

OPTN Heart Transplantation Committee

Descriptive Data Request

Amend Adult Heart Status Extension Requirements Two-Year Monitoring Report

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Executive Summary

- The number of extensions under the criteria of interest fell by nearly 50% post-implementation
- The median days spent waiting at the criteria of interest fell, as did the days spent waiting at the criteria of interest under an extension
- There was little change in the number of extensions or days spent waiting at the Status 1 criteria of interest. Most changes to these metrics were seen for the Status 3 criteria of interest
- The number of extension forms submitted for “MCSD with pump thrombosis” fell from 699 pre-implementation to 3 post-implementation
- The criterion with the highest number of extension forms submitted post-implementation was “MCSD with device infection - Erythema,” although this was a reduction in the proportion of extension forms submitted for this criterion compared to pre-implementation
- The new criterion “MCSD with device infection - Recurrent debridement” saw moderate use post-implementation
- The new criterion “MCSD with life-threatening ventricular arrhythmia after 7 days” saw no use post-implementation

Background/Purpose

On October 27th, 2022, the Organ Procurement and Transplantation Network (OPTN) implemented modifications to heart allocation policy to adjust the requirements for extending several adult heart statuses. The goal of these modifications was to clarify the requirements transplant centers would need to meet in order to justify their candidates remaining at these statuses past the initial qualification period as well as to adjust the duration of initial status qualification and status extension to better reflect candidates' medical urgency and the amount of time necessary to collect the clinical measurements required to justify the appropriate criteria.

Finally, these modifications also included the creation of a new criterion under Adult Status 3 as a “landing pad” for candidates who had previously qualified for Adult Status 1 with life-threatening ventricular arrhythmia but no longer met the status requirements. Prior to this policy implementation, such a candidate would have been assigned to Adult Status 6, but the Committee believed that an assignment of Adult Status 3 would better reflect the medical urgency of such a candidate. This policy implementation therefore also includes the creation of the new Adult Status 3 criterion “Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia After 7 Days.”

Ultimately, this policy involved modifications to the following status criteria:

Adult Status 1

- Venous-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained
 - Clarified that a candidate must be hospitalized to extend this status
- Venous-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained
 - Clarified that a candidate must be hospitalized to extend this status
- Non-dischargeable, surgically implanted, non-endovascular biventricular support device
 - Clarified that a candidate must continue to meet all initial criteria in order to extend this status
- Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia
 - Changed the duration of initial and extension forms at this status from 14 days to 7 days
 - Changed the timeframe over which candidates must have experienced episodes of ventricular fibrillation or ventricular tachycardia from 14 days to 7 days
 - Created a pathway for assigning candidates to Adult Status 3 if this status is not extended

Adult Status 3

- Mechanical circulatory support device (MCSD) with pump thrombosis
 - Amended qualification requirements for this criterion
 - Extended duration of initial qualification to 30 days from 14 days and length of each extension to 90 days from 14 days
 - Clarified that a candidate must continue to meet the initial requirements in order to extend this status
- Mechanical circulatory support device (MCSD) with right heart failure
 - Clarified that a candidate must continue to meet the initial requirements in order to extend this status
 - Increased extension length to 90 days from 14 days
- Mechanical circulatory support device (MCSD) with device infection - Bacteremia
 - Clarified that a candidate must continue to meet the initial requirements in order to extend this status
- Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia
 - Clarified that a candidate must continue to meet the initial requirements in order to extend this status
- Mechanical circulatory support device (MCSD) with device infection - Debridement
 - Added requirement of IV antibiotics to qualify for this status
 - Clarified that a candidate must continue to meet the initial requirements in order to extend this status
- Mechanical circulatory support device (MCSD) with device infection - Recurrent debridement
 - New criterion created with this policy implementation
 - Allows candidate to qualify for this status for 90 days per form submission
- Mechanical circulatory support device (MCSD) with device infection - Erythema
 - Amended qualification requirements for this criterion
 - Clarified that a candidate must continue to meet the initial requirements in order to extend this status
- Mechanical circulatory support device (MCSD) with device infection - Positive culture
 - Clarified that a candidate must continue to meet the initial requirements in order to extend this status
- Mechanical circulatory support device (MCSD) with life threatening ventricular arrhythmia after 7 days
 - New criterion created with this policy implementation
 - Lasts 7 days from initial qualification and for an additional 7 days per extension
 - Pathway for assigning candidates who previously qualified for Status 1 under “Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia” an appropriate level of priority

This report will examine the impact of these modifications at two years after policy implementation.

Strategic Plan Goal or Committee Project Addressed

Increase equity in access to heart transplants

Committee Request

The following metrics stratified by criteria within medical urgency status, and any others subsequently requested by the Committee, will be evaluated:

- The number and percent of waitlist additions
- The number and percent of transplants
- The number of initial and extension forms submitted
- The number of adult heart candidates ever waiting at specific medical urgency criteria
- The number of adult heart candidates ever waiting with at least one extension at the specific medical urgency criteria of interest
- Minimum, maximum, average and median number extensions (consecutive and nonconsecutive) submitted for the specific medical urgency criteria of interest
- The average number of days spent at each of the medical urgency criteria of interest for candidates ever waiting at medical urgency criteria of interest

Data and Methods

We used OPTN data to assess changes in the following populations:

- Adult heart candidates listed and ever waiting between October 27, 2020 and October 26, 2024
- Adult heart transplants occurring between October 27, 2020 and October 26, 2024
- Completed and accepted adult heart status justification forms submitted between October 27, 2020 and October 26, 2024

For analyses of the distribution of the longest sequence of extensions under a criterion, the longest sequence of extensions is found for each criterion for a waiting list ID during the time period of interest. For example, if a registration waited under the criterion “MCSD with device infection - Positive culture” through two extensions, then under the criterion “MCSD with right heart failure” through two extensions before spending three extensions under “MCSD with device infection - Positive culture,” there would be two longest sequences of extension recorded for the registration: one for the criterion “MCSD with right heart failure” with length two and one for the criterion “MCSD with device infection - Positive culture” with length three.

Candidates waiting at one of the criteria of interest at the time of implementation were counted within both the pre and post cohorts. The duration of a status justification form for any of the criteria of interest was reset at the time of implementation, so a candidate waiting under one of the criteria of interest at time of implementation might have a status justification form that lasted for longer than the maximum number of days allowed in either era. However, the time waited under this form was split into pre- and post-implementation components and counted only towards its respective era, so the amount of time contributed by the candidate to each era would be within the expected limits of the status criterion for that era. Additionally, the number of forms and extensions was reset at implementation for these candidates. For example, if a candidate was added to the list for “MCSD with device infection - Positive culture” pre-implementation, extended the status once and was waiting under that criterion at implementation, then extended twice more, they would be considered to have one initial listing and one extension pre-implementation and two consecutive extensions post-implementation.

All analyses are based on OPTN data as of June 06, 2025 and subject to change based on future data submission or correction.

Results

Waiting List

There were 8597 adult heart waiting list additions between October 27, 2020 and October 26, 2022 (pre-implementation) and 10194 between October 27, 2022 and October 26, 2024 (post-implementation). Of these, 471 (5.48%) were candidates registered with one of the criteria of interest at listing pre-implementation, and 583 (5.72%) were candidates registered with one of the criteria of interest at listing post-implementation.

Table 1: Waiting List Additions at Criteria of Interest by Era

Criteria	Pre		Post		Change
	N	%	N	%	
Status 1					
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained	127	1.48%	145	1.42%	+18
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained	154	1.79%	223	2.19%	+69
Non-dischargeable, surgically implanted, non-endovascular LVAD	35	0.41%	37	0.36%	+2
MCSD with life-threatening ventricular arrhythmia	26	0.3%	31	0.3%	+5
Status 3					
MCSD with pump thrombosis	13	0.15%	2	0.02%	-11
MCSD with right heart failure	2	0.02%	3	0.03%	+1
MCSD with device infection - Erythema	7	0.08%	25	0.25%	+18
MCSD with device infection - Debridement	37	0.43%	33	0.32%	-4
MCSD with device infection - Recurrent debridement			29	0.28%	+29
MCSD with device infection - Bacteremia	53	0.62%	49	0.48%	-4
MCSD with device infection - Recurrent bacteremia	6	0.07%	3	0.03%	-3
MCSD with device infection - Positive culture	11	0.13%	3	0.03%	-8
MCSD with life-threatening ventricular arrhythmia after 7 days			0	0%	0

Note:

"MCSD with device infection - Recurrent debridement" and "MCSD with life-threatening ventricular arrhythmia after 7 days" were only available post-implementation

Table 1 shows the number of adult heart registrations with each of the criteria of interest at listing. While there was an increase in the use of all the Status 1 criteria at listing, for most Status 3 criteria there was a decrease in the number of registrations added. The exceptions were 'MCSD with device infection - Erythema,' which had more than three times the number of waiting list additions at this criterion post-implementation compared to pre-implementation, and 'MCSD with right heart failure,' although the total number of registrations with these criteria at listing remained low.

"MCSD with device infection - Recurrent debridement," which was added at implementation, saw 29 registrations listed with this criterion, while the other criterion added at implementation, "MCSD with life-threatening ventricular arrhythmia after 7 days" had 0.

There were 10844 adult heart candidates ever waiting between October 27, 2020 and October 26, 2022 (pre-implementation) and 12468 between October 27, 2022 and October 26, 2024 (post-implementation). Of these, 1027 (9.47%) registrations ever waited at one of the criteria of interest pre-implementation, and 1162 (9.32%) registrations ever waited at one of the criteria of interest post-implementation.

Table 2: Registrations Ever Waiting at Criteria of Interest by Era

Criteria	Pre		Post		Change in Ever Waiting
	N Ever Waiting	N Ever Waiting with Extension	N Ever Waiting	N Ever Waiting with Extension	
Status 1					
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained	226	31 (13.72%)	280	39 (13.93%)	+54
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained	198	20 (10.1%)	317	41 (12.93%)	+119
Non-dischargeable, surgically implanted, non-endovascular LVAD	68	36 (52.94%)	78	41 (52.56%)	+10
MCSD with life-threatening ventricular arrhythmia	64	5 (7.81%)	81	20 (24.69%)	+17
Status 3					
MCSD with pump thrombosis	75	64 (85.33%)	13	7 (53.85%)	-62
MCSD with right heart failure	21	16 (76.19%)	16	11 (68.75%)	-5
MCSD with device infection - Erythema	68	40 (58.82%)	135	89 (65.93%)	+67
MCSD with device infection - Debridement	128	97 (75.78%)	90	74 (82.22%)	-38
MCSD with device infection - Recurrent debridement	0	0 (0%)	60	11 (18.33%)	+60
MCSD with device infection - Bacteremia	185	101 (54.59%)	140	70 (50%)	-45
MCSD with device infection - Recurrent bacteremia	17	3 (17.65%)	9	4 (44.44%)	-8
MCSD with device infection - Positive culture	27	10 (37.04%)	18	5 (27.78%)	-9
MCSD with life-threatening ventricular arrhythmia after 7 days	0	0 (0%)	0	0 (0%)	0
Total	1027	415 (40.41%)	1162	394 (33.91%)	+135

Note:

"MCSD with device infection - Recurrent debridement" and "MCSD with life-threatening ventricular arrhythmia after 7 days" were only available post-implementation

Columns may sum to more than the total number of registrations because candidates could wait at more than one status/criteria

Table 2 and Figure 1 show the number of registrations ever waiting at the criteria of interest pre- vs post-implementation, as well as the proportion of those registrations that ever waited under at least one extension.

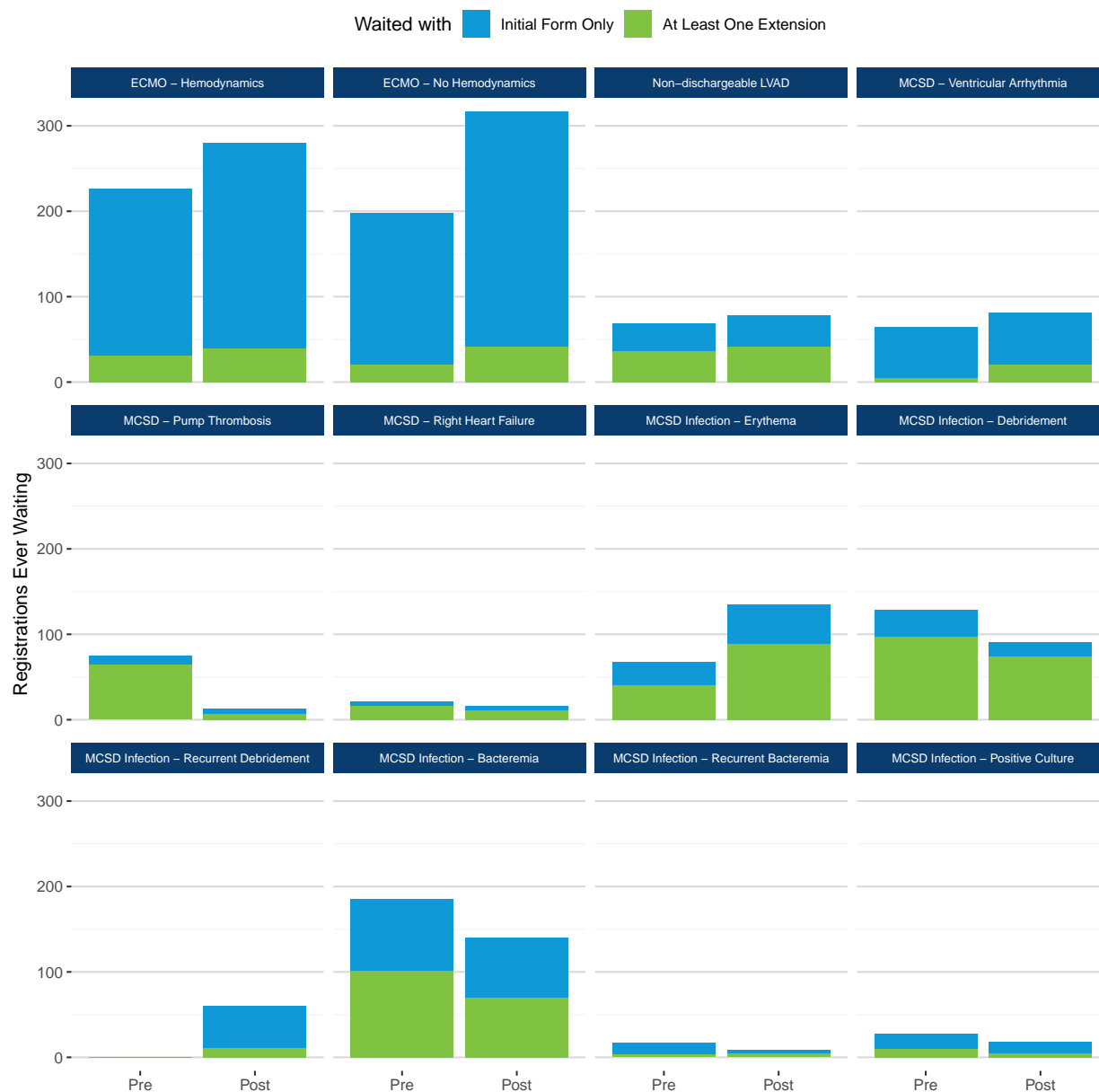
Overall, the number of registrations ever waiting at the criteria of interest increased. The number of registrations ever waiting at all criteria of Status 1 increased with the largest gains among the ECMO criteria. Among the Status 3 criteria of interest, except for "MCSD with device infection - Erythema", the number of registrations ever waiting at the criterion decreased post- vs pre-implementation.

There were five criteria where the proportion of registrations ever waiting with at least one extension decreased post-implementation and six criteria where the proportion increased post-implementation, although the small number of registrations ever waiting at some criteria means these proportions may not be representative. "MCSD

with pump thrombosis” saw a dramatic decrease both in the number of candidates ever waiting at the status and those waiting under an extension post-implementation.

“MCSD with device infection - Recurrent debridement,” which was added at implementation, saw 60 registrations wait at this criterion, while the other criterion added at implementation, “MCSD with life-threatening ventricular arrhythmia after 7 days” had 0. Of the registrations that ever waited under the criterion “MCSD with device infection - Recurrent debridement,” 18.33% waited under at least one extension.

Figure 1: Registrations Ever Waiting at Criteria of Interest by Era and Initial vs Extension



"MCSD with life-threatening ventricular arrhythmia after 7 days" is omitted because no registrations waited with this criterion in either era

There were 3946 status justification forms submitted for the criteria of interest between October 27, 2020 and October 26, 2022 (pre-implementation) and 3000 between October 27, 2022 and October 26, 2024 (post-implementation). Of these, 2664 (67.51%) were extension forms pre-implementation, and 1529 (50.97%) were extension forms post-implementation.

Table 3: Status Justification Forms Submitted for Criteria of Interest by Era and Form Type

Criteria	Initial		Extension	
	Pre	Post	Pre	Post
Status 1				
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained	241 (85.46%)	306 (85.96%)	41 (14.54%)	50 (14.04%)
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained	210 (91.3%)	354 (87.62%)	20 (8.7%)	50 (12.38%)
Non-dischargeable, surgically implanted, non-endovascular LVAD	78 (54.93%)	95 (47.98%)	64 (45.07%)	103 (52.02%)
MCSD with life-threatening ventricular arrhythmia	70 (93.33%)	84 (64.62%)	5 (6.67%)	46 (35.38%)
Status 3				
MCSD with pump thrombosis	102 (12.73%)	8 (72.73%)	699 (87.27%)	3 (27.27%)
MCSD with right heart failure	25 (14.12%)	21 (48.84%)	152 (85.88%)	22 (51.16%)
MCSD with device infection - Erythema	83 (19.67%)	194 (27.4%)	339 (80.33%)	514 (72.6%)
MCSD with device infection - Debridement	214 (18.53%)	127 (23.48%)	941 (81.47%)	414 (76.52%)
MCSD with device infection - Recurrent debridement		70 (76.92%)		21 (23.08%)
MCSD with device infection - Bacteremia	215 (36.01%)	183 (39.02%)	382 (63.99%)	286 (60.98%)
MCSD with device infection - Recurrent bacteremia	19 (73.08%)	8 (61.54%)	7 (26.92%)	5 (38.46%)
MCSD with device infection - Positive culture	25 (64.1%)	21 (58.33%)	14 (35.9%)	15 (41.67%)
MCSD with life-threatening ventricular arrhythmia after 7 days		0 (0%)		0 (0%)
Total	1282 (32.49%)	1471 (49.03%)	2664 (67.51%)	1529 (50.97%)

Note:

"MCSD with device infection - Recurrent debridement" and "MCSD with life-threatening ventricular arrhythmia after 7 days" were only available post-implementation

Table 3 and Figure 2 show the number of initial and extension status justification forms submitted for the criteria of interest in each era.

The number of initial forms submitted for the criteria of interest increased post-implementation, while the number of extension forms decreased. The number of extension forms submitted post-implementation increased for all of the Status 1 criteria of interest. Among the Status 3 criteria of interest, the number of extension forms submitted increased only for "MCSD with device infection - Erythema" and "MCSD with device infection - Positive culture". The largest decrease in extension forms submitted was seen for the criterion "MCSD with pump thrombosis," where the number of extension forms submitted declined from 699 pre-implementation to 3 post-implementation.

The proportion of extension forms submitted increased for all Status 1 criteria of interest, except for "Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained," which remained nearly unchanged. In Status 3, the proportion decreased across all criteria of interest, except for "MCSD with device infection - Bacteremia" and "MCSD with device infection - Positive culture," which saw an increase. The greatest

decrease in the proportion of extension forms post-implementation occurred for “MCSD with pump thrombosis,” which declined from 87.27% pre-implementation to 27.27% post-implementation.

There were 91 justification forms submitted for “MCSD with device infection - Recurrent debridement,” which was added at implementation, of which 70 were initial forms and 21 were extension forms. There were 0 justification forms submitted for the other criterion added at implementation, “MCSD with life-threatening ventricular arrhythmia after 7 days.”

Figure 2: Status Justification Forms Submitted for Criteria of Interest by Era and Form Type



MCSD with life-threatening ventricular arrhythmia after 7 days is omitted because no forms were submitted for this criterion in either era

Table 4: Distribution of Days Spent Waiting Under Criteria of Interest by Era

Criteria	Max Days Waited		Mean Days Waited		Median Days Waited	
	Pre	Post	Pre	Post	Pre	Post
Status 1						
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained	53.16	36.91	5.34	5.46	4.19	4.13
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained	21.90	33.66	4.53	5.16	3.76	3.85
Non-dischargeable, surgically implanted, non-endovascular LVAD	41.98	141.87	11.56	15.43	8.60	9.59
MCSD with life-threatening ventricular arrhythmia	28.17	69.40	6.63	8.46	4.75	5.64
Status 3						
MCSD with pump thrombosis	550.82	180.85	152.37	23.57	94.12	4.67
MCSD with right heart failure	553.09	423.44	117.13	92.34	44.81	57.59
MCSD with device infection - Erythema	547.66	500.54	86.46	71.01	40.67	29.20
MCSD with device infection - Debridement	731.00	581.15	126.90	84.00	52.13	40.90
MCSD with device infection - Recurrent debridement		569.19		82.69		51.12
MCSD with device infection - Bacteremia	731.00	728.76	115.03	119.23	55.34	47.40
MCSD with device infection - Recurrent bacteremia	417.99	352.56	73.15	95.73	50.70	57.00
MCSD with device infection - Positive culture	420.54	451.95	82.21	109.99	43.31	28.52
MCSD with life-threatening ventricular arrhythmia after 7 days		0.00		0.00		0.00

Note:

"MCSD with device infection - Recurrent debridement" and "MCSD with life-threatening ventricular arrhythmia after 7 days" were only available post-implementation

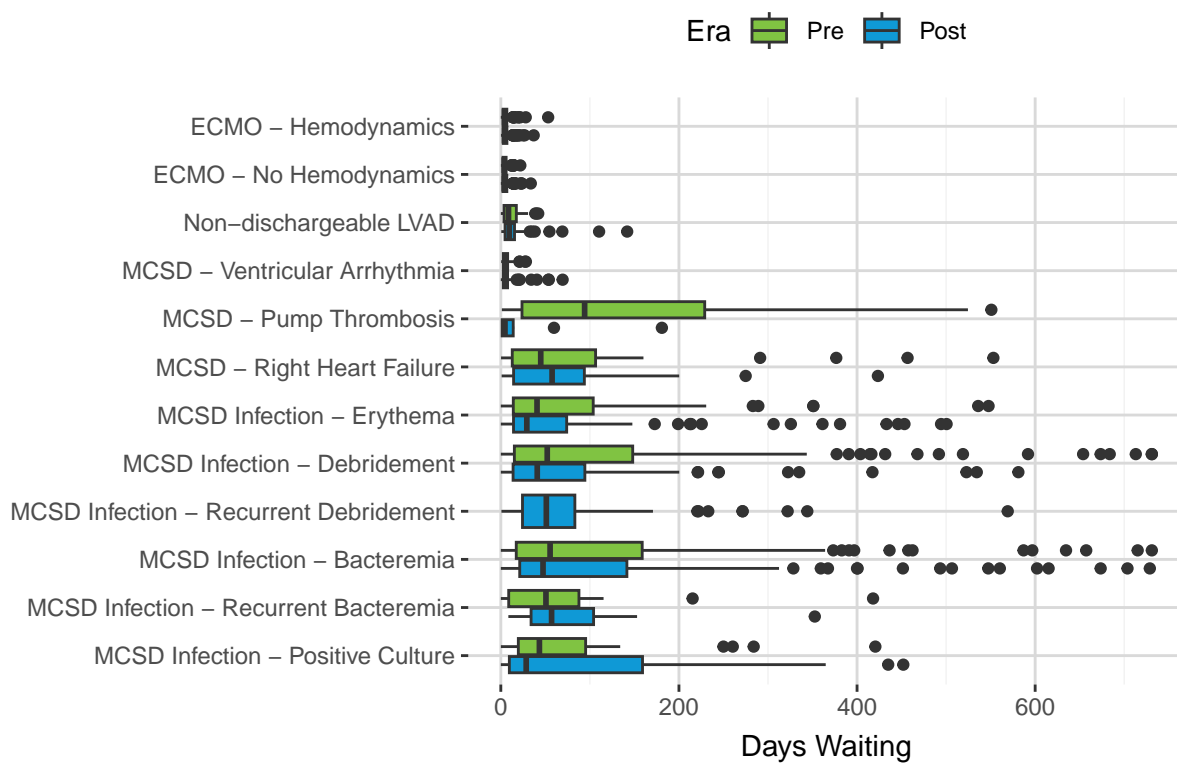
Table 4 and Figure 3 show the distribution of days ever waiting at the criteria of interest pre- vs post-implementation.

The median days waiting in Status 1 criteria of interest remained almost unchanged.

The median days waiting in Status 3 criteria increased for "MCSD with right heart failure" and "MCSD with device infection - Recurrent bacteremia" and decreased for the other criteria with the greatest decrease in "MCSD with pump thrombosis", from 94.12 pre-implementation to 4.67 post-implementation.

For "MCSD with device infection - Recurrent debridement," which was added at implementation, the median days waiting was 51.12. No candidates waited at the other criterion added at implementation, "MCSD with life-threatening ventricular arrhythmia after 7 days."

Figure 3: Distribution of Days Waiting Under Criteria of Interest by Era



"MCSD with life-threatening ventricular arrhythmia after 7 days" is omitted because no forms were submitted for this criterion in either era

Table 5: Distribution of Number of Extensions and Days Spent Waiting Under Non-Consecutive Extensions for Criteria of Interest by Era

Criteria	Max #		Mean #		Median #		Mean Days		Median Days	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Status 1										
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained	6	4	1.3	1.3	1.0	1	5.61	5.32	3.0	4.0
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained	2	4	1.0	1.2	1.0	1	3.65	4.65	3.5	3.0
Non-dischargeable, surgically implanted, non-endovascular LVAD	5	16	1.8	2.5	2.0	1	9.56	15.52	7.5	7.0
MCSD with life-threatening ventricular arrhythmia	1	7	1.0	2.2	1.0	1	7.40	12.71	6.0	5.0
Status 3										
MCSD with pump thrombosis	36	2	11.3	1.1	8.0	1	157.64	29.71	103.0	8.0
MCSD with right heart failure	36	6	9.7	1.8	4.0	1	134.19	90.92	51.0	58.0
MCSD with device infection - Erythema	36	31	8.6	5.9	5.5	3	120.12	79.45	75.0	38.0
MCSD with device infection - Debridement	50	39	9.8	6.0	5.0	3	137.56	79.81	74.0	33.0
MCSD with device infection - Recurrent debridement		5		1.8		1		129.18		90.0
MCSD with device infection - Bacteremia	18	16	4.0	4.3	3.0	3	143.72	154.93	93.0	99.0
MCSD with device infection - Recurrent bacteremia	4	3	2.3	1.5	2.0	1	178.33	97.00	124.0	59.5
MCSD with device infection - Positive culture	3	4	1.7	3.0	1.0	4	102.10	230.60	41.5	274.0
MCSD with life-threatening ventricular arrhythmia after 7 days		0		0.0		0		0.00		0.0

Note:

"MCSD with device infection - Recurrent debridement" and "MCSD with life-threatening ventricular arrhythmia after 7 days" were only available post-implementation

Table 5 and Figure 4 show the distributions of the number of non-consecutive extension forms submitted and days ever waiting under one of the criteria of interest for adult heart registrations pre- vs post-implementation.

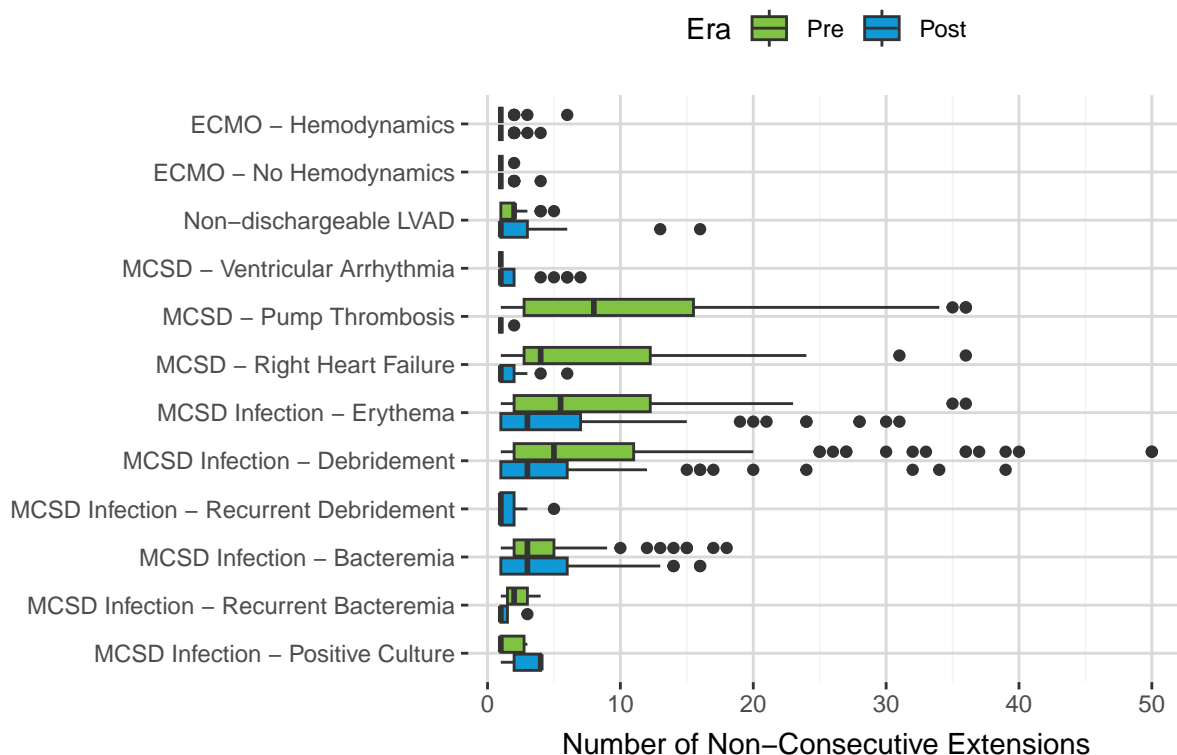
Figure 4 shows the distribution of the number of non-consecutive extensions for adult heart candidates waiting under the criteria of interest. There was little change in the median number of non-consecutive extensions for the Status 1 criteria. For the Status 3 criteria, The median number of non-consecutive extensions fell post-implementation for all criteria except "MCSD with device infection - Bacteremia" (3 pre-implementation, 3 post-implementation) and "MCSD with device infection - Positive culture" (1 pre-implementation, 4 post-implementation). The criterion with the greatest median number of extension forms pre-implementation was "MCSD with pump thrombosis" (median 8 extension forms), while post-implementation it was "MCSD with device infection - Positive culture" (median 4 extension forms).

Figure 5 shows the distribution of the number of days spent under non-consecutive extensions for adult heart candidates waiting under the criteria of interest. There was little change in the median days waiting under non-consecutive extensions for the Status 1 criteria of interest. For the Status 3 criteria of interest, the median days waiting under non-consecutive extensions decreased for all criteria except "MCSD with right heart failure" (median 51 days pre-implementation vs 58 post-implementation), "MCSD with device infection - Bacteremia" (median 93 days pre-implementation vs 99 post-implementation), and "MCSD with device infection - Positive culture" (median 41.5 days pre-implementation vs 274 post-implementation, but this may not be representative

due to low sample size). The most dramatic decrease in median days was seen for “MCSD with pump thrombosis” (median 103 days waiting pre-implementation to 8 post-implementation).

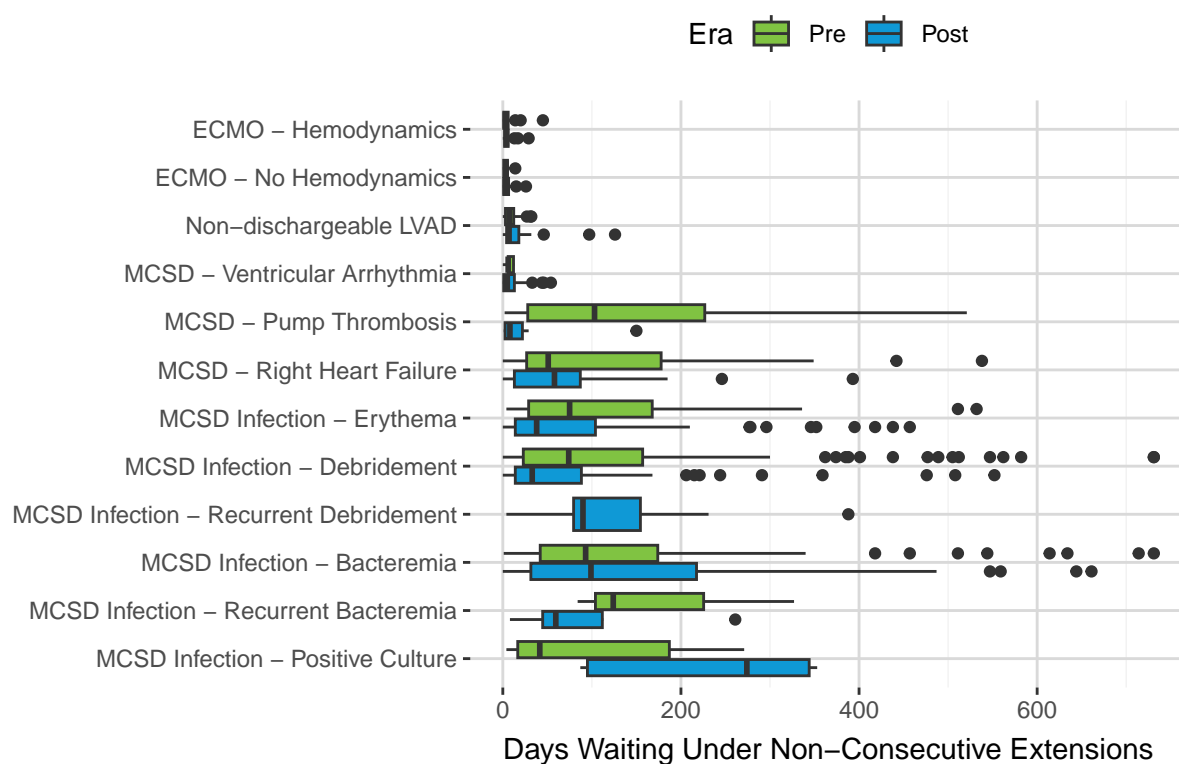
The median number of non-consecutive extensions submitted for “MCSD with device infection - Recurrent debridement,” which was added at implementation, was 1 post-implementation, and the median days waiting under non-consecutive extensions was 90. No candidates waited at the other criterion added at implementation, “MCSD with life-threatening ventricular arrhythmia after 7 days.”

Figure 4: Distribution of Number of Non-Consecutive Extensions for Criteria of Interest by Era



"MCSD with life-threatening ventricular arrhythmia after 7 days" is omitted because no forms were submitted for this criterion in either era

Figure 5: Distribution of Days Waiting Under Non-Consecutive Extensions for Criteria of Interest by Era



"MCSD with life-threatening ventricular arrhythmia after 7 days" is omitted because no forms were submitted for this criterion in either era

Table 6: Distribution of Number of Extensions and Days Spent Waiting Under Longest Sequence of Consecutive Extensions for Criteria of Interest by Era

Criteria	Max #		Mean #		Median #		Mean Days		Median Days	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Status 1										
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained	6	4	1.3	1.3	1.0	1	5.61	5.32	3.0	4.0
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained	2	4	1.0	1.2	1.0	1	3.65	4.65	3.5	3.0
Non-dischargeable, surgically implanted, non-endovascular LVAD	5	13	1.7	2.3	1.5	1	9.33	14.07	7.5	7.0
MCSD with life-threatening ventricular arrhythmia	1	6	1.0	2.1	1.0	1	7.40	11.95	6.0	5.0
Status 3										
MCSD with pump thrombosis	36	2	10.4	1.1	6.5	1	145.81	29.71	87.0	8.0
MCSD with right heart failure	36	5	8.9	1.5	3.0	1	124.38	80.77	37.0	55.0
MCSD with device infection - Erythema	36	30	8.1	5.1	5.0	2	114.35	68.91	69.5	29.0
MCSD with device infection - Debridement	50	34	7.9	4.9	5.0	3	110.38	65.55	61.0	30.5
MCSD with device infection - Recurrent debridement		3		1.6		1		118.64		90.0
MCSD with device infection - Bacteremia	18	14	3.7	3.7	2.0	3	133.29	135.11	86.0	96.0
MCSD with device infection - Recurrent bacteremia	4	3	2.3	1.5	2.0	1	178.33	97.00	124.0	59.5
MCSD with device infection - Positive culture	3	4	1.7	3.0	1.0	4	102.10	230.60	41.5	274.0
MCSD with life-threatening ventricular arrhythmia after 7 days		0		0.0		0		0.00		0.0

Note:

"MCSD with device infection - Recurrent debridement" and "MCSD with life-threatening ventricular arrhythmia after 7 days" were only available post-implementation

Table 6 shows the distributions of the number of extension forms submitted and days waiting during the longest sequence of consecutive extensions under one of the criteria of interest for adult heart candidates pre- vs post-implementation.

Figure 6 shows the distribution of the length of the longest consecutive series of extensions for adult heart candidates waiting under the criteria of interest. There was little change in either the max or the median length of the longest sequence of extensions for most of the Status 1 criteria. Across Status 3 criteria, the median length of the longest consecutive series of extensions increased in "MCSD with device infection - Bacteremia" (from 2 pre-implementation to 3 post-implementation) and "MCSD with device infection - Positive culture" (from 1 pre-implementation to 4 post-implementation). The greatest decrease was in "MCSD with pump thrombosis" (from 6.5 pre-implementation to 1 post-implementation).

Figure 7 shows the distribution of the number of days spent under the longest consecutive series of extensions for adult heart candidates waiting under the criteria of interest. There was little change in the median days waiting under the longest consecutive series of extensions for any of the Status 1 criteria. Among the Status 3 criteria, the median days waiting under the longest consecutive series of extensions decreased for all criteria except "MCSD with right heart failure" (median 37 days pre-implementation vs 55 post-implementation), "MCSD with device infection - Bacteremia" (median 86 days pre-implementation vs 96 post-implementation) and "MCSD with device infection - Positive culture" (median 41.5 days pre-implementation vs 274 post-implementation, but

this may not be representative due to low sample size). The greatest decrease in median days waiting for the longest series of extensions was seen for “MCSD with pump thrombosis” (median 87 days pre-implementation vs 8 post-implementation).

The median longest consecutive series of extensions submitted for “MCSD with device infection - Recurrent debridement,” which was added at implementation, was 1 post-implementation, and the median days waiting under the longest series of extensions was 90. No candidates waited at the other criterion added at implementation, “MCSD with life-threatening ventricular arrhythmia after 7 days.”

Figure 6: Distribution of Lengths of Sequences of Consecutive Extensions for Criteria of Interest by Era

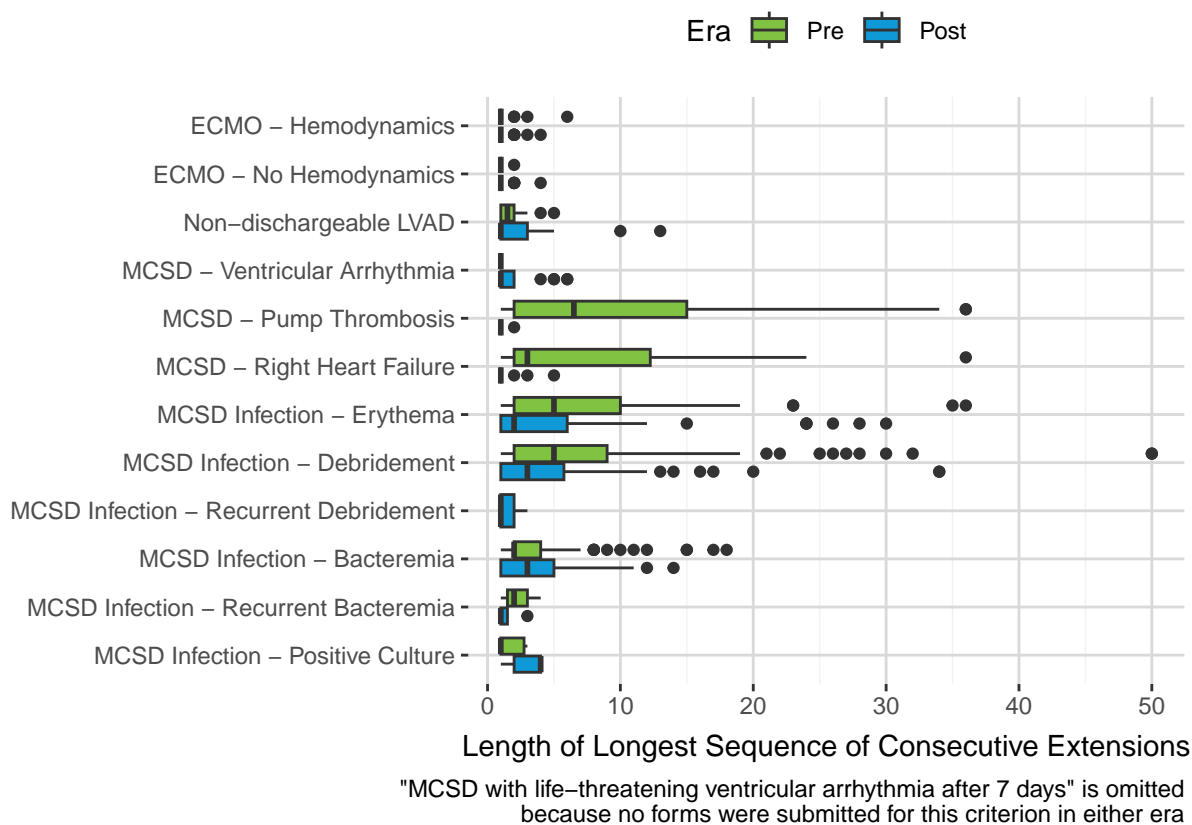
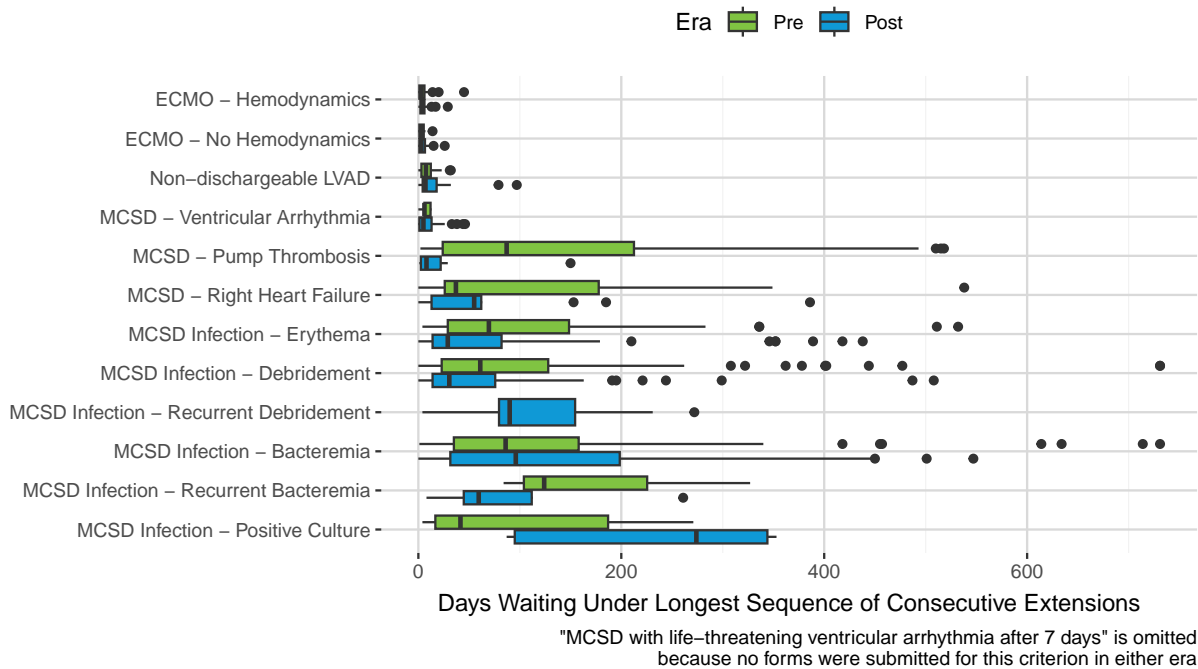


Figure 7: Distribution of Days Waiting Under Longest Consecutive Sequence of Extensions for Criteria of Interest by Era



Transplant

There were 6759 adult heart transplants between October 27, 2020 and October 26, 2022 (pre-implementation) and 8125 between October 27, 2022 and October 26, 2024 (post-implementation). Of these, 589 (8.71%) were candidates waiting with one of the criteria of interest at transplant pre-implementation, and 674 (8.3%) were candidates waiting with one of the criteria of interest at transplant post-implementation.

Table 7: Adult Heart Transplants at Criteria of Interest by Era

Criteria	Pre		Post		Change
	N	%	N	%	
Status 1					
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained	150	2.22%	211	2.6%	+61
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained	135	2%	218	2.68%	+83
Non-dischargeable, surgically implanted, non-endovascular LVAD	51	0.75%	64	0.79%	+13
MCSD with life-threatening ventricular arrhythmia	46	0.68%	63	0.78%	+17
Status 3					
MCSD with pump thrombosis	33	0.49%	1	0.01%	-32
MCSD with right heart failure	9	0.13%	2	0.02%	-7
MCSD with device infection - Erythema	16	0.24%	28	0.34%	+12
MCSD with device infection - Debridement	55	0.81%	16	0.2%	-39
MCSD with device infection - Recurrent debridement			20	0.25%	+20
MCSD with device infection - Bacteremia	76	1.12%	43	0.53%	-33
MCSD with device infection - Recurrent bacteremia	6	0.09%	3	0.04%	-3
MCSD with device infection - Positive culture	12	0.18%	5	0.06%	-7
MCSD with life-threatening ventricular arrhythmia after 7 days			0	0%	0

Note:

"MCSD with device infection - Recurrent debridement" and "MCSD with life-threatening ventricular arrhythmia after 7 days" were only available post-implementation

Table 7 shows the number of adult heart transplants under each of the criteria of interest. All of the Status 1 criteria saw an increase in transplants to the candidates waiting under them, while most of the Status 3 criteria saw a decrease. The criterion with the greatest increase in transplants was "Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained" (135 transplants pre-implementation, 218 post-implementation), while the criterion with the greatest decrease was "MCSD with device infection - Debridement" (55 transplants pre-implementation, 16 post-implementation).

"MCSD with device infection - Recurrent debridement," which was added at implementation, saw 20 registrations transplanted with this criterion, while the other criterion added at implementation, "MCSD with life-threatening ventricular arrhythmia after 7 days" had 0.

Conclusion

The number of extension forms for the criteria of interest declined by nearly 50% post-implementation. There was little change in the number of extensions or time spent waiting under the Status 1 criteria. The greatest change occurred for the Status 3 criterion “MCSD with pump thrombosis,” where there were very few extensions submitted post-implementation.

The criterion “MCSD with life-threatening ventricular arrhythmia after 7 days,” which was added at implementation, saw no use in the two years post-implementation. The other criterion added at implementation, “MCSD with device infection - Recurrent debridement,” saw use in line with the other Status 3 device infection criteria.