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# Association of low center performance evaluations and pediatric heart transplant center behavior in the United States



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## KEYWORDS:

pediatric;  
heart transplant;  
center behavior;  
low center  
performance;  
program specific  
reports

**BACKGROUND:** To date, no study has evaluated the effects of low center performance evaluations (CPE) on pediatric heart transplant center behavior. We sought to assess the impact of low CPE flags on pediatric heart transplant center listing and transplant volumes and center recipient and donor characteristics.

**METHODS:** We included centers performing at least 10 pediatric (age <18 years) transplants during the Scientific Registry of Transplant Recipients reporting period January 2009-June 2011 and evaluated consecutive biannual program specific reports until the last reporting period January 2016-June 2018. We evaluated changes in center behavior at following time points: a year before flagging, a year and two years after the flag; and at last reporting period.

**RESULTS:** During our study period, 24 pediatric centers were non-flagged and 6 were flagged. Compared to non-flagged centers, there was a decline in candidate listings in flagged centers at the last reporting period (mean *increase* of  $5.5 \pm 12.4$  listings vs mean *decrease* of  $14.0 \pm 14.9$  listings;  $p = .003$ ). Similarly, the number of transplants declined in flagged centers (mean *increase* of  $2.6 \pm 9.6$  transplants vs mean *decrease* of  $10.0 \pm 12.8$  transplants;  $p = .012$ ). Flagged centers had declines in listings for patients with restrictive cardiomyopathy, re-transplant, renal dysfunction, those on mechanical ventilation and extracorporeal membrane oxygenation. There was no significant change in donor characteristics between flagged and non-flagged centers.

**CONCLUSIONS:** Low CPE may have unintended negative consequences on center behavior leading to declines in listing and transplant volumes and potentially leading to decreased listing for higher risk recipients.

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**Abbreviations:** SRTR, scientific registry of transplant recipients; CPE, center performance evaluations; CMS, Centers for Medicare and Medicaid Services; OPTN, Organ Procurement and Transplantation Network; HRSA, Health Resources and Services Administration; PSR, program specific reports; DCM, dilated cardiomyopathy; ECMO, extracorporeal membrane oxygenation; eGFR, estimated glomerular filtration rate

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## Introduction

Public reporting of program outcomes and performance running surgical specialties and organ transplantation is controversial. Various reports have shown that reporting of outcomes often has negative consequences. While the intent of such policies is to encourage best practices, oftentimes institutions are reluctant to take on complex or severely ill patients with the concern that publicly available inferior outcomes may lead to negative publicity.<sup>1-3</sup>

The field of transplantation is not immune to these unintended consequences of public performance reporting. Since 2007, publicly reported risk-adjusted outcomes have been included in biannual Scientific Registry of Transplant Recipients (SRTR) reports and used as a primary measure of transplant center quality. With this, centers with low center performance evaluations (CPE) are at risk for “flagging” by the Centers for Medicare and Medicaid Services (CMS) and stand to lose insurance funding both from CMS and private insurance companies.<sup>4,5</sup> It has been shown amongst adult patients awaiting liver and kidney transplantation that low CPE are associated with lower center transplant volumes and increased rates of candidate removal from the waitlist.<sup>6-9</sup>

To date, there have been no studies evaluating how CPE affect pediatric heart transplant center behavior. Thusly, we designed a study with the primary hypothesis that pediatric heart transplant centers with lower CPE were more likely to decrease listing and transplant volumes compared to centers who have never received a low CPE “flag”. Our secondary hypothesis was that centers with lower CPE were more likely to decrease acceptance of higher-risk recipients and donors. We assessed both short-term and long-term change in center behavior by examining changes a year before and a year and two years after centers were flagged as well as changes between the beginning and end of our study period.

## Methods

### Data source

For our study, we used two data sources from the SRTR. This study was exempted from approval by the Cleveland Clinic Institutional Review Board and informed consent was waived because data obtained from routine care were completely de-identified by SRTR prior to their transmission to the investigators.

The first source was patient level data. The SRTR data system includes data on all donor, wait-listed candidates, and transplant recipients in the United States, submitted by the members of the Organ Procurement and Transplantation Network (OPTN), and has been described elsewhere.<sup>10</sup> The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors.

The second source was SRTR national center-level program specific reports (PSR) obtained directly from the SRTR website.<sup>11</sup> These program specific reports contain detailed information about the number of candidates/recipients eligible for each report and pre- and post-transplant performance (e.g., observed and expected events and statistical significance of centers’ standardized mortality ratios). These reports are generated every six months, covering a 2.5-year period

and are used when deciding whether programs meet the required benchmark for post-transplant survival. It is these reports that can lead to a “flag” for low center performance.

### Study cohort

This study included all heart transplant centers that performed at least 10 pediatric (age <18 years) transplants during the reporting period January 2009 - June 2011 (Figure 1). No centers were flagged at the time of the first reporting period. Centers performing <10 transplants over the 2.5-year period were excluded since flagging rules for such centers differ<sup>5,12,13</sup> and because of reduced ability to assess changes in case mix and transplant center volume with sufficient statistical power at these smaller centers. We evaluated consecutive biannual PSR. The last period for which PSR was available was January 2016 -June 2018. We chose the first period available as our “first reporting period” and the last period available as our “last reporting period”.

### Flagging criteria

We looked at whether each center was flagged at any time after the first period. A flag was separately calculated for one-year graft and patient survival. A center was considered flagged if they received either graft survival or patient survival flags based on CMS criteria. A low CPE flag occurs when all 3 of the following conditions are met, with events referring to graft losses or deaths within one year of transplantation<sup>5</sup>:

- a. Observed events -Expected events >3
- b. Observed events /Expected events >1.5
- c. 1-sided  $p < .05$ .

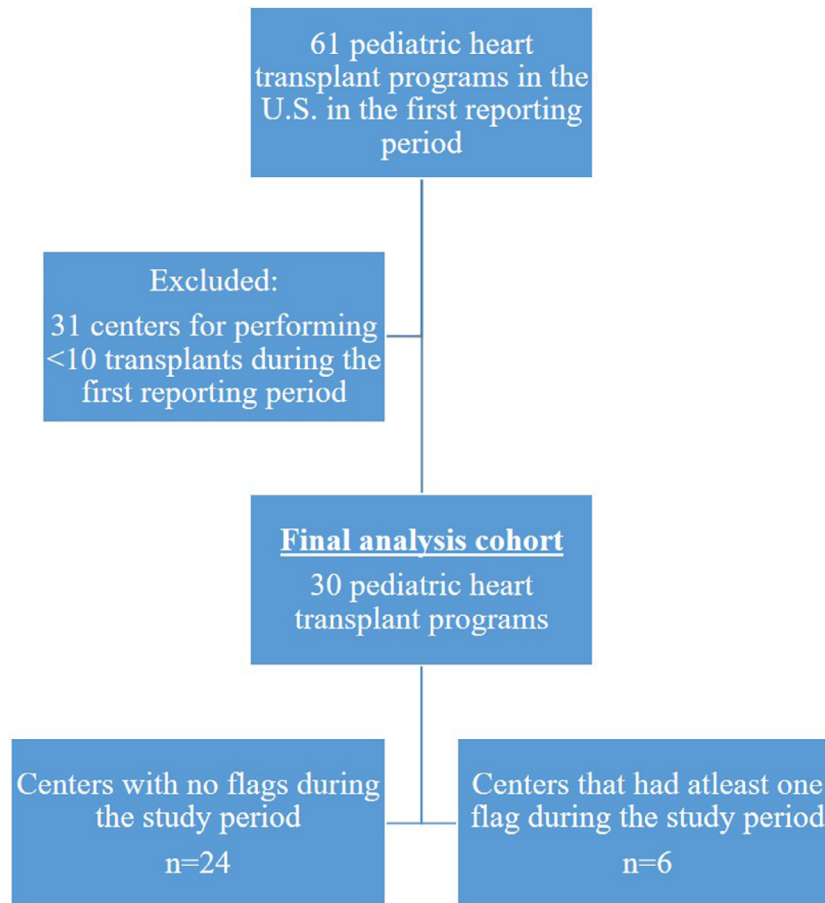
### Study outcomes

Our primary outcome was change in center candidate listing and transplant volume between centers with a flag for lower CPE compared to centers who have never received a low CPE flag. Our secondary outcomes were a change in recipient and donor characteristics in centers with a flag for low CPE compared to centers who have never received a low CPE flag.

### Analysis

Centers were divided into two cohorts: those with no flags for low CPE during the study period (non-flagged centers) and those that had flags for low CPE at any time during the study period (flagged centers). We evaluated changes in the number of listings; number of transplants, recipient and donor characteristics at the following time points: (a) first (January 2009-June 2011) and last reporting period (January 2016-June 2018); (b) a year before and after the center was flagged; and (c) a year before and two years after the center was flagged. Flagged centers had their first flag on the periods ending: December 31, 2011 (n = 2), 12/31/2013 (n = 1), 06/30/2014 (n = 1), 12/31/2014 (n = 2). To assure similar comparison time frame for non-flagged centers, we decided to choose December 31, 2013 as the “flagging date” for the non-flagged centers. Therefore, the 1-year “post-flag” time period for the non-flagged centers is December 31, 2013- December 31, 2014.

To evaluate changes from first to last reporting period, 1-year before and after flag and 1-year before and 2 years after the flag,



**Figure 1** Study cohort.

we calculated the mean of continuous listing, recipient and donor characteristics, and the percentage within each categorical characteristic. For each center, we calculated the difference in mean/percent between the first and the last period. We then compared the first reporting period characteristics, last reporting period characteristics, and changes between flagged and non-flagged using t-tests. We graphed the number of listings in the first and last reporting periods for centers that received a flag and those that didn't receive a flag using boxplots, and evaluated the change in listings and transplants within the flagged group and within the non-flagged group using paired t-tests. Similarly, we graphed the number of transplants and the changes in volume. We also evaluated volume change as percent change from first to last reporting period, and compared flagged centers to non-flagged centers using t-tests. Results were evaluated for consistency using non-parametric Wilcoxon-rank sum tests.

We evaluated changes in observed and expected patient survival between flagged and non-flagged centers at first and last reporting period using t-test. We also evaluated changes in observed and expected patient survival within flagged and non-flagged centers at first and last reporting period using paired sample t-test. A two-sided  $p$ -value of  $<.05$  was considered statistically significant. All analyses were conducted in SAS v. 9.4 (Cary, NC, USA).

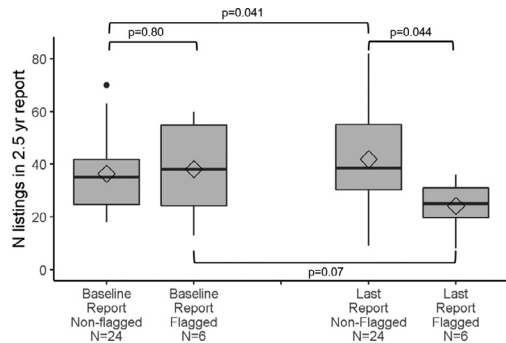
## Results

During our study period, there were 30 pediatric HT centers that met the inclusion criteria. Of these, 6 centers were flagged for low CPE (Figure 1).

### Changing listing and transplant volumes among non-flagged centers and centers flagged for low performance

There was no difference in the mean number of patients listed for heart transplantation between flagged and non-flagged centers during the first 2.5-year reporting period ( $38.2 \pm 19.8$  vs  $36.4 \pm 14.1$ ;  $p = .80$ ). While there was no difference in number of listings between both groups the year after the flag (mean  $10.7 \pm 3.8$  vs  $16.9 \pm 9.8$  among flagged vs non-flagged centers respectively;  $p = .14$ ), and two years after the flag (mean  $12.5 \pm 7.2$  vs  $16.3 \pm 7.6$  among flagged vs non-flagged centers respectively;  $p = .27$ ), there was a significant difference in the number of candidate listings during the last reporting period between flagged and non-flagged centers ( $24.2 \pm 10.1$  vs  $41.9 \pm 19.7$ ;  $p = .044$ ) (Figure 2).

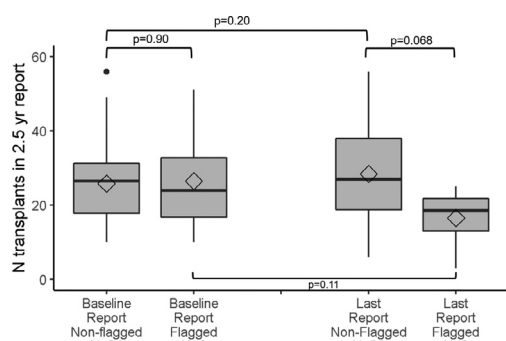
There was no difference in the mean number of patients transplanted at flagged and non-flagged centers during the first reporting period ( $26.5 \pm 14.8$  vs  $25.8 \pm 11.5$ ,  $p = .90$ ). Again, there were no differences in the number of transplants between both groups the year after the flag (mean  $6.3 \pm 2.9$  vs  $11.3 \pm 6.8$  among flagged vs non-flagged centers respectively;  $p = .10$ ) and two years after the flag (mean  $8.8 \pm 4.8$  vs  $12.4 \pm 6.7$  among flagged vs non-flagged centers respectively;  $p = .23$ ). While there was a trend towards lower transplant volume at flagged centers during the last



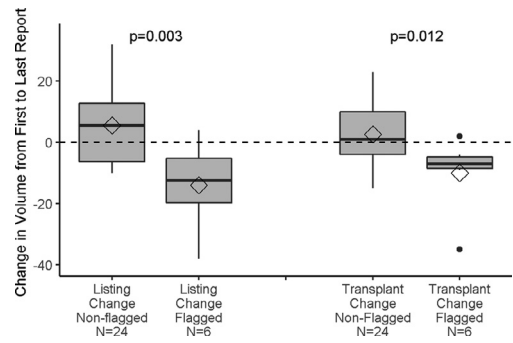
**Figure 2** Number of patients listed for heart transplantation at flagged and non-flagged centers during the first and last reporting period. The box in the boxplot is drawn from the 25th to the 75th percentile, with a line across at the median. The diamond shows the mean. The whiskers go from the minimum to the maximum, and outliers are shown as points.

reporting period this did not achieve significance ( $16.5 \pm 8.1$  vs  $28.4 \pm 14.6$  among flagged vs non-flagged centers respectively;  $p = .068$ ) (Figure 3).

During the study period, there was a decline in candidate listings at centers flagged for low CPE vs a rise in candidate listings at non-flagged centers (mean decrease of  $14.0 \pm 14.9$  vs mean increase of  $5.5 \pm 12.4$  listings;  $p = .003$ ). Similarly, the number of transplants declined in centers flagged for low CPE compared to a rise in the number of transplants in non-flagged centers (mean decrease of  $10.0 \pm 12.8$  vs mean increase of  $2.6 \pm 9.6$  transplants;  $p = .012$ ) (Figure 4). When evaluating percent change in listings from baseline to last reporting period, we found mean percent decrease of  $30.3 \pm 26.4$  listings at flagged centers vs mean percent increase of  $14.1 \pm 35.4$  listings at non-flagged centers ( $p = .008$ ; results consistent with Wilcoxon rank-sum test  $p = .007$ ). When evaluating percent changes in transplants, we found a mean percent decrease of  $34.0 \pm 30.7$  transplants vs mean percent increase of  $10.7 \pm 41.5$  transplants at non-flagged centers ( $p = .02$ ; results consistent with Wilcoxon rank-sum test  $p = .026$ ).



**Figure 3** Number of patients transplanted at flagged and non-flagged centers during the first and last reporting period. The box in the boxplot is drawn from the 25th to the 75th percentile, with a line across at the median. The diamond shows the mean. The whiskers go from the minimum to the maximum, and outliers are shown as points.



**Figure 4** Change in the volume of patients listed and transplanted from first reporting period to last reporting period at flagged and non-flagged centers. The box in the boxplot is drawn from the 25th to the 75th percentile, with a line across at the median. The diamond shows the mean. The whiskers go from the minimum to the maximum, and outliers are shown as points. P-values shown in the plot are for comparison of flagged vs non-flagged centers.

### Assessing short term (1-year before and 1 and 2-years after flag) and long-term (between first and last reporting period) changes in recipient and donor characteristics in response to flags for low center performance

#### Candidate listing characteristics

A year prior to the flag, centers flagged for low CPE had significantly lower proportion of dilated cardiomyopathy (DCM) (22.5 vs 41%) and a higher proportion of patients requiring re-transplantation (11.7 vs 3.1%). Flagged centers also had a higher proportion of patients on extracorporeal membrane oxygenation (ECMO) (19 vs 6.3%) and renal dysfunction [estimated glomerular filtration rate (eGFR)  $<90$  ml/min/1.73m<sup>2</sup>] (47.3% vs 24.5%) ( $p < .05$  for all). A year after the flag however, there were no differences in these characteristics between flagged and non-flagged centers ( $p > .05$  for all). The only difference noted in the year after the flag was that flagged centers had a higher proportion of UNOS Status 1A listings (79.9% vs 61.1%;  $p = .045$ ). Evaluating change in listing characteristics between flagged and non-flagged centers a year before and after flagging, there were three significant differences: decline in restrictive cardiomyopathy (RCM) listings at flagged centers vs rise in non-flagged centers ( $-5.4$  vs  $+0.94\%$ ;  $p = .047$ ); decline in re-transplant listings at flagged centers vs rise in non-flagged centers ( $-7.9$  vs  $+2.4\%$ ;  $p = .012$ ); and decline in listings with renal dysfunction at flagged centers vs rise in non-flagged centers ( $-14.1$  vs  $+2.6\%$ ;  $p = .038$ ). Evaluating changes in listing characteristics between flagged and non-flagged centers a year before and two years after flagging there were four significant differences noted: Flagged centers compared to non-flagged centers continued to demonstrate a decline in RCM ( $-5.7$  vs  $+0.86\%$ ;  $p = .049$ ) and re-transplant listings ( $-6.2$  vs  $+5.9\%$ ;  $p = .019$ ). However, there were also significant declines in patients listed with mechanical ventilation

(-23.6% vs -1.05%;  $p = .002$ ) and ECMO (-15.0 vs +1.1%;  $p = .005$ ) two years after the flag. (Table 1 and Table S1).

When evaluating changes in candidate listing characteristics between flagged and non-flagged centers from first to last reporting period, we did not find any significant differences (Table S2).

### Donor characteristics

A year prior to the flag, centers flagged for low CPE had significantly higher number of African-American donors (41.2 vs 19.9%) and a higher proportion of donor-recipient sex mismatch (62.7 vs 42.8%). A year after the flag, flagged centers had a higher proportion of Caucasian donors (68.8 vs 45.6%) ( $p < .05$  for all). Evaluating change in donor characteristics between flagged and non-flagged centers a year before and after flagging, the only significant difference noted was a rise in the proportion of Caucasian donors in flagged centers (+22.1 vs -9.6%;  $p = .049$ ) (Table 2). Evaluating change in donor characteristics between flagged and non-flagged centers a year before and two years after flagging, the only significant difference noted was a rise in the proportion of donors with history of drug abuse in flagged centers (+14.9 vs +0.17%;  $p = .016$ ) (Table S3). When evaluating changes in donor characteristics between flagged and non-flagged centers from first to last reporting period, flagged centers decreased acceptance of CDC increased risk donors, with a rise of such donors seen in non-flagged centers but this was not statistically significant (-1.9 vs +5.8%;  $p = .055$ ) (Table S4).

### Changing post-transplant patient survival between non flagged centers and centers flagged for low center performance

1-year *observed* survival at first and last reporting period were not significantly different either within or between flagged or non-flagged centers. *Expected* patient survival improved at both flagged and non-flagged centers ( $p = .016$  and  $p < .001$  respectively), however, there were no significant differences in *expected* survival between flagged and non-flagged centers at first or last reporting period. (Table 3).

## Discussion

Ours is the first study evaluating the possible impact of low CPE on pediatric heart transplant center behavior. Our study has two main findings: (a) Centers flagged for low CPE demonstrate a decline in the number of listings and transplantations. (b) Flagging centers for low CPE can potentially lead to decreased listing for higher risk recipients.

The CMS condition of participation required transplant programs to maintain patient and graft survival rates up to 1-year within a tolerance limit set by CMS that is risk adjusted for recipient, donor and organ characteristics. Achieving these risk adjusted post-transplant outcomes are essential for continued certification and reimbursement.<sup>4,5</sup> While the intent of setting these standards is to improve

transplant center performance, our study highlights the often overlooked and unintended consequences of such scrutiny and criticism.

Transplant teams have significant discretion when listing patients for transplantation. The listing practices at transplant centers can be variable<sup>14</sup> and the decision to list someone for transplant may include psychological factors such as those shown to affect donor organ acceptance.<sup>15</sup> The effect of low CPE on adult liver and kidney transplant programs has been explored before.<sup>6-8</sup> Buccini et al. evaluated the effects of low performance evaluation on adult liver transplant programs in the U.S. and found that centers flagged for low performance had significant reductions in listings, transplants and in utilization of higher risk donors.<sup>6</sup> Studies highlighting the impact of low CPE on kidney transplant center behavior have found that centers with low CPE tend to have increased waitlist removals and declining transplant volumes after being flagged.<sup>7,8</sup> Similarly, in our study, we saw a decline in the number of listings and transplants at pediatric heart transplant centers that were flagged for low center performance. What was striking was that such declines in listing and transplant volume may be seen for years after the flag, potentially highlighting the long-lasting effects of such flagging.

There seems to be a complex effect on the selection of recipients at centers that are flagged by CMS for low center performance. In our study, we found that the immediate effects of flagging as assessed by changes in behavior in the first few years after flagging is to decrease recipient case complexity. We found that in the year immediately after the flag, the proportion of patients listed for RCM declined by ~5%, re-transplant by ~8% and renal dysfunction by ~14%. Two years after the flag there continued to be declines in patients listed with RCM and re-transplantation, but there were now lower number of patients listed with mechanical ventilation and ECMO. Various pediatric studies have highlighted mechanical ventilation, ECMO and renal dysfunction as risk factors for post-HT mortality.<sup>16-18</sup> The ISHLT pediatric report of 2014 highlighted that re-transplantation was associated with post-HT mortality both in the short and long-term (at 1,5, 10 and 15 years).<sup>18</sup> Similarly RCM has been shown to be a risk factor for post-transplant mortality.<sup>19,20</sup> It was interesting to note that by the end of the study period (which was 3.5-6.5 years from the time the center was flagged for low center performance), the above-mentioned significance was no longer observed. It leads us to speculate, that fortunately as the centers get further away from the time of the flag, they are no longer as conservative in their approach to selection of recipients. As far as changes in donor selection after flagging, it appeared that before flagging, centers were more willing to transplant from a sex-mismatched donor. It has been shown that sex-mismatched donor-recipient pairs lead to inferior post-HT outcomes.<sup>21,22</sup>

In our study, what is notable is that flagged centers became more conservative in their approach in addition to limiting the number of candidates listed and transplanted. Importantly, flagging did not lead to a greater relative improvement in patient survival at flagged centers over those that were not flagged. A previous study that surveyed

**Table 1** Changes in Listing Candidate Characteristics and Wait-List Duration Among Those Transplanted at Centers With and Without Flags for Low Center Performance One Year Before and After Flag

Listed patient characteristics	Non-flagged centers 1-year before flag (N = 24)	Flagged centers 1-year before flag (N = 6)	<i>p</i> value	Non-flagged centers 1-year after flag (N = 23*)	Flagged centers 1-year after flag (N = 6)	<i>p</i> value	Differences in characteristic in non-flagged centers (N = 23*)	Differences in characteristic in flagged centers (N = 6)	<i>p</i> value
Age (years)	5.4 ± 1.8	4.7 ± 1.4	.36 <sup>a</sup>	6.0 ± 1.6	6.0 ± 2.4	.95 <sup>a</sup>	0.66 ± 2.5	1.3 ± 3.1	.61 <sup>a</sup>
Age < 1 (%)	37.2 ± 11.8	43.8 ± 16.2	.27 <sup>a</sup>	33.5 ± 16.0	41.8 ± 14.2	.26 <sup>a</sup>	-4.0 ± 22.8	-2.0 ± 24.2	.85 <sup>a</sup>
Height (cm)	100.8 ± 13.5	93.6 ± 10.5	.24 <sup>a</sup>	104.3 ± 12.6	102.3 ± 16.1	.74 <sup>a</sup>	4.0 ± 19.1	8.6 ± 21.3	.61 <sup>a</sup>
Weight (kg)	23.9 ± 8.5	19.9 ± 6.5	.28 <sup>a</sup>	24.8 ± 6.6	23.6 ± 8.0	.72 <sup>a</sup>	0.93 ± 10.7	3.7 ± 11.1	.57 <sup>a</sup>
Sex (%)									
Male	53.0 ± 13.5	52.6 ± 8.2	.94 <sup>a</sup>	55.3 ± 13.8	54.3 ± 22.0	.89 <sup>a</sup>	2.6 ± 22.0	1.7 ± 25.6	.94 <sup>a</sup>
Female	47.0 ± 13.5	47.4 ± 8.2	.94 <sup>a</sup>	44.7 ± 13.8	45.7 ± 22.0	.89 <sup>a</sup>	-2.6 ± 22.0	-1.7 ± 25.6	.94 <sup>a</sup>
Race/ethnicity (%)									
Caucasian	50.5 ± 20.7	66.2 ± 15.5	.094 <sup>a</sup>	47.5 ± 15.7	55.0 ± 15.5	.31 <sup>a</sup>	-2.1 ± 18.8	-11.2 ± 22.6	.32 <sup>a</sup>
African american	23.3 ± 21.6	22.8 ± 15.6	.96 <sup>a</sup>	24.3 ± 18.4	31.1 ± 16.2	.41 <sup>a</sup>	0.86 ± 15.0	8.3 ± 22.0	.33 <sup>a</sup>
Hispanic	20.9 ± 19.5	5.6 ± 8.3	.073 <sup>a</sup>	21.5 ± 16.8	9.2 ± 9.3	.098 <sup>a</sup>	0.13 ± 18.7	3.6 ± 3.8	.66 <sup>a</sup>
Other	5.4 ± 9.5	5.4 ± 8.7	.99 <sup>a</sup>	6.7 ± 9.1	4.7 ± 8.2	.63 <sup>a</sup>	1.1 ± 9.1	-0.69 ± 6.7	.65 <sup>a</sup>
Diagnosis (%)									
DCM	41.0 ± 21.2	22.5 ± 7.0	<b>.045<sup>a</sup></b>	35.3 ± 16.6	35.1 ± 17.4	.98 <sup>a</sup>	-6.2 ± 22.3	12.6 ± 16.6	.065 <sup>a</sup>
RCM	3.8 ± 4.8	6.4 ± 7.3	.30 <sup>a</sup>	4.5 ± 5.6	1.04 ± 2.6	.15 <sup>a</sup>	0.94 ± 6.3	-5.4 ± 8.0	<b>.047<sup>a</sup></b>
HCM	3.0 ± 6.5	1.2 ± 2.9	.51 <sup>a</sup>	3.1 ± 4.5	2.4 ± 3.8	.76 <sup>a</sup>	0.77 ± 7.7	1.2 ± 5.5	.89 <sup>a</sup>
CHD	47.1 ± 19.6	57.3 ± 12.2	.24 <sup>a</sup>	49.9 ± 15.0	57.6 ± 15.7	.28 <sup>a</sup>	2.5 ± 22.5	0.31 ± 21.5	.83 <sup>a</sup>
Re-transplant	3.1 ± 5.8	11.7 ± 7.3	<b>.005<sup>a</sup></b>	5.7 ± 6.1	3.8 ± 6.8	.52 <sup>a</sup>	2.4 ± 7.0	-7.9 ± 12.7	<b>.012<sup>a</sup></b>
Listing Status (%)									
1A	72.4 ± 17.2	76.3 ± 21.9	.64 <sup>a</sup>	61.1 ± 20.2	79.9 ± 15.9	<b>.045<sup>a</sup></b>	-11.0 ± 18.4	3.6 ± 17.4	.092 <sup>a</sup>
1B/2	25.1 ± 17.6	20.4 ± 16.0	.56 <sup>a</sup>	36.7 ± 19.4	17.0 ± 13.4	<b>.027<sup>a</sup></b>	11.0 ± 20.3	-3.4 ± 13.2	.11 <sup>a</sup>
Blood Type O (%)	50.8 ± 16.8	39.9 ± 9.0	.14 <sup>a</sup>	43.2 ± 13.1	48.7 ± 13.7	.37 <sup>a</sup>	-7.6 ± 22.9	8.9 ± 17.6	.11 <sup>a</sup>
ECMO (%)	6.3 ± 8.1	19.0 ± 8.9	<b>.002<sup>a</sup></b>	7.3 ± 8.8	10.4 ± 10.3	.46 <sup>a</sup>	1.6 ± 11.0	-8.6 ± 14.8	.070 <sup>a</sup>
Ventilator (%)	20.2 ± 16.0	31.2 ± 13.0	.13 <sup>a</sup>	20.8 ± 15.3	28.1 ± 16.3	.32 <sup>a</sup>	-0.20 ± 17.1	-3.1 ± 24.8	.74 <sup>a</sup>
IV Inotropes (%)	46.8 ± 25.6	57.7 ± 17.7	.33 <sup>a</sup>	44.7 ± 26.2	48.1 ± 16.2	.76 <sup>a</sup>	-4.1 ± 21.3	-9.6 ± 19.2	.57 <sup>a</sup>
VAD (%)	12.5 ± 14.2	6.4 ± 7.3	.32 <sup>a</sup>	10.0 ± 10.2	8.9 ± 9.8	.83 <sup>a</sup>	-3.1 ± 17.0	2.6 ± 12.5	.45 <sup>a</sup>
eGFR < 90ml/min/1.73m <sup>2</sup> (%)	24.5 ± 12.8	47.3 ± 19.3	<b>.001<sup>a</sup></b>	27.2 ± 17.9	33.2 ± 14.6	.45 <sup>a</sup>	2.6 ± 17.9	-14.1 ± 10.4	<b>.038<sup>a</sup></b>
Medicaid (%)	48.5 ± 20.4	53.9 ± 18.0	.56 <sup>a</sup>	48.5 ± 16.3	64.3 ± 24.1	.066 <sup>a</sup>	-1.2 ± 18.2	10.4 ± 17.9	.17 <sup>a</sup>
Private Insurance (%)	43.0 ± 14.5	43.3 ± 18.6	.96 <sup>a</sup>	42.7 ± 15.5	34.3 ± 25.0	.31 <sup>a</sup>	0.39 ± 15.9	-9.0 ± 20.3	.23 <sup>a</sup>
Waitlist duration (among transplanted)*	105.6 ± 57.5	152.0 ± 137.2	.20 <sup>a</sup>	179.2 ± 149.8	134.6 ± 103.4	.50 <sup>a</sup>	78.0 ± 129.3	-17.5 ± 49.7	.091 <sup>a</sup>

CHD: congenital heart disease; DCM: dilated cardiomyopathy; ECMO: extracorporeal membrane oxygenation; eGFR: estimated glomerular filtration rate; HCM: hypertrophic cardiomyopathy; IV: intravenous; RCM: restrictive cardiomyopathy; VAD: ventricular assist device.

Statistics presented as Mean ± SD; *p*-values: a = *t*-test.

Bolded *p* values significant (*p* < 0.05).

\*N = 23 because 1/24 centers had 0 listings and transplant recipients in the year post flag and only change in volume was available; changes in all listing characteristics for that center were missing.



**Table 2** Changes in Donor Characteristics at Centers with and Without Flags for Low Center Performance One Year Before and After Flag

Donor characteristics	Non-flagged centers 1-year before flag (N = 24)	Flagged centers 1-year before flag (N = 6)	p value	Non-flagged centers 1-year after flag (N = 23*)	Flagged centers 1-year after flag (N = 6)	p value	Differences in characteristic in non-flagged centers (N = 23*)	Differences in characteristic in flagged centers (N = 6)	p value
Age (years)	8.3 ± 2.8	6.0 ± 1.9	.063 <sup>a</sup>	8.2 ± 3.0	7.4 ± 5.0	.64 <sup>a</sup>	-0.04 ± 4.2	1.5 ± 6.1	.48 <sup>a</sup>
Height (cm)	120.4 ± 19.4	109.0 ± 18.6	.21 <sup>a</sup>	116.6 ± 18.2	115.0 ± 24.0	.85 <sup>a</sup>	-2.9 ± 28.0	5.9 ± 38.8	.53 <sup>a</sup>
Weight (kg)	34.4 ± 11.1	27.3 ± 7.0	.15 <sup>a</sup>	32.4 ± 11.1	31.0 ± 14.6	.81 <sup>a</sup>	-1.6 ± 15.5	3.7 ± 20.0	.48 <sup>a</sup>
Sex (%)									
Male	62.5 ± 15.2	69.4 ± 19.3	.36 <sup>a</sup>	56.9 ± 21.8	54.4 ± 29.4	.81 <sup>a</sup>	-3.9 ± 22.5	15.0 ± 47.8	.41 <sup>a</sup>
Female	37.5 ± 15.2	30.6 ± 19.3	.36 <sup>a</sup>	43.1 ± 21.8	45.6 ± 29.4	.81 <sup>a</sup>	3.9 ± 22.5	15.0 ± 47.8	.41 <sup>a</sup>
Race/Ethnicity (%)									
Caucasian	57.1 ± 19.2	46.6 ± 28.9	.29 <sup>a</sup>	45.6 ± 21.5	68.8 ± 24.4	<b>.030<sup>a</sup></b>	-9.6 ± 32.1	22.1 ± 39.7	<b>.049<sup>a</sup></b>
African american	19.9 ± 19.2	41.2 ± 31.7	<b>.042<sup>a</sup></b>	24.9 ± 16.4	29.4 ± 21.4	.58 <sup>a</sup>	4.2 ± 19.6	-11.8 ± 45.2	.20 <sup>a</sup>
Hispanic	21.1 ± 18.5	8.3 ± 7.0	.11 <sup>a</sup>	23.3 ± 24.3	1.9 ± 4.5	.043 <sup>a</sup>	1.3 ± 28.7	-6.5 ± 6.1	.52 <sup>a</sup>
Other	1.9 ± 3.6	3.8 ± 6.4	.34 <sup>a</sup>	6.2 ± 10.4	0.00 ± 0.00	.16 <sup>a</sup>	4.1 ± 11.1	-3.8 ± 6.4	.11 <sup>a</sup>
Cause of death (%)									
Anoxia	40.9 ± 23.3	34.3 ± 12.5	.51 <sup>a</sup>	45.8 ± 20.5	28.7 ± 22.3	.086 <sup>a</sup>	3.8 ± 30.0	-5.6 ± 29.8	.50 <sup>a</sup>
Trauma	48.4 ± 17.7	54.9 ± 12.9	.41 <sup>a</sup>	43.8 ± 18.2	69.2 ± 21.0	<b>.006<sup>a</sup></b>	-3.8 ± 25.5	14.3 ± 21.1	.12 <sup>a</sup>
Stroke	7.1 ± 10.9	10.8 ± 10.1	.46 <sup>a</sup>	6.9 ± 9.1	2.1 ± 5.1	.23 <sup>a</sup>	-0.52 ± 15.9	-8.7 ± 10.9	.25 <sup>a</sup>
Other	3.6 ± 6.3	0.00 ± 0.00	.18 <sup>a</sup>	3.5 ± 5.7	0.00 ± 0.00	.15 <sup>a</sup>	0.53 ± 7.9	0.00 ± 0.00	.87 <sup>a</sup>
CDC increased risk donor** (%)	11.0 ± 13.7	7.9 ± 7.7	.60 <sup>a</sup>	10.2 ± 9.5	3.9 ± 6.1	.14 <sup>a</sup>	0.19 ± 16.5	-4.0 ± 11.7	.57 <sup>a</sup>
History of donor drug abuse (%)	11.0 ± 9.2	2.5 ± 3.8	<b>.035<sup>a</sup></b>	9.6 ± 11.0	10.4 ± 20.0	.89 <sup>a</sup>	-1.9 ± 14.0	7.9 ± 21.9	.18 <sup>a</sup>
Donor diabetes (%)	0.49 ± 1.7	1.2 ± 2.9	.45 <sup>a</sup>	4.8 ± 20.8	0.00 ± 0.00	.58 <sup>a</sup>	4.3 ± 21.0	-1.2 ± 2.9	.53 <sup>a</sup>
Donor hypertension (%)	1.02 ± 2.4	1.2 ± 2.9	.88 <sup>a</sup>	1.2 ± 2.7	0.00 ± 0.00	.29 <sup>a</sup>	0.14 ± 3.5	-1.2 ± 2.9	.41 <sup>a</sup>
Donor-recipient sex mismatch (%)	42.8 ± 14.0	62.7 ± 20.4	<b>.008<sup>a</sup></b>	44.8 ± 17.4	46.1 ± 35.5	.90 <sup>a</sup>	0.88 ± 18.2	-16.6 ± 49.8	.17 <sup>a</sup>
Ischemic time >4 hours (%)	33.1 ± 22.3	34.0 ± 38.9	.94 <sup>a</sup>	32.7 ± 24.3	31.7 ± 31.4	.94 <sup>a</sup>	-0.44 ± 21.6	-2.3 ± 13.8	.84 <sup>a</sup>

CDC: Centers for Disease Control and Prevention.

Statistics presented as Mean ± SD; p-values: a = t-test.

Bolded p values significant (p < 0.05).

\*N=23 because 1/24 centers had 0 listings and transplant recipients in the year post flag and only change in volume was available; changes in all donor characteristics for that center were missing.

\*\*Refers to Public Health Service Increased risk donors which are donors deemed to be at higher risk for HIV prior to 2013 and HIV, HBV and HCV after 2013.

**Table 3** Comparing Observed and Expected 1-Year Patient Survival Within and Between Flagged and Non-Flagged Centers at First and Last Reporting Period

	First reporting period(%)	Last reporting period(%)	<i>p</i> value(within-group)
Observed patient survival			
1-year survival at flagged centers	87.4 (9.1)	92.6 (6.7)	.19 <sup>b</sup>
1-year survival at non-flagged centers	91.6 (7.4)	94.5 (5.2)	.14 <sup>b</sup>
<i>p</i> -value (flag vs no-flag)	0.24 <sup>a</sup>	0.46 <sup>a</sup>	
Expected patient survival			
1-year survival at flagged centers	90.1 (2.3)	93.9 (0.84)	<b>.016<sup>b</sup></b>
1-year survival at non-flagged centers	91.5 (1.8)	93.9 (1.1)	<b>&lt;.001<sup>b</sup></b>
<i>p</i> -value (flag vs no-flag)	0.11 <sup>a</sup>	0.96 <sup>a</sup>	

Statistics presented as Mean (SD); *p*-values: a = *t*-test, b = paired sample *t*-test.

Bolded *p* values significant (*p*<0.05)

transplant practitioners similarly found that low CPE leads a center to become conservative in their selection of recipients.<sup>23</sup> The intent of flagging is to identify programs that are truly deficient in the care that they provide during the waitlist and post-transplant period that would lead to inferior outcomes. It is known that not all recipient and donor variables that may account for post-transplant outcomes are currently captured by the SRTR thus leading to incorrect risk adjustment.<sup>24,25</sup> It is often the sickest children that derive the greatest benefit from HT.<sup>26</sup> We express concern that high risk candidates may be at increased disadvantage from low CPE. A center receiving such a flag is unlikely to list higher risk groups such as patients with Fontan circulation, those with end-organ dysfunction and sensitized recipients (Panel Reactive Antibodies >10%). Unfortunately, the SRTR does not capture patients evaluated for transplant that are ultimately not listed. Understanding how low CPE affects center decision to list higher risk candidates should be studied to understand the full impact of these flags.

We propose a variety of ways in which we can improve upon the current evaluation metrics of center performance:

- (a) Rather than a myopic focus on 1-year post-transplant graft and patient survival, the regulatory bodies should focus on a metric that combines a center's waitlist mortality, duration on the waitlist, transplant rates, donor organ acceptance rates along with longer post-transplant survival time periods (5 year or 10-year survival). We realize that there may be criticism to this approach, however, a more wholesome integration of all aspects from the time the patient is waitlisted may provide a better understanding of transplant center quality.
- (b) Secondly, all regulatory agencies evaluating transplant center performance such as the CMS, HRSA, Membership and Professional Standards Committee and private insurance companies utilize their own processes when deeming a low performance center. These flagging criteria should be standardized, unified and transparent for all centers.
- (c) Any new program specific reporting must include patient reported outcomes. These are vital to understand

and have not been given much attention when scoring a center's performance.

- (d) The SRTR risk adjustment models take into account a number of variables that are currently collected. These variables although extensive do not capture all the necessary variables that identifies a patient's true clinical acuity and therefore has the potential for incorrect risk adjustment.<sup>24,25,27</sup> It has been shown that by including additional co-morbidities, the risk adjustment models can be bolstered.<sup>28</sup> Also, automatic capturing and addition of electronic medical record data would allow for integration of recent vital signs, clinical condition and laboratory values that would add to accurate risk adjustment.<sup>29</sup> Also initiatives that have been undertaken by adult liver and kidney transplant program such as the Transplant Quality Improvement Program (TransQIP) in which additional recipient, donor and surgical outcomes variables were added to standard UNOS variables to improve risk adjustment and compare surgical outcomes data should be encouraged for pediatric heart transplant programs.<sup>30</sup>
- (e) Linking SRTR data to existing pediatric administrative, clinical and surgical databases such as the Pediatric Health Information System, Advanced Cardiac Therapies Improving Outcomes Network, Pediatric Inter-agency Registry for Mechanical Circulatory Support, Pediatric Cardiac Critical Care Consortium, Pediatric Acute Care Cardiology Collaborative, Cardiac Neurodevelopmental Outcomes Collaborative and Congenital Heart Surgeons Society database to enhance collection of variables utilized for risk adjustment and also to enhance post-transplant outcomes data related to surgical and neurodevelopmental data is crucial and currently unknown.
- (f) Finally, there should be a culture shift such that the focus is not punitive for the transplant centers. For example, UNOS has launched the Collaborative Improvement and Innovation Network project, an initiative for kidney transplant recipients that focuses on increasing utilization for moderate to high (50-100%) Kidney Donor Profile Index kidneys and found that by introducing a collaborative and non-punitive approach

they were able to increase utilization of kidneys that would be discarded.<sup>31</sup>

While our study has some very important findings, we would like to highlight several limitations of our work. Our study is observational and retrospective by design and hence correlations should not be directly interpreted as causative. While we particularly evaluated changes in center practices from the time a center was flagged for low CPE, it could very well be that anticipated results may be known to centers at varying time intervals prior to that and center practices may already have shifted prior to public flagging of a center. In our analysis, there were no significant differences in candidate listing and transplant volumes in the year and two years after the flag. We are unable to comment if this is because of the limited sample size of pediatric patients transplanted at each center (type II error) or because centers took a longer time to change this aspect of their practice after receiving a flag. It is also possible that once flagged, insurance companies' limited their number of insured patients from being listed at such centers, which may explain the decline in volumes at flagged centers. The decline in volumes may also be secondary to families wanting to go to centers with higher reported graft/patient survival. We did not have any information about the number of donor organs that were turned down by centers with low CPE vs those that did not have any flags for low CPE and hence are unable to comment on changes in these practices. In addition, the variables capturing donor and recipient risk for this current analysis were limited to those collected on standard OPTN forms and as such changes in other characteristics may have been unobserved. Given there have been recent changes to CMS flagging rules,<sup>32</sup> the impact of these new changes on center performance are unknown and will need to be evaluated in a future study.

## Conclusion

Flagging centers for low center performance may have unintended negative consequences on center behavior. Pediatric heart transplant centers with low CPE tend to decrease their number of patient listings and transplant volumes. These centers may also potentially decrease listing children presumed to be higher risk for inferior heart transplant survival. Such measures have the possibility to decrease access to transplant for a critical group of children with end-stage heart failure.

## Disclosure statement

Dr. Joseph Rossano reports personal fees from Amgen, personal fees from Abiomed, personal fees from Bayer, personal fees from

Novartis, personal fees from Cytokinetics, personal fees from MyoKardia. None of the other authors have any disclosures to report. The authors report no conflict of interest.

## Author contributions

All authors (S.A., G.B., J.R., J.S., M.R., S.A., and J.D.S.) have contributed to the design, analysis and interpretation of

data; drafting of the manuscript along with revisions; and participated in the final approval of the manuscript submitted.

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## Supplementary materials

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.jhealun.2021.04.008>.

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