Final Report

OPTN Heart Transplantation Committee | Descriptive Data Request

Amend Adult Heart Status Extension Requirements One-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 327 pre-implementation to 0 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" 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

- Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained
  - Clarified that a candidate must be hospitalized to extend this status
- Veno-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 one year 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, 2021 and October 26, 2023
- Adult heart transplants occurring between October 27, 2021 and October 26, 2023
- Completed and accepted adult heart status justification forms submitted between October 27, 2021 and October 26, 2023

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 March 08, 2024 and subject to change based on future data submission or correction.

Results

Waiting List

There were 4261 adult heart waiting list additions between October 27, 2021 and October 26, 2022 (pre-implementation) and 5016 between October 27, 2022 and October 26, 2023 (post-implementation). Of these, 247 (5.8%) were candidates registered with one of the criteria of interest at listing pre-implementation, and 283 (5.64%) 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

	Pre		Post		
Criteria	N	%	N	%	Change
Status 1					
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained	64	1.5%	71	1.42%	+7
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained	81	1.9%	104	2.07%	+23
Non-dischargeable, surgically implanted, non-endovascular LVAD	15	0.35%	19	0.38%	+4
MCSD with life-threatening ventricular arrhythmia	19	0.45%	13	0.26%	-6
Status 3					
MCSD with pump thrombosis	6	0.14%	2	0.04%	-4
MCSD with right heart failure	2	0.05%	2	0.04%	0
MCSD with device infection - Erythema	5	0.12%	15	0.3%	+10
MCSD with device infection - Debridement	21	0.49%	16	0.32%	-5
MCSD with device infection - Recurrent debridement			12	0.24%	+12
MCSD with device infection - Bacteremia	26	0.61%	26	0.52%	0
MCSD with device infection - Recurrent bacteremia	3	0.07%	2	0.04%	-1
MCSD with device infection - Positive culture	5	0.12%	1	0.02%	-4
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 except "MCSD with life-threatening ventricular arrhythmia," for most Status 3 criteria there was no change or a slight decrease in the number of registrations added. The exception was "MCSD with device infection - Erythema," which had triple the number of waiting list additions at this criterion post-implementation compared to pre-implementation, although the total number of registrations with this criterion at listing remained low.

"MCSD with device infection - Recurrent debridement," which was added at implementation, saw 12 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 6554 adult heart candidates ever waiting between October 27, 2021 and October 26, 2022 (pre-implementation) and 7243 between October 27, 2022 and October 26, 2023 (post-implementation). Of these, 576 (8.79%) candidates ever waited at one of the criteria of interest pre-implementation, and 602 (8.31%) candidates 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		
	N Ever Waiting	N Ever Waiting with Extension	N Ever Waiting	N Ever Waiting with Extension	Change in Ever Waiting
Status 1					
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained	115	20 (17.39%)	137	17 (12.41%)	+22
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained	104	11 (10.58%)	148	20 (13.51%)	+44
Non-dischargeable, surgically implanted, non-endovascular LVAD	39	23 (58.97%)	39	20 (51.28%)	0
MCSD with life-threatening ventricular arrhythmia	47	4 (8.51%)	34	7 (20.59%)	-13
Status 3					
MCSD with pump thrombosis	40	35 (87.5%)	8	5 (62.5%)	-32
MCSD with right heart failure	11	8 (72.73%)	10	6 (60%)	-1
MCSD with device infection - Erythema	42	27 (64.29%)	81	54 (66.67%)	+39
MCSD with device infection - Debridement	82	68 (82.93%)	57	49 (85.96%)	-25
MCSD with device infection - Recurrent debridement	0	0 (0%)	30	6 (20%)	+30
MCSD with device infection - Bacteremia	102	61 (59.8%)	82	40 (48.78%)	-20
MCSD with device infection - Recurrent bacteremia	7	2 (28.57%)	5	2 (40%)	-2
MCSD with device infection - Positive culture	15	5 (33.33%)	11	4 (36.36%)	-4
MCSD with life-threatening ventricular arrhythmia after 7 days	0	0 (0%)	0	0 (0%)	0
Total	576	258 (44.79%)	602	220 (36.54%)	+26

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 candidates 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 slightly. The largest gains were among the Status 1 VA ECMO criteria. Among the Status 3 criteria of interest, the number of candidates ever waiting at "Non-dischargeable, surgically implanted, non-endovascular LVAD," "MCSD with pump thrombosis," and "MCSD with device infection - Debridement" decreased, while the number of candidates ever waiting at "MCSD with device infection - Erythema" increased. There was little change in the number of registrations ever waiting at the other criteria of interest.

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 30 registrations wait at this criterion, while the other criterion added at implementation, "MCSD with life-threatening ventricular arrhythmia" had 0. Of the registrations that ever waited under the criterion "MCSD with device infection - Recurrent debridement," 20% 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 2031 status justification forms submitted for the criteria of interest between October 27, 2021 and October 26, 2022 (pre-implementation) and 1482 between October 27, 2022 and October 26, 2023 (post-implementation). Of these, 1372 (67.55%) were extension forms pre-implementation, and 748 (50.47%) were extension forms post-implementation.

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

	Initial		Extension	
Criteria	Pre	Post	Pre	Post
Status 1				
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained	125 (83.33%)	145 (87.35%)	25 (16.67%)	21 (12.65%)
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained	106 (90.6%)	163 (85.79%)	11 (9.4%)	27 (14.21%)
Non-dischargeable, surgically implanted, non-endovascular LVAD	41 (50.62%)	48 (52.75%)	40 (49.38%)	43 (47.25%)
MCSD with life-threatening ventricular arrhythmia	50 (94.34%)	35 (56.45%)	3 (5.66%)	27 (43.55%)
Status 3				
MCSD with pump thrombosis	42 (11.38%)	3 (100%)	327 (88.62%)	0 (0%)
MCSD with right heart failure	9 (15.25%)	12 (46.15%)	50 (84.75%)	14 (53.85%)
MCSD with device infection - Erythema	45 (20.64%)	114 (32.57%)	173 (79.36%)	236 (67.43%)
MCSD with device infection - Debridement	107 (16.64%)	61 (21.11%)	536 (83.36%)	228 (78.89%)
MCSD with device infection - Recurrent debridement		36 (80%)		9 (20%)
MCSD with device infection - Bacteremia	117 (37.26%)	100 (42.37%)	197 (62.74%)	136 (57.63%)
MCSD with device infection - Recurrent bacteremia	6 (54.55%)	4 (80%)	5 (45.45%)	1 (20%)
MCSD with device infection - Positive culture	11 (68.75%)	13 (68.42%)	5 (31.25%)	6 (31.58%)
MCSD with life-threatening ventricular arrhythmia after 7 days		0 (0%)		0 (0%)
Total	659 (32.45%)	734 (49.53%)	1372 (67.55%)	748 (50.47%)

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 except for "Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained." Among the Status 3 criteria of interest, only 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 327 pre-implementation to 0 post-implementation.

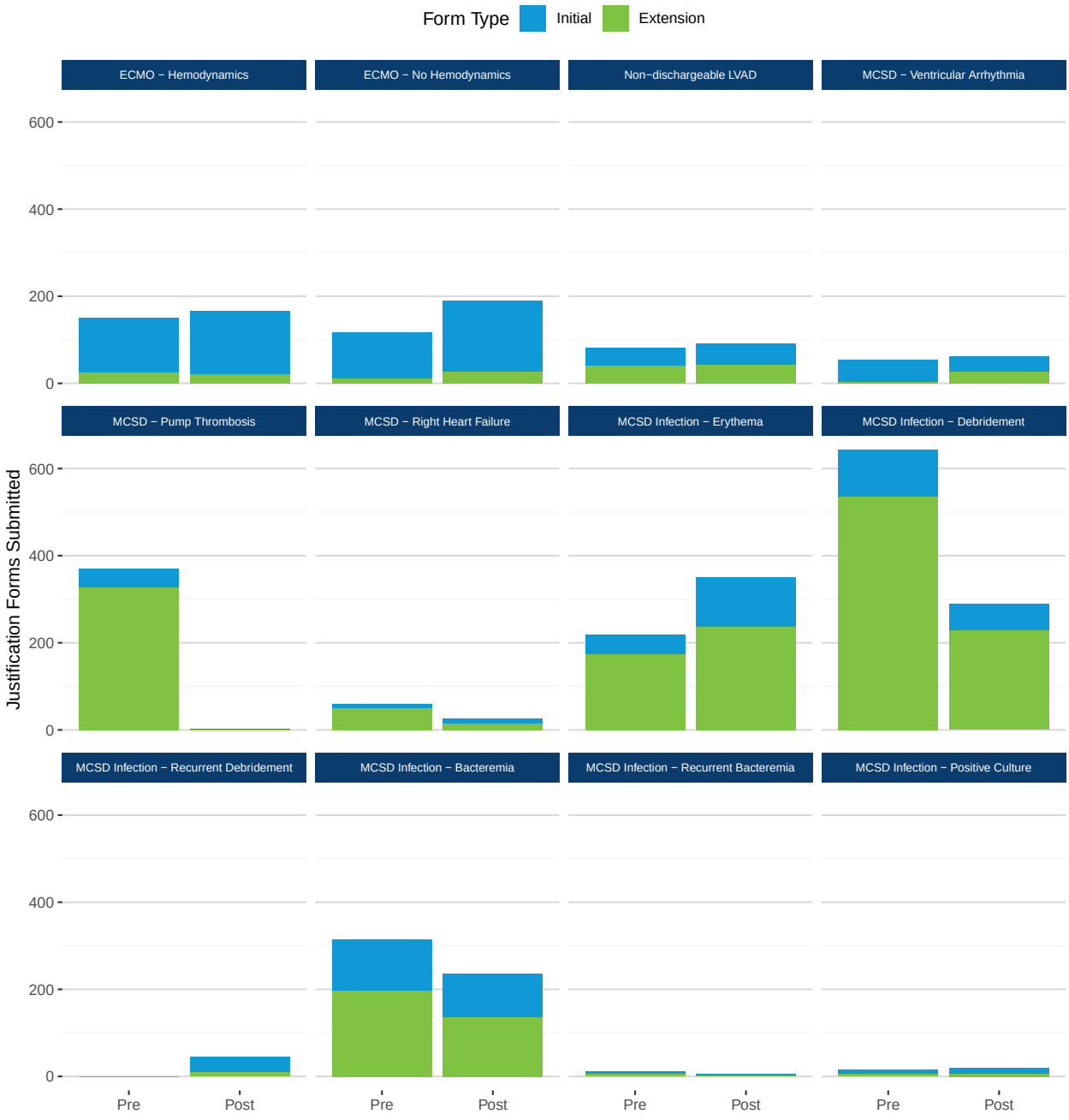
To further investigate the lack of extension forms submitted for "MCSD with pump thrombosis," we examined the eight registrations ever waiting under this status criterion "MCSD with pump thrombosis" post-implementation (see Table 2). Of these eight registrations ever waiting, one moved to Status 2 under a device complication

criterion, one remained Status 3 with a device recall exception, and one was registered close to the end of the one-year cohort so any status extensions fell outside the time period analyzed. The remaining five all transitioned to Status 4. There were therefore no extensions of the criterion "MCSD with pump thrombosis" in the first year post-implementation, and a high proportion of registrations waiting under this criterion transitioned to Status 4 rather than extending.

The proportion of extension forms submitted declined for all criteria post-implementation, with the exception of "Oxygenation (VA ECMO) - Hemodynamic Values not obtained," "MCSD with life-threatening ventricular arrhythmia," and "MCSD with device infection - Positive culture." The greatest decrease in the proportion of extension forms post-implementation occurred for "MCSD with pump thrombosis," which declined from 88.62% pre-implementation to 0% post-implementation.

There were 45 justification forms submitted for "MCSD with device infection - Recurrent debridement," which was added at implementation, of which 36 were initial forms and 9 were extension forms. There were 0 justification forms submitted for the other criterion added at implementation, "MCSD with life-threatening ventricular arrhythmia."

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

	Max Days Waited		Mean Days Waited		Median Days Waited	
Criteria	Pre	Post	Pre	Post	Pre	Post
Status 1						
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained	27.98	26.72	5.68	4.90	5.03	3.77
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained	14.68	33.66	4.43	5.15	3.61	3.82
Non-dischargeable, surgically implanted, non-endovascular LVAD	32.38	54.56	11.92	13.81	8.68	9.99
MCSD with life-threatening ventricular arrhythmia	28.17	69.40	6.57	9.92	4.79	4.20
Status 3						
MCSD with pump thrombosis	364.50	15.00	131.98	5.02	108.65	3.09
MCSD with right heart failure	195.41	365.00	72.82	104.99	28.32	56.84
MCSD with device infection - Erythema	365.00	325.31	71.20	57.08	36.46	29.04
MCSD with device infection - Debridement	365.00	365.00	109.73	72.05	63.57	40.34
MCSD with device infection - Recurrent debridement		319.63		82.13		51.12
MCSD with device infection - Bacteremia	365.00	365.00	108.28	101.43	65.97	44.90
MCSD with device infection - Recurrent bacteremia	315.54	104.15	91.45	59.19	35.08	57.00
MCSD with device infection - Positive culture	260.46	210.49	55.94	75.78	31.46	33.05
MCSD with life-threatening ventricular arrhythmia after 7 days		0.00		0.00		0.00

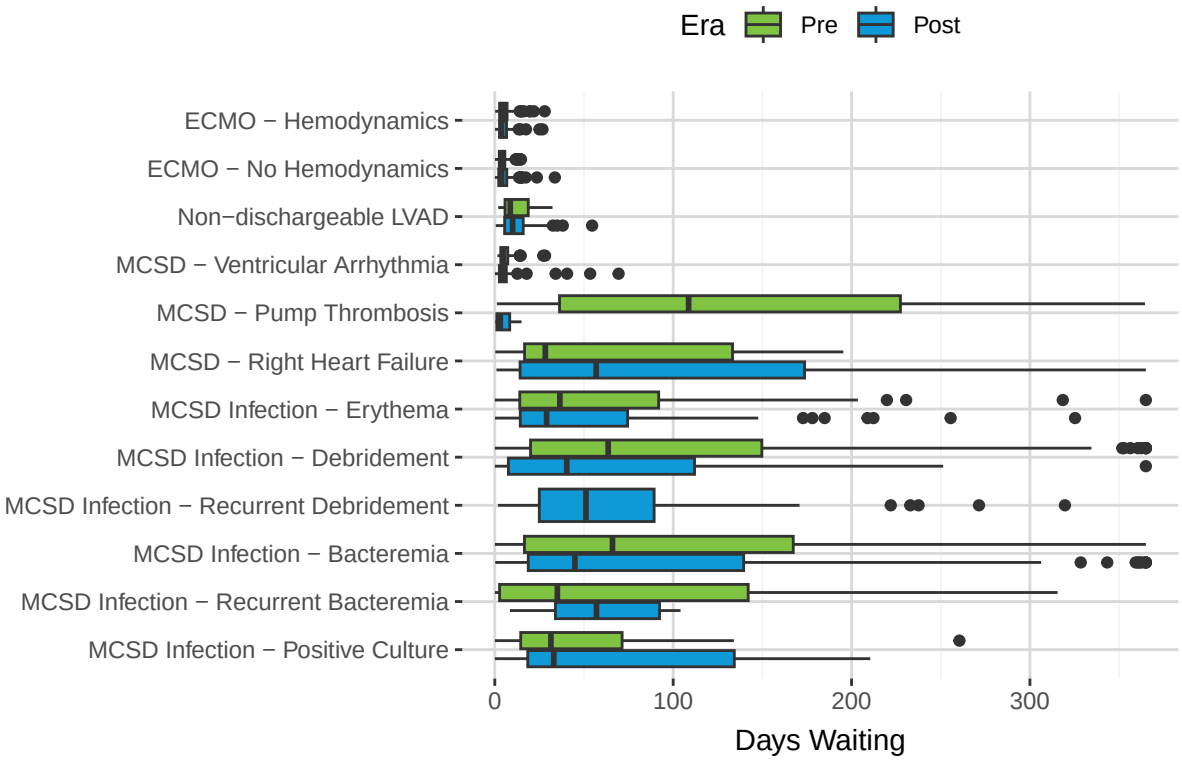
Note:
"MCSD with device infection - Recurrent debridement" and "MCSD with life-threatening ventricular arrhythmia after 7 days" were only available post-implementation

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 decreased post-implementation for "MCSD with life-threatening ventricular arrhythmia," "MCSD with pump thrombosis," "MCSD with device infection - Erythema," "MCSD with device infection - Debridement," and "MCSD with device infection - Bacteremia," and increased for all other criteria of interest. The greatest increase in the median days waiting post-implementation occurred for "MCSD with right heart failure," which rose from a median of 28.32 to 56.84 days waiting post-implementation. The greatest decrease in median days waiting post-implementation was seen for "MCSD with pump thrombosis," where the median days waiting fell from 108.65 pre-implementation to 3.09 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 and Days Spent Waiting Under Non-Consecutive Extensions for Criteria of Interest by Era

	Max #		Mean #		Median #		Mean Days		Median Days	
Criteria	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Status 1										
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained	3	3	1.2	1.2	1.0	1.0	5.15	4.00	3.0	3.0
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained	1	4	1.0	1.2	1.0	1.0	4.09	5.00	4.0	5.0
Non-dischargeable, surgically implanted, non-endovascular LVAD	4	5	1.8	2.1	2.0	1.5	8.91	12.80	9.0	8.0
MCSD with life-threatening ventricular arrhythmia	1	7	1.0	3.1	1.0	2.0	7.50	20.11	8.5	10.0
Status 3										
MCSD with pump thrombosis	25	1	9.8	1.0	9.0	1.0	135.06	5.80	124.0	4.0
MCSD with right heart failure	14	4	6.9	2.0	5.5	1.5	87.75	108.88	64.5	74.5
MCSD with device infection - Erythema	25	21	6.7	4.6	4.0	3.5	89.33	58.81	49.0	42.0
MCSD with device infection - Debridement	26	24	8.1	5.2	5.5	3.0	111.51	67.41	74.0	30.0
MCSD with device infection - Recurrent debridement		3		1.5		1.0		103.33		88.5
MCSD with device infection - Bacteremia	10	10	3.5	3.9	3.0	3.0	119.80	134.12	96.0	105.0
MCSD with device infection - Recurrent bacteremia	4	1	3.0	1.0	3.0	1.0	219.50	29.00	219.5	29.0
MCSD with device infection - Positive culture	2	2	1.2	1.5	1.0	1.5	47.00	74.50	10.0	84.5
MCSD with life-threatening ventricular arrhythmia after 7 days		0		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 candidates pre- vs post-implementation.

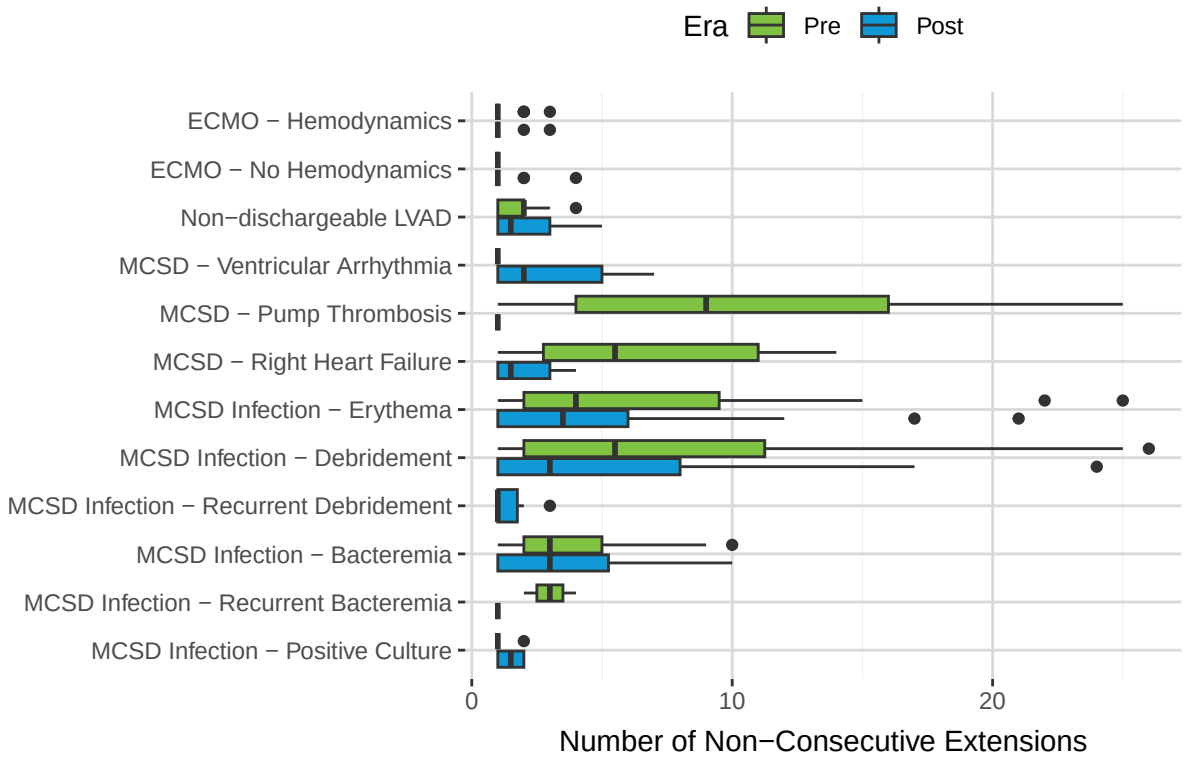
Figure 4 shows the distribution of the number of non-consecutive extensions for adult heart candidates waiting under the criteria of interest. There was little change in the median number of non-consecutive extensions for the Status 1 criteria. For the Status 3 criteria, The median number of non-consecutive 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, 1.5 post-implementation). The criterion with the greatest median number of extension forms pre-implementation was "MCSD with pump thrombosis" (median 9 extension forms), while post-implementation it was "MCSD with device infection - Erythema" (median 3.5 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 64.5 days pre-implementation vs 74.5 post-implementation), "MCSD with device infection - Bacteremia" (median 96 days pre-implementation vs 105 post-implementation), and "MCSD with device infection - Positive culture" (median 10 days pre-implementation vs 84.5 post-implementation, but this may not be representative due to low sample size). The most dramatic decrease was seen for "MCSD with device infection - Recurrent

bacteremia" (median 219.5 days waiting pre-implementation to 29 post-implementation). Post-implementation the criterion with the greatest nonconsecutive days waiting was "MCSD with device infection - Bacteremia" (median 105 days waiting).

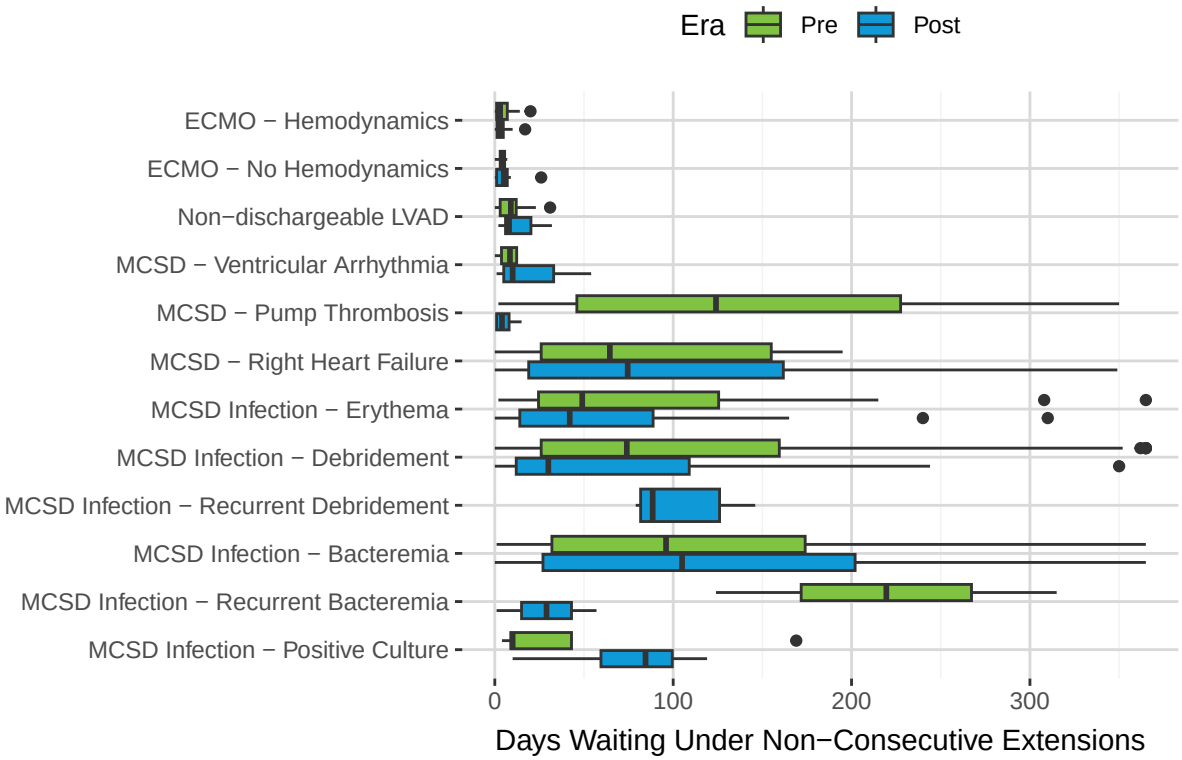
The median number of non-consecutive extensions submitted for "MCSD with device infection - Recurrent debridement," which was added at implementation, was 1 post-implementation, and the median days waiting under non-consecutive extensions was 88.5. No candidates waited at the other criterion added at 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 and Days Spent Waiting Under Longest Sequence of Consecutive Extensions for Criteria of Interest by Era

	Max #		Mean #		Median #		Mean Days		Median Days	
Criteria	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Status 1										
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained	3	3	1.2	1.2	1	1.0	5.15	4.00	3.0	3.0
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained	1	4	1.0	1.2	1	1.0	4.09	5.00	4.0	5.0
Non-dischargeable, surgically implanted, non-endovascular LVAD	4	5	1.7	2.1	2	1.5	8.83	12.80	9.0	8.0
MCSD with life-threatening ventricular arrhythmia	1	6	1.0	2.9	1	2.0	7.50	18.33	8.5	10.0
Status 3										
MCSD with pump thrombosis	21	1	9.1	1.0	9	1.0	125.14	5.80	118.0	4.0
MCSD with right heart failure	14	4	6.6	1.8	5	1.0	86.00	97.12	59.5	58.5
MCSD with device infection - Erythema	25	21	6.3	4.0	4	2.5	85.52	51.93	49.0	35.0
MCSD with device infection - Debridement	26	24	7.1	4.5	5	2.0	98.06	59.94	72.0	28.0
MCSD with device infection - Recurrent debridement		2		1.3		1.0		99.50		88.5
MCSD with device infection - Bacteremia	10	10	3.2	3.5	3	3.0	113.64	123.58	91.0	96.0
MCSD with device infection - Recurrent bacteremia	4	1	3.0	1.0	3	1.0	219.50	29.00	219.5	29.0
MCSD with device infection - Positive culture	2	2	1.2	1.5	1	1.5	47.00	74.50	10.0	84.5
MCSD with life-threatening ventricular arrhythmia after 7 days		0		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 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 7 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 criteria of interest. However, the median length of the longest consecutive series of extensions did fall for “MCSD with pump thrombosis” (9 pre-implementation, 1 post-implementation), “MCSD with right heart failure” (5 pre-implementation, 1 post-implementation), and “MCSD with device infection - Debridement” (5 pre-implementation, 2 post-implementation). Pre-implementation the criterion with the longest median length of consecutive extensions was “MCSD with pump thrombosis” (median 9 extensions), while post-implementation it was “MCSD with device infection - Bacteremia” (median 3 extensions).

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 device infection - Bacteremia” (median 91 days pre-implementation vs 96 post-implementation) and “MCSD with device infection - Positive culture” (median 10 days pre-implementation vs 84.5 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 device infection - Recurrent bacteremia” (median 219.5 days

pre-implementation vs 29 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 88.5. 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

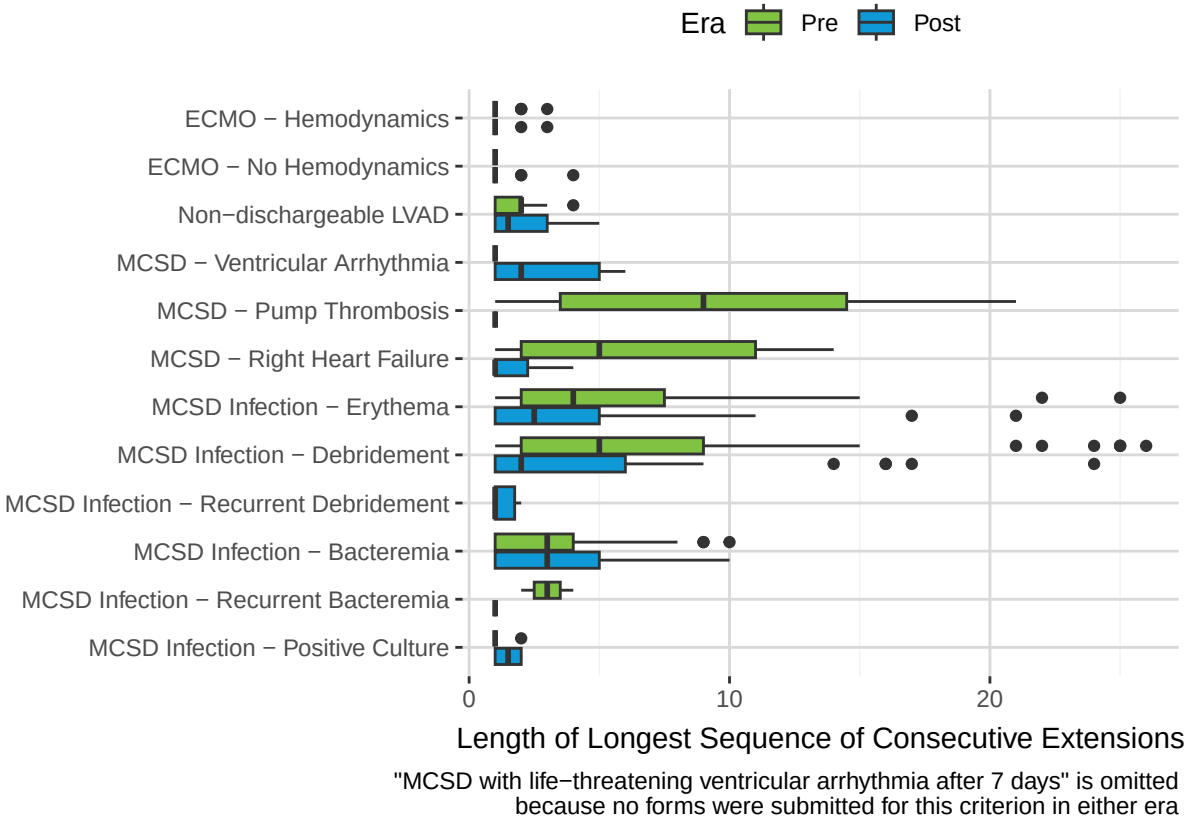
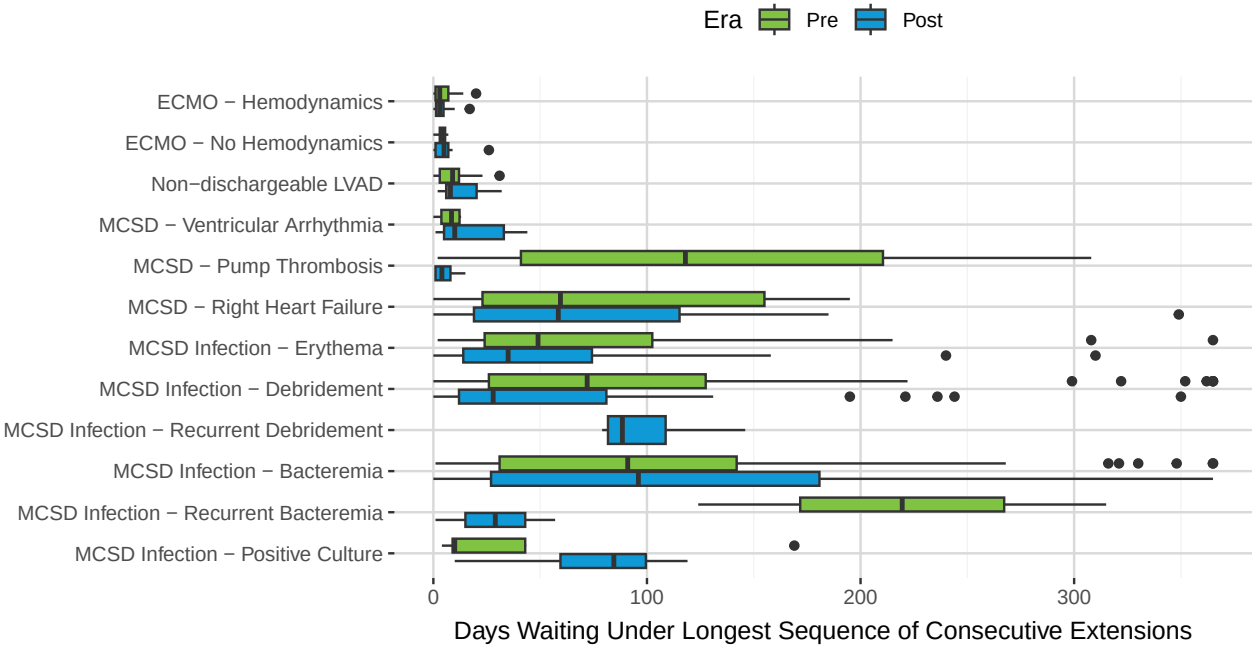


Figure 7: Distribution of Days Waiting Under Longest Consecutive Sequence of Extensions for Criteria of Interest by Era



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

Transplant

There were 3449 adult heart transplants between October 27, 2021 and October 26, 2022 (pre-implementation) and 4034 between October 27, 2022 and October 26, 2023 (post-implementation). Of these, 313 (9.08%) were candidates waiting with one of the criteria of interest at transplant pre-implementation, and 325 (8.06%) 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

	Pre		Post		
Criteria	N	%	N	%	Change
Status 1					
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values obtained	73	2.12%	104	2.58%	+31
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic values not obtained	72	2.09%	109	2.7%	+37
Non-dischargeable, surgically implanted, non-endovascular LVAD	29	0.84%	28	0.69%	-1
MCSD with life-threatening ventricular arrhythmia			24	0.59%	+24
Status 3					
MCSD with pump thrombosis	16	0.46%	0	0%	-16
MCSD with right heart failure	3	0.09%	1	0.02%	-2
MCSD with device infection - Erythema	10	0.29%	13	0.32%	+3
MCSD with device infection - Debridement	29	0.84%	10	0.25%	-19
MCSD with device infection - Recurrent debridement			10	0.25%	+10
MCSD with device infection - Bacteremia	38	1.1%	21	0.52%	-17
MCSD with device infection - Recurrent bacteremia	3	0.09%	3	0.07%	0
MCSD with device infection - Positive culture	6	0.17%	2	0.05%	-4
MCSD with life-threatening ventricular arrhythmia after 7 days	0	0%	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 registrations with each of the criteria of interest at transplant. Most 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" (72 transplants pre-implementation, 109 post-implementation), while the criterion with the greatest decrease was "MCSD with device infection - Debridement" (29 transplants pre-implementation, 10 post-implementation).

"MCSD with device infection - Recurrent debridement," which was added at implementation, saw 10 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 "MCSD with pump thrombosis" criterion: there were very few registrations qualifying under this criterion and no extensions submitted at all post-implementation.

The criterion "MCSD with life-threatening ventricular arrhythmia after 7 days," which was added at implementation, saw no use in the first year 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.