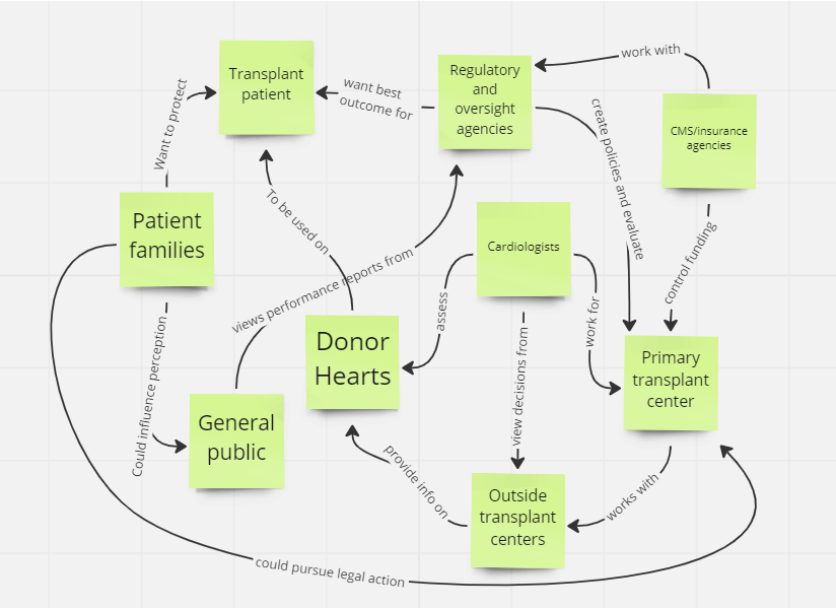
For data collection, I reviewed a collection of secondary sources, including academic journal publications and news articles written by professionals within the heart transplantation field, as well as informational websites generated by organizations involved in the pediatric transplant process. I also implemented transcripts from interviews throughout my analysis, which

were recently conducted alongside my technical capstone team with various pediatric specialists who are employed at both the UVA hospital and other transplant centers across the United States. In my review of literature, I examined the factors used in the decision-making process of a pediatric cardiologist and what outside influences may be playing a role in their assessment of a donor heart. For the interviews, I focused on identifying what goes through the mind of a specialist as they assess a donor and what may cause them to decline a heart. I believe that the use of these research methods was necessary to ensure that I gained a combination of personal insights and peer-reviewed data sources that could be used in my analysis.

Analysis

In analyzing the problem of high donor discard rates throughout the United States, which is consequently increasing the number of pediatric patients who die on the waitlist, I applied Latour's Actor Network Theory to the various individuals and organizations that are creating influence on the pediatric decision-making process. The larger technological system at hand is the overall process of donor assessment, while the individual actors within the system include the donor heart, cardiologists, transplant patients, regulatory agencies, insurance companies, patient families, transplant centers, and the public. An analysis of the interactions between these various actors can be used to show how outside influences are causing organ discard rates within pediatric heart transplantation to reach almost 50%. A diagram of these various actors and the relationships that exist between them can be seen in Figure 1:

Figure 1: ANT Diagram for Pediatric Heart Assessment



The first set of actors exerting influence on the decision-making process is the regulatory and oversight agencies, with specific emphasis on the metrics set in place by the SRTR and used by the OPTN and UNOS to monitor transplant program success. Current performance measures set in place by the SRTR exclusively focus on post-transplant outcomes, with possible repercussions for centers that do not meet such measures ranging from probation and financial costs to closure (Butler et al., 2019). Given these measures, it is likely that transplant centers will take actions that maximize transplant success rates to avoid sanctions, even if this increases discard rates or patient time on the waitlist. To add to this, recent studies have shown that these policies encourage transplant centers to decline "marginal" donors, despite evidence showing that centers that accept fewer donor hearts have higher waitlist mortality without improvement in post-transplant outcomes (Godown et al., 2019). Thus, the regulatory agencies exert an unintended negative influence on the cardiologists through their chosen metrics for evaluating

success. The public may also play a role in this dynamic, as the performance reviews documented by the SRTR for each transplant center are available for public view on the organization's website. Therefore, cardiologists may feel additional pressure to keep transplant success rates high knowing that poor outcomes could create a negative public reputation for the transplant center.

The Centers for Medicare and Medicaid Services (CMS) and private insurance agencies are another set of actors that may result in increased pressure on transplant centers during decision making. These insurance programs typically review SRTR reports to determine program certification for participation in Medicare (Butler et al., 2019). Since 2007, the CMS established a one-year post-transplant outcome metric that flagged transplant centers that did not meet its criteria, with a potential loss of insurance funding for low-performing centers (Amdani et al., 2021). A recent study from a Cleveland clinic-led study found that flagged centers were more likely than non-flagged centers to have a decrease in candidate listings three to six years after receiving the flag. The study also found that flagged centers had immediate declines in listing for high-risk patients, such as patients on mechanical ventilation (Contrera, 2021). This evidence suggests that current methods for evaluating centers to determine funding for insurance may result in more harm than good for both the cardiologists assessing the donor hearts and the patients on the transplant waitlist. As a case in point, St. Luke's Medical Center, historically regarded as a top transplant center, lost its funding from CMS in 2018, which forced patients on the waitlist to pay out of pocket for surgeries or transfer to another hospital (Ornstein & Hixenbaugh, 2018).

Some professionals in the transplant industry have provided a counterargument to the above points, saying that the policies set in place by regulatory agencies can help transplant

centers to achieve better outcomes for their patients. Specifically, recent articles have stated that criteria focusing on post-transplant outcomes encourages transplant centers to implement best practices to ensure that their surgeries are successful (Amdani et al., 2021). While it is true that the current evaluation criteria can push transplant centers to perform transplants more efficiently, one must also take into consideration the fact that focusing solely on the outcomes of surgeries can lead to potentially useful hearts being discarded, thus neglecting the children that are on the waitlist. Ideally, regulatory organizations and insurance agencies should be inclusive of this group by creating policies that focus on the combined mortality rate of transplantations and the waitlist, as well as other factors such as donor utililization rates. This change would most likely result in transplant centers being more open to accepting marginal donor hearts and a reduction in the national discard rates of donor hearts.

In addition to regulatory agencies and CMS services, information that is presented from other transplant centers regarding a potential donor heart may cause a cardiologist to take extra precautions in accepting a suitable organ. According to a recent interview with a pediatric specialist at Columbia University, many cardiologists find that a donor heart that has been rejected by a multitude of other transplant centers is a factor that is hard to ignore and places doubt in their decision to accept that donor heart (Richmond, 2023). Recent published studies have agreed with this opinion, stating that some transplant centers may mimic the decline decision of other centers who previously were offered the organ, even in the face of an otherwise acceptable organ (Butler et al., 2019). These interactions between different transplant centers create an interesting dilemma for cardiologists that certainly may play a critical role in the discard rates of pediatric donor hearts. It is probable that cardiologists would have accepted

many of these donor hearts if it were not for the fact that other transplant centers had previously determined a reason to reject them.

The final sector of actors involved in the network of pediatric donor assessment are the families of pediatric heart transplant patients, which have important interactions with the transplant centers, public, and individual cardiologists. A recent journal article from 2020 suggests that current rules governing discussions between medical teams and parents of a pediatric patient about increased-risk donor hearts are resulting in decreased utilization of donors (Lelkes, Patel, Joong, & Gossett, 2020). Specifically, the article notes that the parents of a pediatric patient are forced to decide in isolation from the expertise of the medical team on whether to accept certain types of high-risk donor hearts for surgery on their child. This may result in more hearts being rejected, as parents could view the high-risk heart as being too risky for surgery even if the medical team determines otherwise. In addition to this factor, families of pediatric patients can interact with transplant centers and cardiologists in legal ways. In 2008, a court case, Longnecker vs Loyola University Medical, was conducted in which the wife of a heart transplant patient filed a suit against the medical center after her husband died following a transplantation. The wife argued that Mr. Longnecker received a marginal "hypertrophic heart" that led to the unsuccessful surgery, and blamed the hospital and its employees for medical negligence by not correctly assessing the heart (Kreisman, 2022). Thus, the risk of facing legal consequences for a poor transplant outcome may cause cardiologists and transplant centers to decline marginal donor hearts, especially when considering the publicity that such legal actions could draw to the center.

It can be seen through this analysis that a large set of actors exist within the pediatric heart transplant setting that impact the donor assessment process. One of the main principles of

Actor Network Theory is that removing an actor from the network will affect the functioning of the entire network. This concept can be applied to the donor assessment process, as removing the regulatory agencies or interactions between cardiologists and other transplant centers could cause a serious disruption to occur. While it may not be necessary to remove these interactions to help reduce discard rates, changes will most likely need to be made with how certain policies and operations are set up to ensure that cardiologists are given as many opportunities as possible to accept donor hearts that they deem appropriate for transplantation.

Conclusion

In conclusion, pediatric heart transplantation has seen a wide range of improvements in its techniques and methods over the past decades, but continues to suffer from high organ discard rates. In an attempt to explain the reasoning for the high discard rates, recent publications have pointed out that there is a lack of clear guidelines for cardiologists to follow when performing a donor assessment, as well as behavioral factors such as omission bias. While these theories may certainly be part of the problem, I present a new argument that emphasizes the network of outside actors involved in the decision-making process which are causing donor hearts to be unnecessarily discarded. This network of actors includes the donor hearts, cardiologists, transplant centers, transplant patients, patient families, regulatory agencies, Medicare and insurance companies, and the general public, all of whom influence the larger donor assessment technological system. Using Latour's Actor Network Theory, clear connections can be drawn between these various actors that influence the behavior of transplant centers and are causing donor hearts that could have saved lives to go unused.

Ideally, members of this external network surrounding the heart transplant decision-making process (with specific emphasis on the transplant centers, insurance companies, and

regulatory agencies) will read this analysis and change how transplant success is evaluated. Other countries' heart transplant policies, as well as policies of different organ transplant networks within the US, have resulted in increased utilization rates, signifying that change is possible and can lead to success (Shweiger et al., 2020). For example, allocation systems used in Spain use protocols that incorporate ramifications for rejecting a donor organ that is later accepted by another team, which encourages teams to consider marginal donors (Butler et al., 2019). Policies such as these should be used by heart transplant actors within the United States as inspiration for how current regulations and criteria can be revised to allow transplant centers and cardiologists to make the best decisions possible.

To build off of this research, case studies could be conducted that look more in-depth at the differences in decision-making and transplant evaluation criteria between the systems in the United States and other countries. Future research could also look at artificial intelligence or risk models and what the implications of taking the human aspect out of decision making could result in. Ultimately, it is with hopeful anticipation that this paper's research, combined with future work, will cause changes to be made within pediatric donor assessment that allow cardiologists to make clear, confident decisions that save hundreds of young childrens' lives each year.

References

Amdani, S., Boyle, G., Rossano, J., Scheel, J., Richmond, M., Arrigain, S., & Schold, J. D. (2021). Association of Low Center Performance Evaluations and Pediatric Heart Transplant Center Behavior in the United States. *The Journal of Heart and Lung Transplantation*, 40(8), 831-840. doi:10.1016/j.healun.2021.04.008

Baez Hernandez, N., Kirk, R., Davies, R., Bano, M., Sutcliffe, D., Pirolli, T., … Butts, R. J. (2020). A comprehensive strategy in donor acceptance: Impact on pediatric waitlist and heart transplant outcomes. *Pediatric Transplantation*, 24(6). https://doi.org/10.1111/petr.13764

Bansal, C. (2023, March 13). Capstone Team Interview (C. Hyldahl; O. Kaczmarskyj; J. Laruffa; A. Wan; A. Miller; & L. Snavely, Interviewers).

Bock, M. (2022). Pediatric Heart Transplantation: Practice Essentials, Background, Indications. EMedicine. Retrieved from https://emedicine.medscape.com/article/1011927-overview#:~:text=According%20to%20the%20registry%20of

Butler, A., Chapman, G., Johnson, J., & Amodeo, A. (2019). Behavioral economics - A framework for donor organ decision-making in pediatric heart transplantation. *Pediatric Transplantation*, 1–8. https://doi.org/10.1111/petr.13655

Contrera, K. (2021, November 01). Evaluating pediatric heart transplant center performances: Unintended consequences and a new way forward. Retrieved February 28, 2023, from https://consultqd.clevelandclinic.org/evaluating-pediatric-heart-transplant-center-performances-unintended-consequences-and-a-new-way-forward/

Conway, J., Ballweg, J. A., Fenton, M., Kindel, S., Chrisant, M., Weintraub, R. G., … Dipchand, A. I. (2020). Review of the impact of donor characteristics on pediatric heart transplant outcomes. *Pediatric Transplantation*, 24(3). https://doi.org/10.1111/petr.13680

Cresswell, K. M., Worth, A., & Sheikh, A. (2010). Actor-network theory and its role in understanding the implementation of information technology developments in Healthcare. *BMC Medical Informatics and Decision Making*, *10*(1). doi:10.1186/1472-6947-10-67

Denfield, S., Azeka, E., & Irving, C. (2020). Pediatric cardiac waitlist mortality - Still too high. *Wiley Periodicals*, 1–6. https://doi.org/10.1111/petr.13671

Dipchand, A. I., & Laks, J. A. (2019). Pediatric heart transplantation: Long-term outcomes. *Indian Journal of Thoracic and Cardiovascular Surgery*, 36(S2), 175-189. doi:10.1007/s12055-019-00820-3

Dipchand, A. I., Kirk, R., Miera, O., & Davies, R. R. (2020). Accepting pediatric donor hearts: How do we make the best decision? *Pediatric Transplantation*, 24(3). https://doi.org/10.1111/petr.13670

Godown, J., Kirk, R., Joong, A., Lal, A. K., McCulloch, M., Peng, D. M., . . . Gossett, J. G. (2019). Variability in donor selection among pediatric heart transplant providers: Results from an international survey. *Pediatric Transplantation*, 23(5). doi:10.1111/petr.13417

Gossett, J. G., Amdani, S., Khulbey, S., Punnoose, A. R., Rosenthal, D. N., Smith, J., … Davies, R. R. (2020). Review of interactions between high-risk pediatric heart transplant

12 recipients and marginal donors including utilization of risk score models. *Pediatric Transplantation*, e13665. https://doi.org/10.1111/petr.13665

Heart Transplant. (2019). Retrieved from Johns Hopkins Medicine website: https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/heart-transplant

Javier, M., Delmo, E., & Hetzer, R. (2021). Evolution of heart transplantation since Barnard's first. *PubMed Central*, 11, 171–182. https://doi.org/10.21037/cdt-20-289

Kreisman, R. (2022). What Proof is Needed for a Transplant Malpractice Action? Retrieved from https://www.robertkreisman.com/what-proof-is-needed-for-a-transplant-malpractice-action.html

Latour, B. (1992). Where are the missing masses? The sociology of a few mundane artifacts. *Shaping Technology/Building Society: Studies in Sociotechnical Change*, 225–258.

Lelkes, E., Patel, A., Joong, A., & Gossett, J. (2020, May 01). Should decision making be shared in high-risk pediatric heart donation? Retrieved March 1, 2023, from https://journalofethics.ama-assn.org/article/should-decision-making-be-shared-high-risk-pediatric-heart-donation/2020-05

Morales, D. L. S., Dreyer, W. J., Denfield, S. W., Heinle, J. S., McKenzie, E. D., Graves, D. E., … Fraser, C. D. (2007). Over two decades of pediatric heart transplantation: How has

13 survival changed? *The Journal of Thoracic and Cardiovascular Surgery*, 133(3), 632–639. https://doi.org/10.1016/j.jtcvs.2006.09.055

Norman, R. (2022, March 16). Long-term success: Stanford's experience in heart transplantation over five decades. Retrieved from Department of Cardiothoracic Surgery website: https://med.stanford.edu/ctsurgery/about-the-department/news/2022/stanford-experience-in-heart-transplantation-over-five-decades.html

OPTN: Organ Procurement and Transplantation Network - OPTN. (n.d.). Retrieved March 13, 2023, from https://optn.transplant.hrsa.gov/

Ornstein, C., & Hixenbaugh, M. (2018, August 17). St. Luke's Heart Transplant Program to lose Medicare funding Today. Retrieved February 28, 2023, from https://www.propublica.org/article/st-lukes-heart-transplant-program-to-lose-medicare-funding-today

Richmond, A. (2023, February 15). Capstone Team Interview (C. Hyldahl; O. Kaczmarskyj; J. Laruffa; A. Wan; A. Miller; & L. Snavely, Interviewers).

Shweiger, M., Everitt, M., & Chen, S. (2020). Review of the discard and/or refusal rate of offered donor hearts to pediatric waitlisted candidates. *Pediatric Transplantation*., 1–7. https://doi.org/DOI: 10.1111/petr.13674

The Scientific Registry of Transplant Recipients (SRTR). (n.d.). Retrieved March 13, 2023, from https://srtr.transplant.hrsa.gov/

Urschel, S., & West, L. J. (2016). Abo-incompatible heart transplantation. *Current Opinion in Pediatrics*, 28(5), 613-619. doi:10.1097/mop.0000000000000398

What is UNOS?: About United Network for Organ Sharing. (2022, April 21). Retrieved March 13, 2023, from https://unos.org/about/#:~:text=UNOS%20is%20involved%20in%20many,that%20occurs%20in%20the%20U.S.

Zafar, F., Castleberry, C., Khan, M. S., Mehta, V., Bryant, R., Lorts, A., . . . Morales, D. L. (2015). Pediatric heart transplant waiting list mortality in the era of ventricular assist devices. *The Journal of Heart and Lung Transplantation, 34*(1), 82-88. doi:10.1016/j.healun.2014.09.018