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A Widening Gap – Fewer Donor Hearts for More Children Waiting

Eleven years ago, we had the pleasure of transplanting a 2-month-old little girl with dilated cardiomyopathy and severe LV dysfunction. She waited on inotropes for 15 days. One year ago, her brother presented at 2 months-old with dilated cardiomyopathy and severe LV dysfunction. Almost identical presentation...except, he waited for 6 months and required a ventricular assist device. Unfortunately, this is not a unique situation; wait times are getting longer. In mid-March, an update about a multi-center study "Improving Pediatric Donor Heart Utilization with Predictive Analytics" went out. Aside from some "great work!" responses, someone lobbed the grenade into the thread "seems like we have been getting fewer offers recently, anyone else?"This exploded into 59 responses, a Doodle poll, a late afternoon Zoom meeting and an acknowledgment that wait times are universally getting longer and declining offers, or fewer donors, is not an isolated, only-at-my-hospital problem but potentially a nationwide crisis.

Using publicly available data from Scientific Registry for Transplant Recipients (SRTR), we found three important trends. First, we confirmed that wait times are indeed increasing for 1A and 1B, although not 2 (Figure 1). Second, we found some interesting donation trends over the last 5 years (Figure 2). There has been a slow, but steady increase in DCD donors through the beginning of 2025, and since then has plateaued. DBD donation has been stagnant over the 5 years but has seen a significant decline in the last 6-12 months, which largely accounts for the overall decrease in donors in that time frame. These national raw numbers seem to confirm the bedside frustration. Thankfully, and through the efforts of this PHTS community, there has not been a change in waitlist mortality during that timeframe. The next obvious question: why?

There are several theories to why the change. I want to highlight some of the ideas here with one main goal in mind: a rallying cry for the pediatric heart transplant community.In many ways, an article in the PHTS Newsletter is preaching to the choir. However, our voices unified with all the stories of heartbreak and success can make a compelling argument for change.

Since COVID-19 spread across the globe, five short (and long) years ago, there have been many changes in all aspects of life.Pediatric heart transplants, despite lockdowns and infectious risk uncertainty, proceeded relatively unimpeded mostly because we had to. Children were going to die without heart transplants. Unfortunately, over the last five years, wait times have been getting longer for many of the smallest patients, despite honest efforts by the United Network for Organ Sharing (UNOS) and its private parter, the Organ Procurement and Transplantation Network (OPTN), as well as individual transplant centers and organ procurement organizations (OPO) across the United States.So then, why is there a widening gap in available donors and desperate candidates?

One reason could simply be that our ability as a pediatric cardiac community in maintaining critically ill children for transplant continues to improve. However idealistic this sounds, this does not appear to be the sole driver as waitlist mortality for those listed status 1A remains around 10-15%.[1] One major barrier to improvement is a lack of new or improved life support options for the smaller pediatric patients. The current ventricular assist device landscape for children < 20 kg relies almost exclusively on paracorporeal systems designed and approved 20+ years ago. Tremendous work has been done through organizations such as Advanced Cardiac Therapies Improving Outcomes Network (ACTION) to improve management with these devices. Infants, especially those with complex congenital heart disease, remain at high risk for decompensation and death while on device.[2]

On the supply side, donation continues to evolve.As we showed above, the last year has had a significant decline in brain-death donors. The overall donation rate has not plummeted quite as much, suggesting there is some mitigation of the decline by DCD donors. Are some of the previously BD donors proceeding to donation via DCD? There are a couple of arguments that suggest some of the DCD donors may have previously been considered for BD donation. In 2023, the consensus guideline for brain death or death by neurologic criteria (DNC) were updated.[3] Observation for patients younger than 24 months must be observed for at least 48 hours prior to initiating BD evaluation, while those over 24 months must be observed for at least 24 hours. Furthermore, stricter guidelines were set up regarding medications that suppress CNS function, such that if levels are unavailable to allow for at least 5 half-lives to pass and longer if there is renal or hepatic dysfunction, as well as account for age-dependent metabolism. For instance, an infant (< 28 days) given a single dose of fentanyl, which has an average half-life of 5.5 hours, which would mean a BD examination is not appropriate for at least 27.5 hours after administration.However, that half-life increases significantly if they were on a fentanyl infusion with half-lives reported as long at 21 hours for children < 14 years who were on continuous infusions.Theoretically, that could delay any BD evaluation for up to 105 hours. These are important safeguards to ensure that BD is permanent. For a family, though, knowing their child is neurologically devastated and considering donation, they may not want to wait multiple days to proceed with withdrawal of life-sustaining therapies or declaration of brain-death. Opting for withdrawal of life-sustaining therapies and choosing DCD donation provides an opportunity for families to give the gift of life without a more prolonged futile hospital stay. It may even be possible to get an initial BD evaluation, find out their child is apneic, and opt to proceed with DCD donation to avoid waiting another 12+ hours for the second exam. To be clear, there is no specific evidence for this practice at this time, but they are real possibilities.

Culminating with the passing of the OPO Final Rule (42 C.F.R pt. 486) in December 2020, there has been a growing push by CMS to increase overall organ donation in the United States. The OPO Final Rule implemented two, and only two, metrics for OPOs by which they maintain certification: donation rates (number of actual donors compared to potential donors) and transplant rates (number of organs transplant compared to potential donors). There has been speculation that this has led to a push for abdominal organ donation via DCD at the potential expense of heart donation, where abdominal normothermic regional perfusion (NRP) has not been as controversial as thoraco-abdominal NRP.

Another temporal relationship noted with donations has to do with public relations. An investigation that started in 2020 by the Senate Finance Committee found “serious errors in the procurement and transplant system are shockingly common.” In 2021, a US Digital

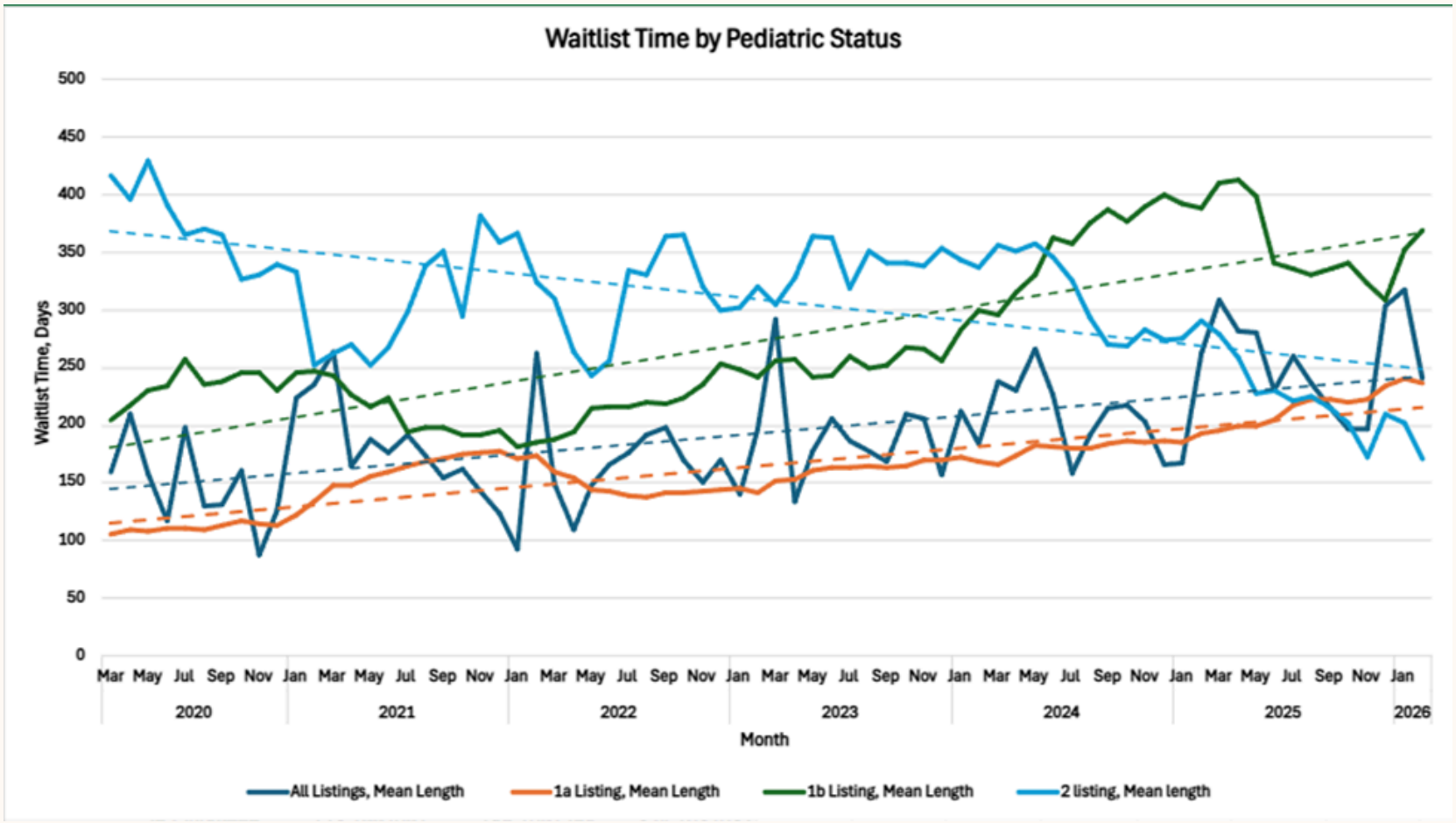
report titled “Lives Are at Stake” found multiple concerns with the technologies used by UNOS to run their systems.[4]Then in August 2022, a Department of Health and Human Services (DHHS) Office of the Inspector General report noted multiple basic cybersecurity failures going so far as to conclude “UNOS has been the sole organization managing the OPTN, during which time concerning reports have emerged that organ donation system has become unsafe, inequitable, self-dealing and retaliatory.”[5] On September 22, 2023, the US Congress passed the US Procurement and Transplantation Network Act (commonly known as the OPTN Modernization Act) to try to address many of the concerns brought up through government investigations. With both this much focus on the problems, as well as increased government meddling in a time of extreme partisanship, it likely casts significant doubts on the integrity and altruism of organ donation.

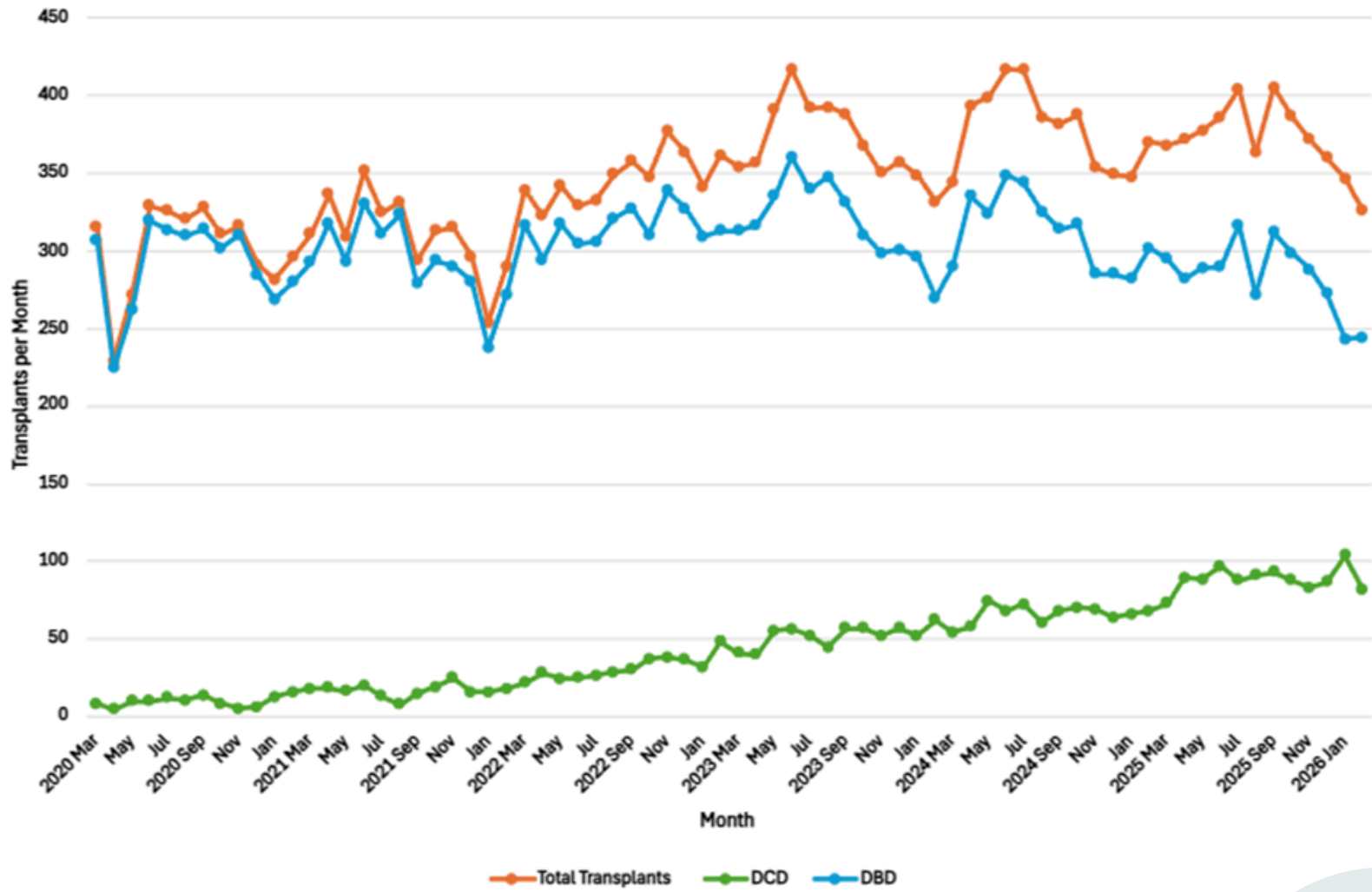
Simultaneously, major media outlets including the New York Times and the Washington Post published a series of investigative articles on the US transplant system that highlighted through narrative some of systemic problems in the system. While sound journalism and reasonable reporting were the norm, sensational headlines such as “Lives Lost, Organs Wasted”[6] and “Organ Transplant System ‘in Chaos’ as Waiting Lists are Ignored”,[7] may have provided additional anecdotal fuel for potential donors to back out.
The bottom line is that the waiting times for pediatric heart transplantation continue to get longer with fewer donors for more recipients. PHTS is poised to bring together key stakeholders including OPTN, OPOs, transplant hospitals and, most importantly, transplant donors and recipients and their families to explore the root causes of this shift. Reforms are needed – and it is a matter of life and death.

Special thanks to Mike McCulloch at University of Virginia for pushing the donor science forward and accidentally starting an online riot; to Brian Madden at Lurie Children’s for deftly pulling and quickly analyzing the SRTR data; and to the 34 other pediatric heart transplant folks on our initial discussion about how best to sound the alarm on this important issue.

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Waitlist Time by Pediatric Status
Waitlist Time, Days
500
450
400
350
300
250
200
150
100
50
0
Mar May Jul Sep Nov Jan Mar May Jul Sep Nov Jan Mar May Jul Sep Nov Jan Mar May Jul Sep Nov Jan Mar May Jul Sep Nov Jan Mar May Jul Sep Nov Jan
2020
2021
2022
2023
2024
2025
2026
Month
All Listings, Mean Length
1a Listing, Mean Length
1b Listing, Mean Length
2 listing, Mean length


Transplants by DBD or DCD
Transplants per Month
450
400
350
300
250
200
150
100
50
0
2020 Mar May Jul 2020 Sep Nov Jan 2021 Mar May Jul 2021 Sep Nov Jan 2022 Mar May Jul 2022 Sep Nov Jan 2023 Mar May Jul 2023 Sep Nov Jan 2024 Mar May Jul 2024 Sep Nov Jan 2025 Mar May Jul 2025 Sep Nov 2026 Jan
Month
Total Transplants
DCD
DBD