Final Report

OPTN Heart Committee | Descriptive Data Request

1-Year Monitoring of Heart Policy to Address Patient Safety Following Device Recall

DHHS Contract No. 250-2019-00001C
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Heart Committee
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By:
Alina Martinez, MS
Kelsi Lindblad, PhD
UNOS Research Department

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Background/Purpose

Mechanical circulatory support devices (MCSD) have long been an essential treatment for severe heart failure [1]. MCSDs are commonly used for bridge-to-transplant therapy, as well as temporary bridge-to recovery therapy and a permanent solution to severe heart failure. MCSDs are also used as destination therapy for many individuals with heart failure. Beginning in June 2021 and continuing through June 2022, the FDA issued multiple recall notices related to a specific type of MCSD. In a February 2022 letter to the OPTN Heart Transplantation Committee, the device manufacturer stated that the device's delay in restarting or failing to restart was linked to a total of ten deaths worldwide.

The OPTN Executive Committee, acting on behalf of the OPTN Board of Directors, [2] approved the Committee's policy change on July 11, 2022 as allowed for in the emergency actions pathway established in OPTN Bylaw 11.7. The emergency policy allowed a transplant program to proactively assign a heart candidate with a FDA recalled heart device to a more urgent and appropriate heart status. Transplant programs can now request an exception for an adult heart status 1, 2, or 3 in the event that a transplant candidate's implanted MCSD is subject to a recall by the FDA, even if the candidate is not hospitalized at the time. On December 5, 2022, the OPTN Board of Directors approved adoption of the policy as permanent.

This report examines the impact of the modifications to adult heart policy to address patient safety following device recall at 1-year post-implementation.

Strategic Plan Goal or Committee Project Addressed

Improve waitlisted patient, living donor, and transplant recipient outcomes

[1]Sen, Ayan, Joel S. Larson, Kianoush B. Kashani, Stacy L. Libricz, Bhavesh M. Patel, Pramod K. Guru, Cory M. Alwardt, Octavio Pajaro, and J. Christopher Farmer. "Mechanical Circulatory Assist Devices: a Primer for Critical Care and Emergency Physicians." Critical Care (London, England) 20, no. 1 (2016): 153–153. https://doi.org/10.1186/s13054-016-1328-z. Stehlik, Josef, and James K Kirklin. "The Long and Winding Road to an Effective Left Ventricular Assist Device: The Demise of Medtronic's HVAD." Circulation (New York, N.Y.) 144, no. 7 (2021): 509–11. https://doi.org/10.1161/CIRCULATIONAHA.121.056027.

[2]OPTN Bylaws, Article IV Executive Committee, (December 6, 2021), ("Considers any issues that require expedited action between meetings of the Board of Directors.").

Committee Request

This report assesses the impact of the modified heart policy to address patient safety following device recall post-implementation. As outlined in the monitoring plan for this policy change, specific measures examined will include:

- The number and percent of all heart registrations that submitted a device recall exception
- The number and percent of registrations ever waiting by medical urgency status and criteria within medical urgency status (including device recall exception)
- The number and percent of waitlist additions by medical urgency status and criteria within medical urgency status (including device recall exception) between July 14, 2022 and July 13, 2023
- The number and percent of waitlist additions by medical urgency status and criteria within medical urgency status (including device recall exception) and by month between July 14, 2022 and July 13, 2023
- The number and percent of transplants by medical urgency status (including device recall exception)

Data and Methods

Data Sources:

These analyses use data from the OPTN waiting list and the Transplant Candidate Registration (TCR) form.

Cohort:

- Adult (age >= 18) candidates ever waiting on the heart waiting list between July 14, 2022 and July 13, 2023
- Adult (age >= 18) candidates added to the heart waiting list between July 14, 2022 and July 13, 2023
- Adult (age >= 18) heart transplants performed between July 14, 2022 and July 13, 2023

Methods:

The number and percent of all registrations, waitlist additions, and transplants that submitted a device recall exception was calculated based on a cohort of adult (age >= 18) candidates on the heart waiting list between July 14, 2022 and July 13, 2023. The percent of registrations that submitted a device recall exception was assessed based on the proportion of registrations that submitted a device recall exception, and the total number of adult heart registrations ever waiting on the heart waiting list.

Adult candidates ever waiting were stratified by medical urgency status at their most recent time point.

Waitlist additions were stratified by medical urgency status and month of addition to waitlist.

Adult heart transplants were stratified by medical urgency status.

Since candidates with Adult Status 5 and Adult Status 6 have no qualifying criteria, the counts of candidates ever waiting and waiting list additions are given in each table of this report.

Based on OPTN data as of Nov 10, 2023. Data subject to change based on future data submission or correction.

Results

There were a total of 7736 adult heart registrations ever waiting and 3892 adult waitlist additions between July 14, 2022 and July 13, 2023. 114 of all adult registrations ever waiting and 17 adult watilist additions submitted a device recall exception. The device recall exception submissions accounted for 1.47% of all adult registrations ever waiting, and 0.44% of adult waitlist additions. Moreover, of the 3969 adult heart transplants performed between July 14, 2022 and July 13, 2023, 86 submitted a device recall exception. This accounted for 2.17% of adult heart transplants between July 14, 2022 and July 13, 2023.

Figure 1. Percent of Registrations Ever Waiting by Medical Urgency Status and Criteria within Medical Urgency Status

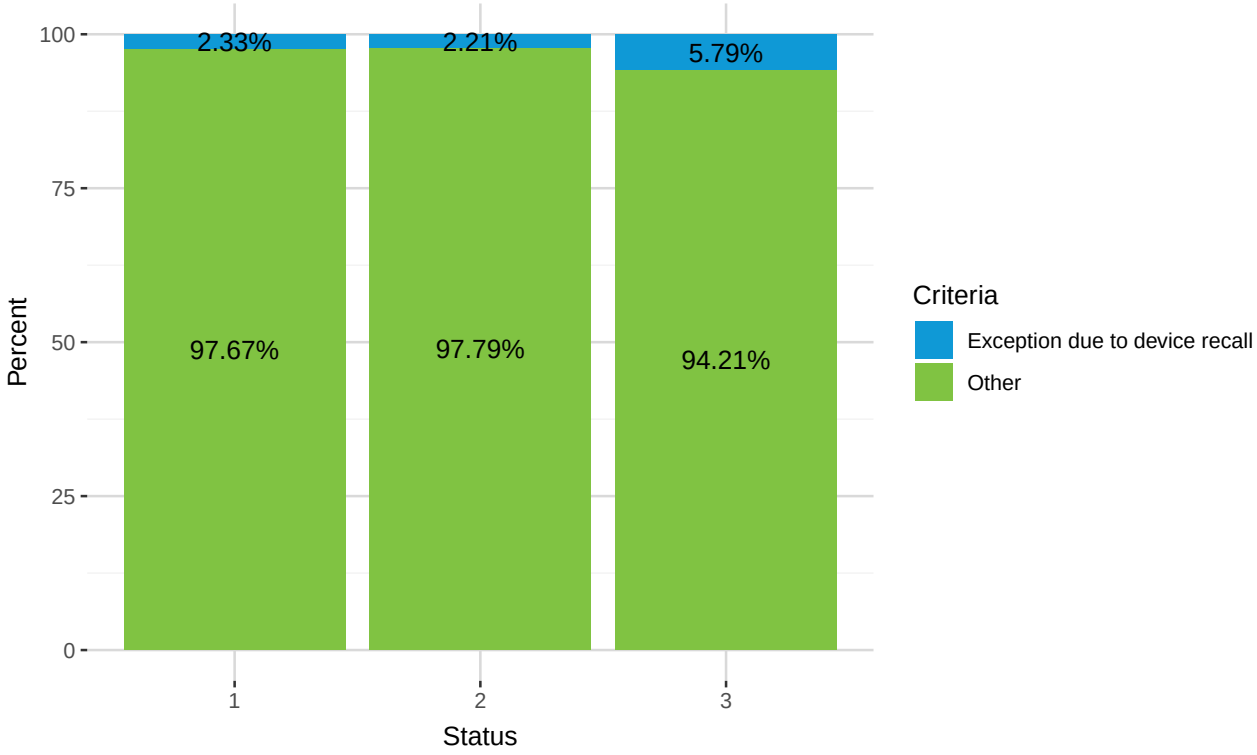

Figure 1 summarizes the percent of adult registrations ever waiting by medical urgency status and criteria within medical urgency status (including device recall exception) at their most recent point. Adult Status 3 represented the largest percentage of registrations by status that submitted a device recall exception, while Adult Status 2 had the lowest percentage.

Figure 2. Number of Registrations with 'Exception due to Device Recall' Criteria by Status

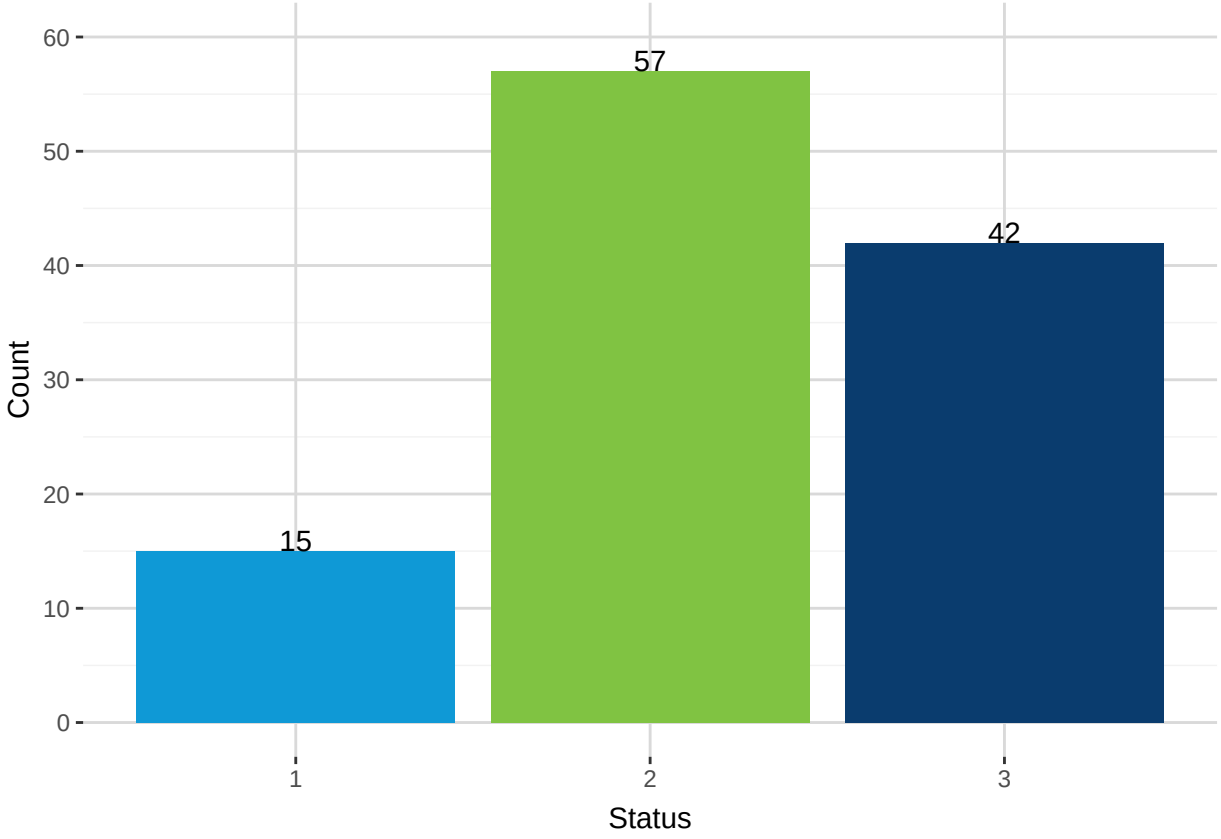

Figure 2 shows the number of adult registrations that submitted a device recall exception. A total of 114 registrations submitted a device recall exception, which accounted for 1.47% of all adult heart registrations between July 14, 2022 and July 13, 2023. Adult Status 2 had the largest number of registrations that submitted device recall exception.

Table 1. Number and Percent of Registrations Ever Waiting by Medical Urgency Status and Criteria within Medical Urgency Status

Status	Criteria Description	N	%
Adult Status 1	BIVAD/Ventricular Episodes	37	5.74
	Exception	311	48.22
	Exception due to device recall	**15**	**2.33**
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	38	5.89
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	133	20.62
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	111	17.21
Adult Status 2	Exception	1288	49.98
	Exception due to device recall	**57**	**2.21**
	Intra-aortic ballon pump - Hemodynamic Values not obtained	17	0.66
	Intra-aortic ballon pump - Hemodynamic Values obtained	616	23.90
	Mechanical circulatory support device(MCSD) with malfunction	52	2.02
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	35	1.36
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	50	1.94
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	412	15.99
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	27	1.05
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	23	0.89
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	149	20.52
	Exception	223	30.72
	Exception due to device recall	**42**	**5.79**
	Intra-aortic balloon pump after 14 days	8	1.10
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	24	3.31
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	69	9.50
	Mechanical circulatory support device (MCSD) with device infection - Debridement	37	5.10
	Mechanical circulatory support device (MCSD) with device infection - Erythema	28	3.86
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	10	1.38
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	5	0.69
	Mechanical circulatory support device (MCSD) with device infection - Recurrent Debridement	13	1.79
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	0.14
	Mechanical circulatory support device (MCSD) with pump thrombosis	10	1.38
	Mechanical circulatory support device (MCSD) with right heart failure	4	0.55
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	97	13.36

	Percutaneous endovascular circulatory support device after 14 days	5	0.69
	Veno-arterial extracorporeal membrane oxygenation (VA ECMO) after 7 days	1	0.14
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	191	7.55
	Congenital heart disease	193	7.63
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1429	56.50
	Exception	264	10.44
	Inotropes without hemodynamic monitoring	264	10.44
	Ischemic heart disease with intractable angina	54	2.14
	Retransplant	134	5.30
Adult Status 5	No criteria for this status	238	100.00
Adult Status 6	No criteria for this status	1021	100.00

Table 1 summarizes the number and percent of adult registrations ever waiting by medical urgency status and criteria within medical urgency status (including device recall exception) at their most recent point.

Figure 3. Percent of Waitlist Additions by Medical Urgency Status and Criteria within Medical Urgency Status (at listing)

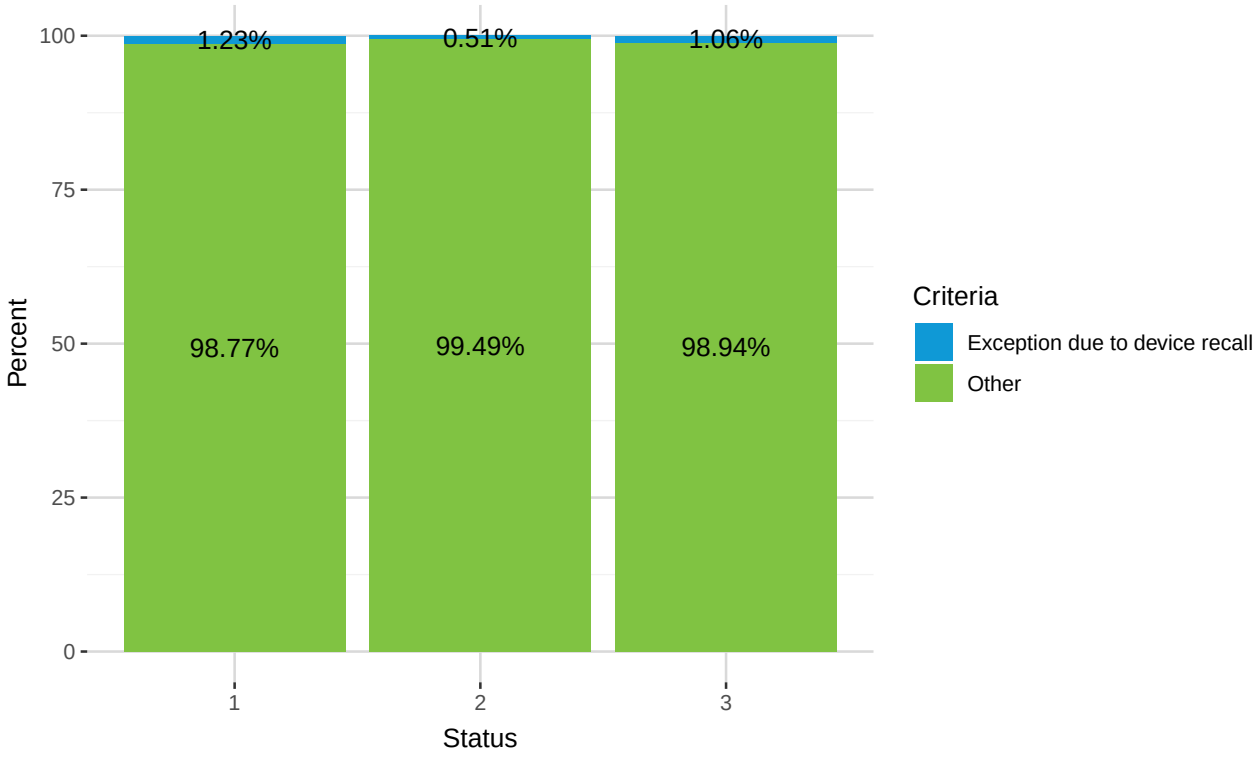

Figure 3 summarizes the percent of adult waitlist additions by medical urgency status and criteria within medical urgency status (including device recall exception) between July 14, 2022 and July 13, 2023. Overall, Adult Status 1 represented the largest percentage of registrations by status that submitted a device recall exception.

Figure 4. Number of Waitlist Additions with 'Exception due to Device Recall' Criteria by Status (at listing)

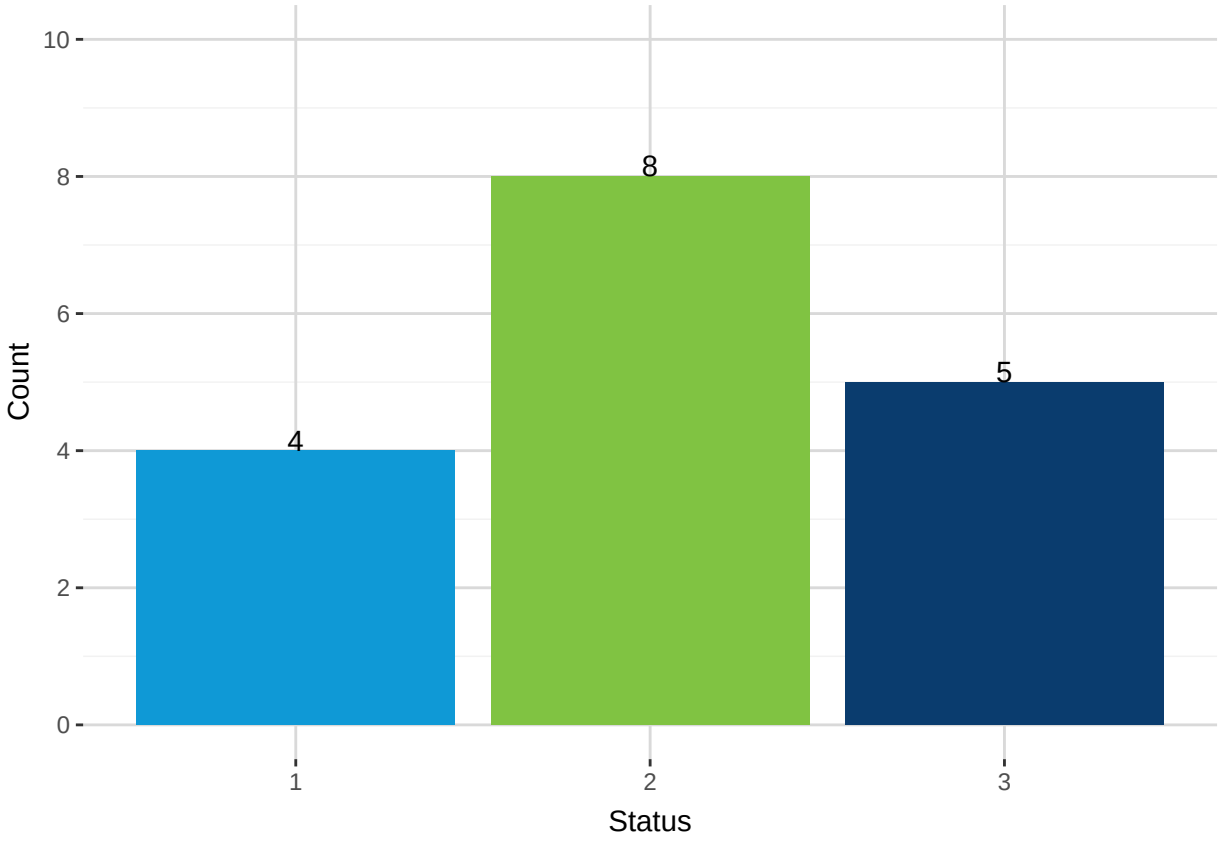

Figure 4 shows the number of adult waitlist additions that submitted a device recall exception between July 14, 2022 and July 13, 2023. Overall, Adult Status 2 had the largest number of waitlist additions with 'exception due to device recall' criteria.

Table 2. Number and Percent of Waitlist Additions by Medical Urgency Status and Criteria within Medical Urgency Status (at listing)

Inital Status	Criteria Description	N	%
Adult Status 1	BIVAD/Ventricular Episodes	15	4.62
	Exception	111	34.15
	Exception due to device recall	**4**	**1.23**
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	18	5.54
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	112	34.46
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	65	20.00
Adult Status 2	Exception	609	38.84
	Exception due to device recall	**8**	**0.51**
	Intra-aortic ballon pump - Hemodynamic Values not obtained	16	1.02
	Intra-aortic ballon pump - Hemodynamic Values obtained	481	30.68
	Mechanical circulatory support device(MCSD) with malfunction	14	0.89
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	37	2.36
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	35	2.23
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	318	20.28
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	25	1.59
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	25	1.59
Adult Status 3	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	80	16.95
	Exception	165	34.96
	Exception due to device recall	**5**	**1.06**
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	3	0.64
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	28	5.93
	Mechanical circulatory support device (MCSD) with device infection - Debridement	22	4.66
	Mechanical circulatory support device (MCSD) with device infection - Erythema	11	2.33
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	3	0.64
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	4	0.85
	Mechanical circulatory support device (MCSD) with device infection - Recurrent Debridement	9	1.91
	Mechanical circulatory support device (MCSD) with pump thrombosis	1	0.21
	Mechanical circulatory support device (MCSD) with right heart failure	2	0.42
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	139	29.45
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	164	10.74
	Congenital heart disease	142	9.30

	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	522	34.18
	Exception	193	12.64
Adult Status 4	Inotropes without hemodynamic monitoring	394	25.80
	Ischemic heart disease with intractable angina	32	2.10
	Retransplant	80	5.24
Adult Status 5	No criteria for this status	158	100.00
Adult Status 6	No criteria for this status	748	100.00

Table 2 summarizes the number and percent of adult waitlist additions by medical urgency status and criteria within medical urgency status (including device recall exception) between July 14, 2022 and July 13, 2023.

Figure 5. Number of Waitlist Additions with 'Exception due to Device Recall' Criteria by Medical Urgency Status and Month

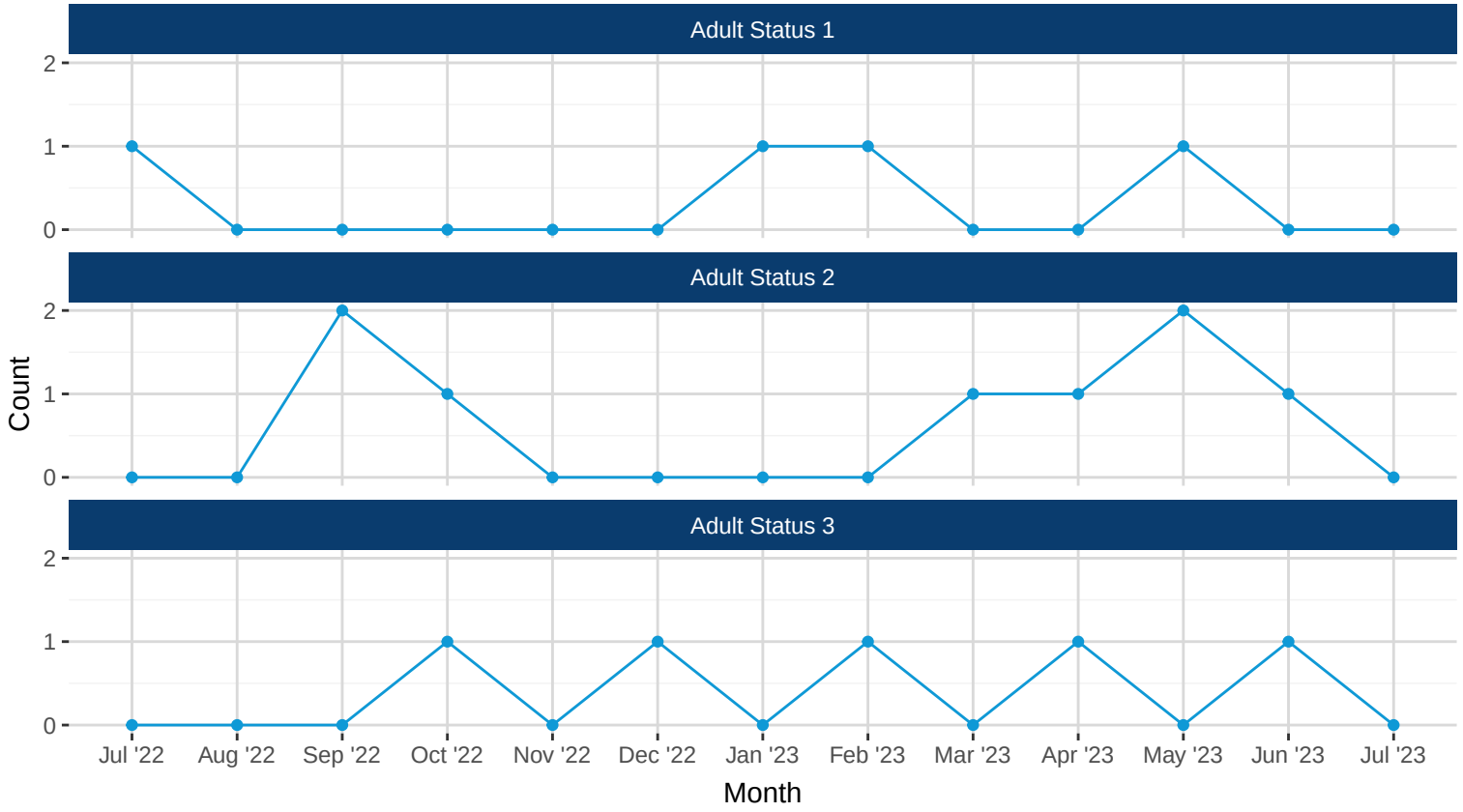

Figure 5 shows the number of adult waitlist additions per month that submitted a device recall exception between July 14, 2022 and July 13, 2023 . Note: July 2022 and July 2023 appear as incomplete months due to the timing of project implementation.

Table 3. Number of Waitlist Additions Qualifying by Device Recall by Status and Month

Initial Status	Registration Month	Number of Additions	Percent of Additions within Status and Month(%)
Adult Status 1	Jul 2022	1	6.667
	Aug 2022	0	0.000
	Sep 2022	0	0.000
	Oct 2022	0	0.000
	Nov 2022	0	0.000
	Dec 2022	0	0.000
	Jan 2023	1	2.778
	Feb 2023	1	3.846
	Mar 2023	0	0.000
	Apr 2023	0	0.000
	May 2023	1	3.846
	Jun 2023	0	0.000
	Jul 2023	0	0.000
Adult Status 2	Jul 2022	0	0.000
	Aug 2022	0	0.000
	Sep 2022	2	1.613
	Oct 2022	1	0.943
	Nov 2022	0	0.000
	Dec 2022	0	0.000
	Jan 2023	0	0.000
	Feb 2023	0	0.000
	Mar 2023	1	0.559
	Apr 2023	1	0.909
	May 2023	2	1.143
	Jun 2023	1	0.690
	Jul 2023	0	0.000
	Jul 2022	0	0.000
	Aug 2022	0	0.000

Adult Status 3	Sep 2022	0	0.000
	Oct 2022	1	3.846
	Nov 2022	0	0.000
	Dec 2022	1	2.564
	Jan 2023	0	0.000
	Feb 2023	1	3.125
	Mar 2023	0	0.000
	Apr 2023	1	3.448
	May 2023	0	0.000
	Jun 2023	1	1.754
	Jul 2023	0	0.000

Table 3 summarizes the number and percent of adult waitlist additions per month that submitted a device recall exception between July 14, 2022 and July 13, 2023.

Figure 6. Percent of Transplants by Medical Urgency Status and Criteria within Medical Urgency Status (including device recall exception)

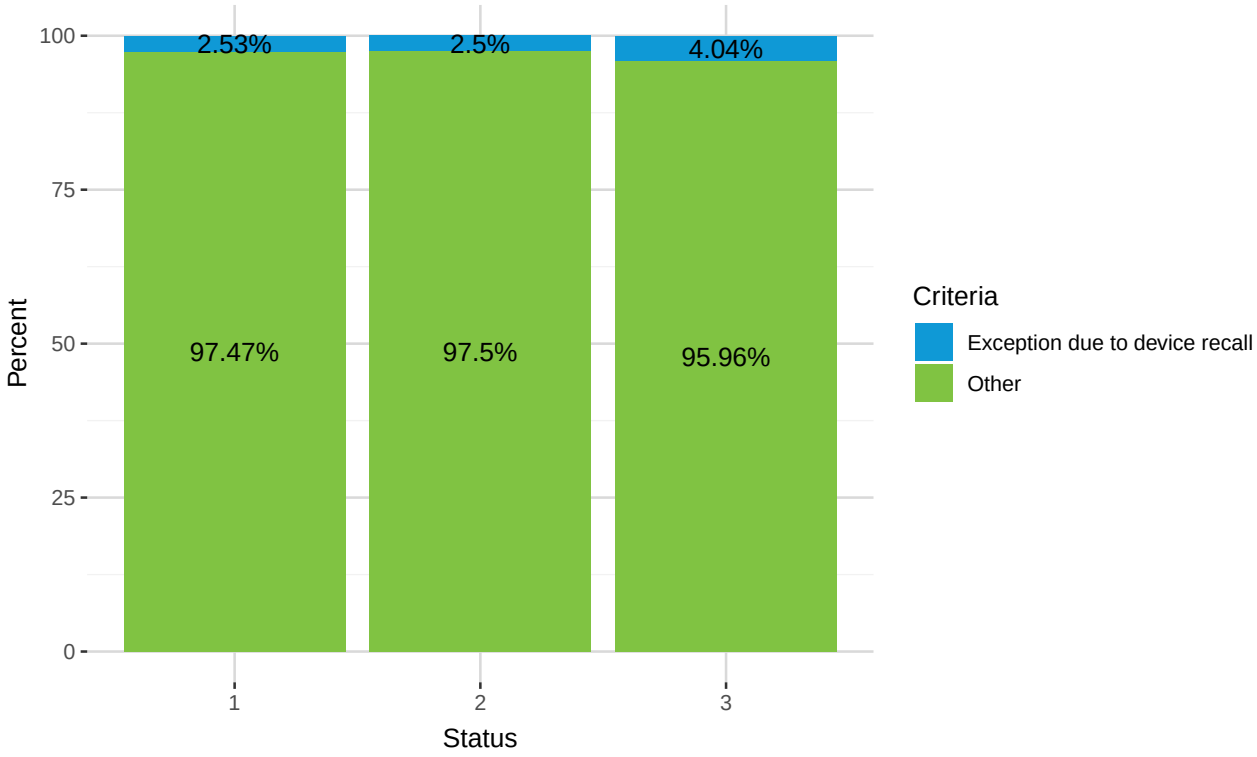

Figure 6 summarizes the percent of adult transplants by medical urgency status and criteria within medical urgency status (including device recall exception) between July 14, 2022 and July 13, 2023. Overall, Adult Status 3 represented the largest percentage of transplants by status that submitted a device recall exception.

Figure 7. Number of Transplants with 'Exception due to Device Recall' Criteria by Status

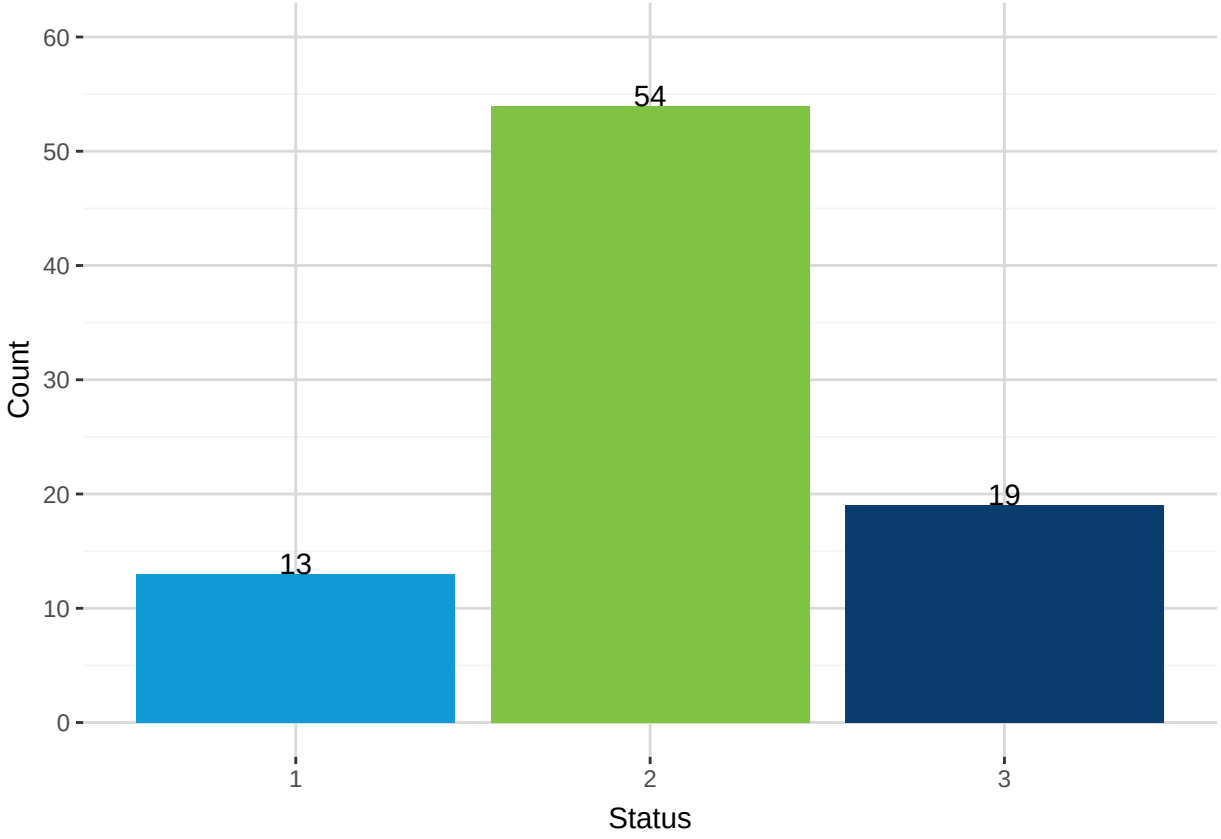

Figure 7 shows the number of adult transplants that submitted a device recall exception. A total of 86 transplants submitted a device recall exception, which accounted for 2.17% of adult heart transplants between July 14, 2022 and July 13, 2023. Overall, Adult Status 2 represented the largest number of transplants that submitted device recall exception.

Table 4. Number and Percent of Transplants by Medical Urgency Status and Criteria within Medical Urgency Status (including device recall exception)

Status	Criteria Description	N	%
Adult Status 1	BIVAD/Ventricular Episodes	29	5.65
	Exception	242	47.17
	Exception due to device recall	**13**	**2.53**
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	28	5.46
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	110	21.44
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	91	17.74
Adult Status 2	Exception	1058	48.89
	Exception due to device recall	**54**	**2.50**
	Intra-aortic ballon pump - Hemodynamic Values not obtained	15	0.69
	Intra-aortic ballon pump - Hemodynamic Values obtained	544	25.14
	Mechanical circulatory support device(MCSD) with malfunction	45	2.08
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	29	1.34
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	42	1.94
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	342	15.80
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	17	0.79
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	18	0.83
Adult Status 3	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	119	25.32
	Exception	158	33.62
	Exception due to device recall	**19**	**4.04**
	Intra-aortic balloon pump after 14 days	2	0.43
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	9	1.91
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	31	6.60
	Mechanical circulatory support device (MCSD) with device infection - Debridement	18	3.83
	Mechanical circulatory support device (MCSD) with device infection - Erythema	9	1.91
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	6	1.28
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	4	0.85
	Mechanical circulatory support device (MCSD) with device infection - Recurrent Debridement	6	1.28
	Mechanical circulatory support device (MCSD) with pump thrombosis	5	1.06
	Mechanical circulatory support device (MCSD) with right heart failure	1	0.21
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	82	17.45
	Percutaneous endovascular circulatory support device after 14 days	1	0.21

Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	65	11.17
	Congenital heart disease	43	7.39
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	228	39.18
	Exception	96	16.49
	Inotropes without hemodynamic monitoring	93	15.98
	Ischemic heart disease with intractable angina	18	3.09
	Retransplant	39	6.70
Adult Status 5	No criteria for this status	47	100.00
Adult Status 6	No criteria for this status	192	100.00

Table 4 summarizes the number and percent of adult heart transplants that submitted a device recall exception.

Conclusion

Device recall exception submissions accounted for a very small percentage of adult heart registrations, waitlist additions, and transplants between July 14, 2022, and July 13, 2023. Moreover, since the implementation of this policy, device recall exception submissions have not increased over time. Adult Status 2 represented the largest number of adult heart registrations, waitlist additions, and transplants that submitted a device recall exception. Conversely, Adult Status 1 represented the smallest number of adult heart registrations, waitlist additions, and transplants that submitted a device recall exception.