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Should Decision Making Be Shared in High-Risk Pediatric Heart Donation?

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Abstract

This article considers complexities of shared decision making in pediatric heart transplantation and suggests that decisions about pediatric heart transplantation should be shared between a clinical team and parents. This article also considers goals of shared decision making involving Public Health Service increased-risk donors and recommends policy changes to strengthen decision sharing.

Need for Pediatric Donor Hearts

Heart transplantation (HTx) is the standard of care for children with end-stage heart failure, with approximately 500 pediatric heart transplants performed annually in the United States.¹ A significant shortage of available organs exists, however, leading to long wait list times and significant morbidity. According to the Organ Procurement and Transplantation Network (OPTN), the average waiting time on the list for a pediatric patient from 2007 to 2014 was 115 days, with children ages 1 to 5 years waiting an average of 139 days (OPTN database). Indeed, of the 4392 children listed for HTx during this time frame, 457 (10.4%) died prior to HTx and still others were removed from the waiting list because they became “too sick to transplant.”

In this article, we discuss the complexities and nuances of the decision to proceed with pediatric HTx, and we maintain that this decision should be a truly shared decision between the medical team and the parents of a pediatric patient. We argue that the rules governing discussions about increased-risk donors result in a decreased utilization of donors in a system in which more pediatric donors are needed, despite the negligible risk of infectious transmission.^{2,3} We instead suggest a systematic change in which nondissent is used when increased-risk donors are involved.

Increased-Risk Donors

Limited **organ availability** makes increasing utilization of donor hearts critically important. In 2004, the United Network for Organ Sharing (UNOS) labeled organ donors Public Health Service increased-risk (PHS-IR) donors if they met Centers for Disease Control and Prevention criteria for “high-risk” behaviors (see Table). This donor category is intended to identify donors who, despite being negative for infections such as HIV and

hepatitis on all serologic testing, may have become infected during the short window of time when they could have acquired the disease but tests could be negative. Based on OPTN data, in 2018, 10% of pediatric and 35% of adult donors were labeled “increased risk” for transmission of HIV, hepatitis B (HBV), or hepatitis C (HCV) (OPTN database).

Table. 2013 US Public Health Service Increased Risk Guidelines^a

“MSM [men who have sex with men] in the preceding 12 months
“Non-medical injection drug use in preceding 12 months”
“People who have had sex in exchange for money or drugs in the preceding 12 months”
“People who have had sex with a person known or suspected to have HIV, HBV, or HCV infection in the preceding 12 months”
“Women who have had sex with a man with a history of MSM behavior in the preceding 12 months”
“People who have had sex with a person who had sex in exchange for money or drugs in the preceding 12 months”
“People who have had sex with a person who injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 12 months”
“A child who is \leq 18 months of age and born to a mother known to be infected with, or at increased risk for HIV, HBV, or HCV infection”
“A child who has been breastfed within the preceding 12 months and the mother is known to be infected with, or at increased risk for, HIV infection”
“People who have been in lockup, jail, prison, or a juvenile correctional facility for more than 72 consecutive hours in the preceding 12 months”
“People who have been newly diagnosed with, or have been treated for, syphilis, gonorrhea, Chlamydia, or genital ulcers in the preceding 12 months”
“People who have been on hemodialysis in the preceding 12 months (hepatitis C only)”
“When a deceased potential organ donor’s medical/behavioral history cannot be obtained or risk factors cannot be determined, the donor should be considered at increased risk for HIV, HBV, and HCV infection because the donor’s risk for infection is unknown”
“When a deceased potential organ donor’s blood specimen is hemodiluted, the donor should be considered at increased risk for HIV, HBV, and HCV infection because the donor’s risk for infection is unknown”

^a Adapted from Organ Procurement and Transplantation Network.⁴

Currently, transplant programs are mandated to inform candidates and families about the general risks of disease transmission from organ donors, obtain their permission to consider PHS-IR donors, and then document informed consent (IC) at the time of HTx if the organ is from a PHS-IR donor. Despite a widely publicized adult case of transmission of HIV and HCV from a donor in 2007,⁵ there are no reported cases of donor-derived HIV, HBV, or HCV infections in pediatric solid organs.^{4,5,6,7} The overall risk of an IR donor with negative nucleic acid testing actually transmitting HIV is estimated to be 0.04 to 0.49 per 10 000 donors.⁸ Accepting a PHS-IR organ has not been shown to adversely impact survival of either pediatric or adult heart transplant recipients.^{2,9,10} Nevertheless,

the waiting time for children often exceeds 6 months, with a wait list mortality of more than 10%.¹

Despite the negligible risk of infectious transmission from PHS-IR donors,^{2,3} most grafts from donors that are designated as IR are declined.¹¹ Indeed, heart transplant providers themselves have varied opinions about accepting PHS-IR hearts. (Depending on why the hearts are listed as PHS-IR, 46% to 98% of heart transplant providers would accept these grafts.¹²) And parents are more likely to decline these grafts.¹¹ Not utilizing grafts from these donors leads to a longer wait time, which in turn results in increased mortality risk.¹³ Thus, by excluding PHS-IR donors, the risk of a child not surviving until HTx increases without a correlative improvement in outcome.

Decision Sharing With Pediatric Patients

The decision to pursue HTx for a pediatric patient is best done via a shared decision-making (SDM) approach in which clinicians and parents “make decisions together using the best available evidence” when faced with the task of making decisions and in which parents “are supported to consider options, voice their preferences, and make informed decisions.”¹⁴ Pursuing HTx necessitates agreement and investment by the interdisciplinary medical team and the family. Reaching this agreement involves discussion of myriad complex aspects, each with a unique risk-benefit profile, including death on the waiting list and death after HTx. All of these aspects are discussed as part of the overarching SDM process of opting for (or against) HTx.

Of all of the risks in the decision to pursue HTx, only PHS-IR is singled out for a separate consent at time of organ acceptance,¹⁵ which we believe undermines SDM. It is likely that, by enforcing a separate consent, the OPTN intended parents to explore the implication of a PHS-IR donated heart (the implication being that, in fact, the outcomes are not different but wait times are longer if declined) during the time-sensitive period when they evaluate an offer. However, OPTN’s singling out PHS-IR hearts for a separate consent forces parents to decide in isolation from the clinical expertise of the medical team. This procedural and technical choice discredits the earlier collaborative process in which the decision to proceed with HTx was made.^{16,17} It falsely places the choice to accept a PHS-IR donor heart in an SDM context when it actually belongs within the informed consent model. Specifically, we argue that the choice to proceed with a PHS-IR donor heart is best made via informed nondissent, thus protecting the role of SDM in HTx.^{18,19}

No to Separate Informed Consent

Pediatric patients are thought to have **developing autonomy** and do not give consent for their own medical care; rather, parents provide informed consent.²⁰ Parents do so by acting as surrogate decision makers using the best-interest standard, as they have a fiduciary responsibility to their child to maximize his or her well-being. This responsibility is highlighted in parents’ decision to choose HTx for their child, a decision dictated by their belief in their obligations to their child and respect for their child’s future personhood.

Parents’ decision to pursue HTx is a difficult one and should occur in the context of a rigorous SDM model.²¹ Parents must decide with the health care team if HTx is right for their child, but not necessarily which heart is the best. At the time of listing, disclosure and **counseling of families** about risks, including risks of potential disease transmission from the donor, is a necessary and important part of the SDM approach. Once the

decision has been made to pursue HTx, the transplant providers decide whether specific donor offers are appropriate for a patient. For example, the transplant team will decide whether the upper age limit of the donor or anticipated longer ischemic times (which may result in a worse outcome) are relevant for a given patient and leave these decisions out of the SDM process.²² However, for PHS-IR donor hearts, for which outcomes are equivalent to standard risk donors hearts,² the requirement of additional IC negates the nuanced assessment and responsibility of the providers. Although a transplant team may find a heart acceptable and determine it to be from a “good” donor, the parents’ decision to not accept a PHS-IR heart can overrule this assessment. To do so harms pediatric patients by increasing wait times and risk of death, since there is no evidence of a tangible difference in outcomes with these grafts compared to standard-risk grafts—not only in infectious risks, but also in survival.^{2,9,10}

Following the publicized case of infection transmission from a serologically negative donor in 2008, Halpern et al eloquently argued that standardization of the disclosure of risk to patients awaiting HTx was needed but warned against relaying organ-specific risks: “the disclosure of organ-specific risks may not increase the ability of patients to make welfare-promoting decisions” because “some patients might select organs not on the basis of actual risk,” and “finally, because the organ-specific disclosure of risk requires extra time precisely when time is at a premium, it could prevent the optimal use of the organ supply.”⁷ The UNOS PHS-IR policy, in an attempt to standardize disclosure, instead emphasizes the organ-specific risks.⁴

With improved screening for donors, which is currently being implemented, the risk of contracting HIV, HBV, and HCV from serology-negative donors remain negligible. The risk is akin to minimal risk of transmission of infections with blood product transfusions²³ compared to potentially life-threatening risk of withholding transfusions. Given the evidence that patients who don’t receive an organ have higher rates of mortality than if they receive one from a PHS-IR donor,²⁴ we propose that this policy be modified to respect an overarching shared decision that parents make with their transplant team to pursue HTx for their child.

Proposed Policy Reform

We argue that UNOS and OPTN should reverse the policy that transplant programs must obtain IC at the time of HTx for serology-negative donor hearts with PHS-IR risks identified pretransplantation. Instead, we propose a model of what Kon describes as “informed non-dissent.”^{18,19} In this model, the discussion of PHS-IR donors is integrated into IC for HTx. When parents initially consent to HTx, physicians should disclose the risks of infection transmission from the donor, including but not limited to HIV and hepatitis, and explain the minimal risk of a false negative result associated with PHS-IR donors.²⁵ Equally important is the careful discussion of the context of the dramatically greater risk of mortality from declining these organs. We argue it should be determined at the time of consent if a parent declines the use of grafts from PHS-IR donors, and this decision (which can be revisited as a patient awaits a heart and may be getting sicker) would be part of the HTx team’s determination of which donor heart may be appropriate for the child. This policy reform thus would allow for veracity about what PHS-IR indicates while respecting the autonomous decision of parents to pursue HTx for their child. Resultantly, the decision making would be more comprehensive and truer to the SDM model.

Conclusion

In this proposed policy reform for pediatric HTx, we argue that SDM should be a comprehensive approach at the time of listing for HTx. The necessity for a separate consent at the time of organ offer gives the appearance of higher import and implies that the onus is on the parents—not the transplant team—to make this decision. The weightiness of this responsibility may undo the entirety of the SDM process. If a family and the medical team have decided—together—to pursue HTx for a pediatric patient, the goal for that patient should be to find an acceptable donor as soon as possible. Given the number of children who die each year awaiting HTx, we should remove barriers and increase the utilization of what are ultimately “good” organs. Changing the policy for PHS-IR donors to consent at the time of listing, and thereby honoring SDM for HTx, is a necessary step to improve the mortality of patients awaiting a heart transplant.

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