Final Report

OPTN Heart Committee | Descriptive Data Request

6-Month Monitoring of Heart Policy to Address Patient Safety Following Device Recall

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Heart Committee
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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 six months post-implementation, and will be followed by a monitoring report at one year post-implementation. This reporting timeline is subject to change based on the results.

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 January 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 January 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 January 13, 2023
- Adult (age >= 18) candidates added to the heart waiting list between July 14, 2022 and January 13, 2023
- Adult (age >= 18) heart transplants performed between July 14, 2022 and January 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 January 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 Apr 14, 2023. Data subject to change based on future data submission or correction.

Results

There were a total of 5205 adult heart registrations ever waiting and 1821 adult waitlist additions between July 14, 2022 and January 13, 2023. 82 of all adult registrations ever waiting and 6 adult watilist additions submitted a 'device recall exception'. The 'device recall exception' submissions accounted for 1.58% of all adult registrations ever waiting, and 0.33% of adult waitlist additions. Moreover, of the 1923 adult heart transplants performed between July 14, 2022 and January 13, 2023, 51 submitted a 'device recall exception'. This accounted for 2.65% of adult heart transplants between July 14, 2022 and January 13, 2023.

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

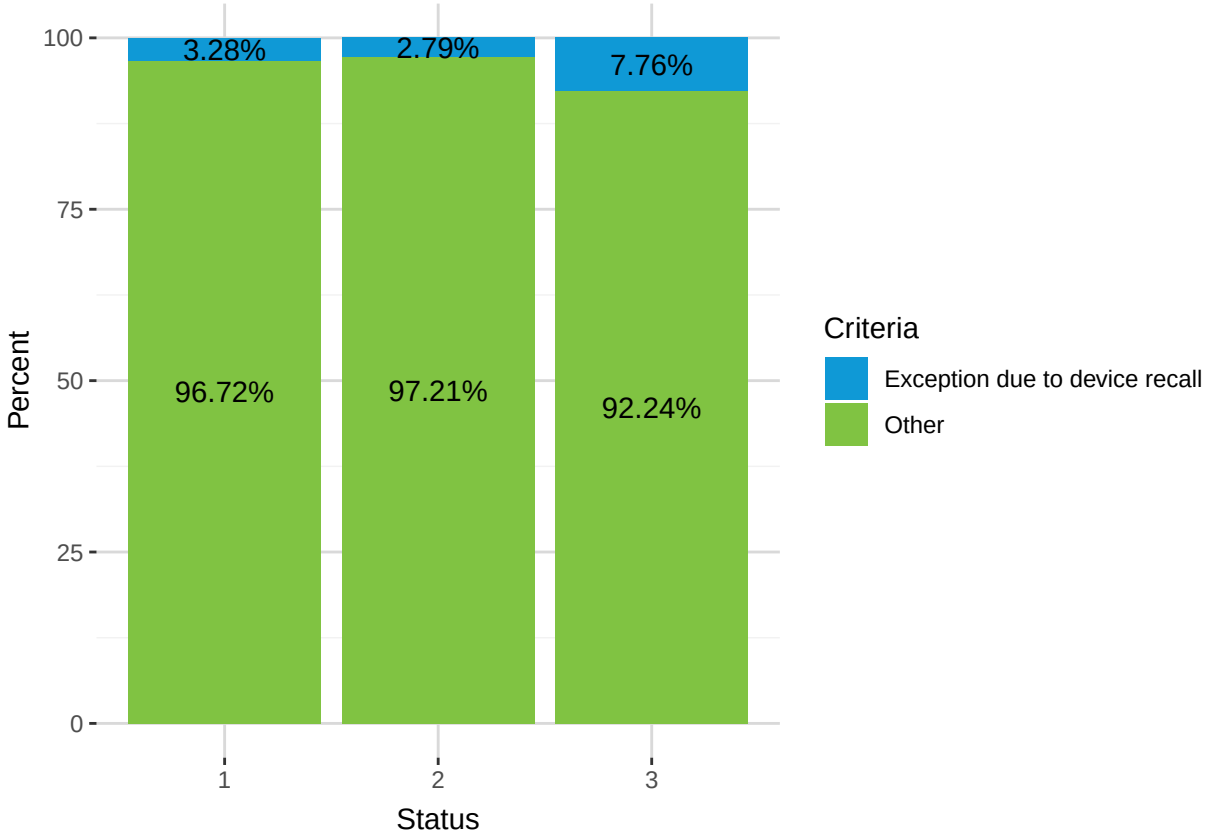

Figure 1 summarizes the percent of adult registrations ever waiting by medical urgency status and criteria within medical urgency status (including 'device recall exception') at their most recent point. Adult Status 3 represents the largest percentage of registrations by status that submitted a 'device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

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

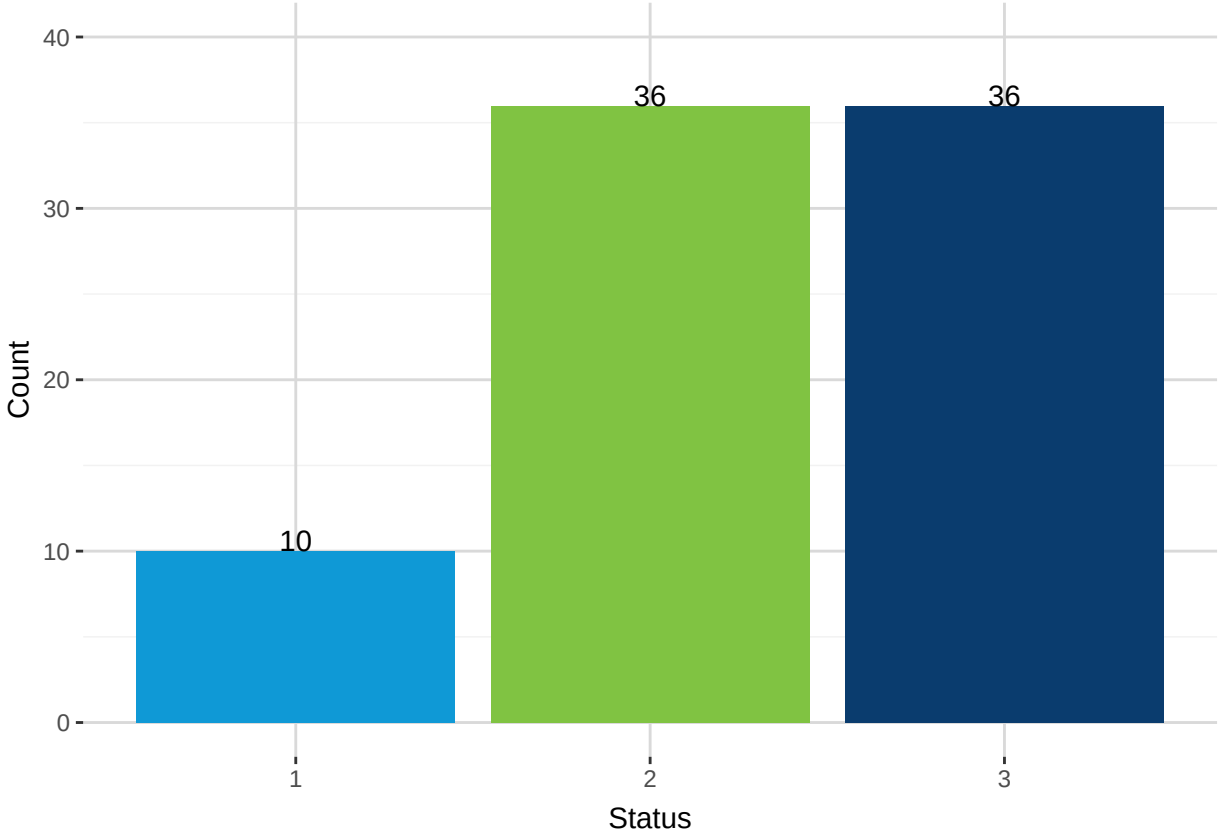

Figure 2 shows the number of adult registrations that submitted a 'device recall exception'. A total of 82 registrations submitted a 'device recall exception', which accounted for 1.58 % of all adult heart registrations between July 14, 2022 and January 13, 2023. Both Adult Status 2 and Adult Status 3 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	21	6.89
	Exception	143	46.89
	Exception due to device recall	**10**	**3.28**
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	20	6.56
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	56	18.36
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	55	18.03
Adult Status 2	Exception	635	49.22
	Exception due to device recall	**36**	**2.79**
	Intra-aortic ballon pump - Hemodynamic Values not obtained	10	0.78
	Intra-aortic ballon pump - Hemodynamic Values obtained	338	26.20
	Mechanical circulatory support device(MCSD) with malfunction	27	2.09
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	18	1.40
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	30	2.33
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	173	13.41
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	9	0.70
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	14	1.09
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	101	21.77
	Exception	130	28.02
	Exception due to device recall	**36**	**7.76**
	Intra-aortic balloon pump after 14 days	8	1.72
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	15	3.23
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	52	11.21
	Mechanical circulatory support device (MCSD) with device infection - Debridement	23	4.96
	Mechanical circulatory support device (MCSD) with device infection - Erythema	14	3.02
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	5	1.08
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	4	0.86
	Mechanical circulatory support device (MCSD) with device infection - Recurrent Debridement	7	1.51
	Mechanical circulatory support device (MCSD) with pump thrombosis	9	1.94
	Mechanical circulatory support device (MCSD) with right heart failure	2	0.43
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	52	11.21
	Percutaneous endovascular circulatory support device after 14 days	5	1.08

	Veno-arterial extracorporeal membrane oxygenation (VA ECMO) after 7 days	1	0.22
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	159	7.56
	Congenital heart disease	165	7.84
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1266	60.17
	Exception	170	8.08
	Inotropes without hemodynamic monitoring	189	8.98
	Ischemic heart disease with intractable angina	48	2.28
	Retransplant	107	5.09
Adult Status 5	No criteria for this status	182	100.00
Adult Status 6	No criteria for this status	860	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)

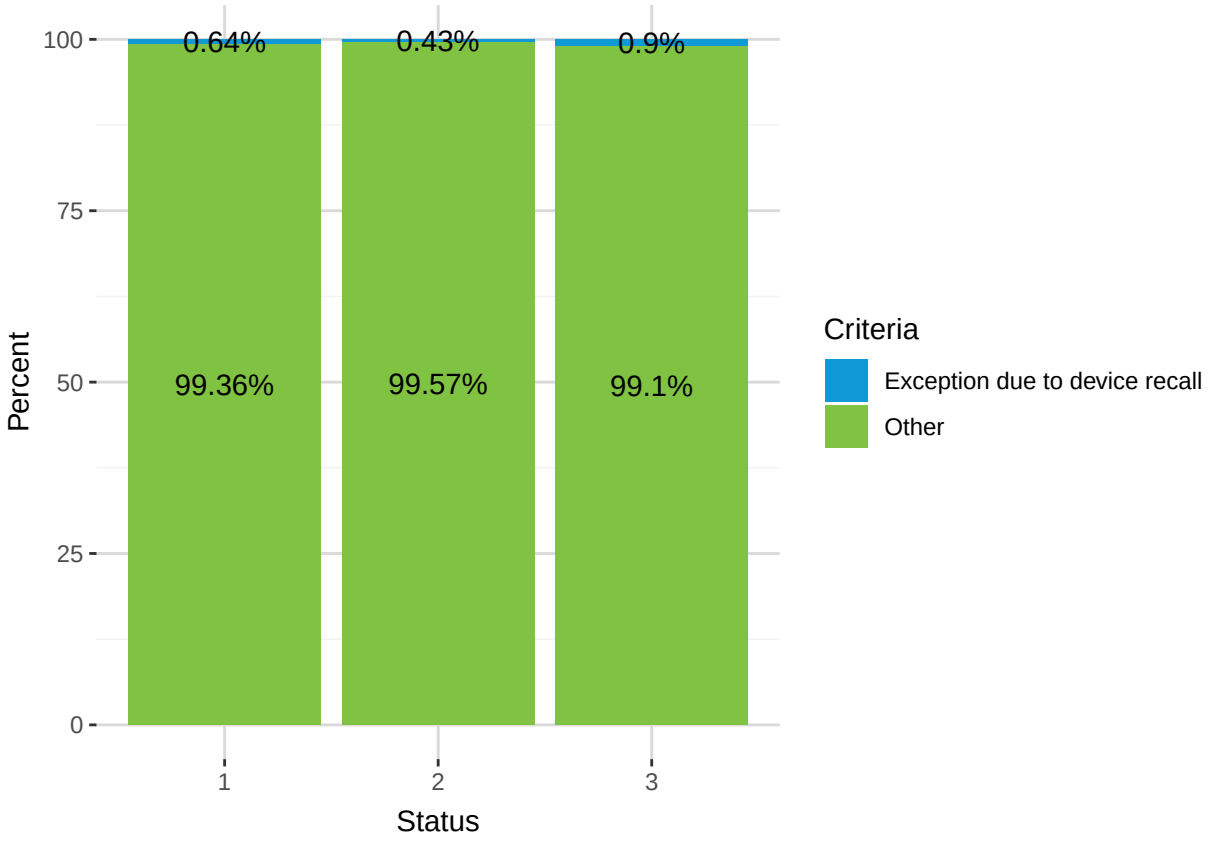

Figure 3 summarizes the percent of adult waitlist additions by medical urgency status and criteria within medical urgency status (including 'device recall exception') between July 14, 2022 and January 13, 2023. Overall, Adult Status 3 represented the largest percentage of registrations by status that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

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

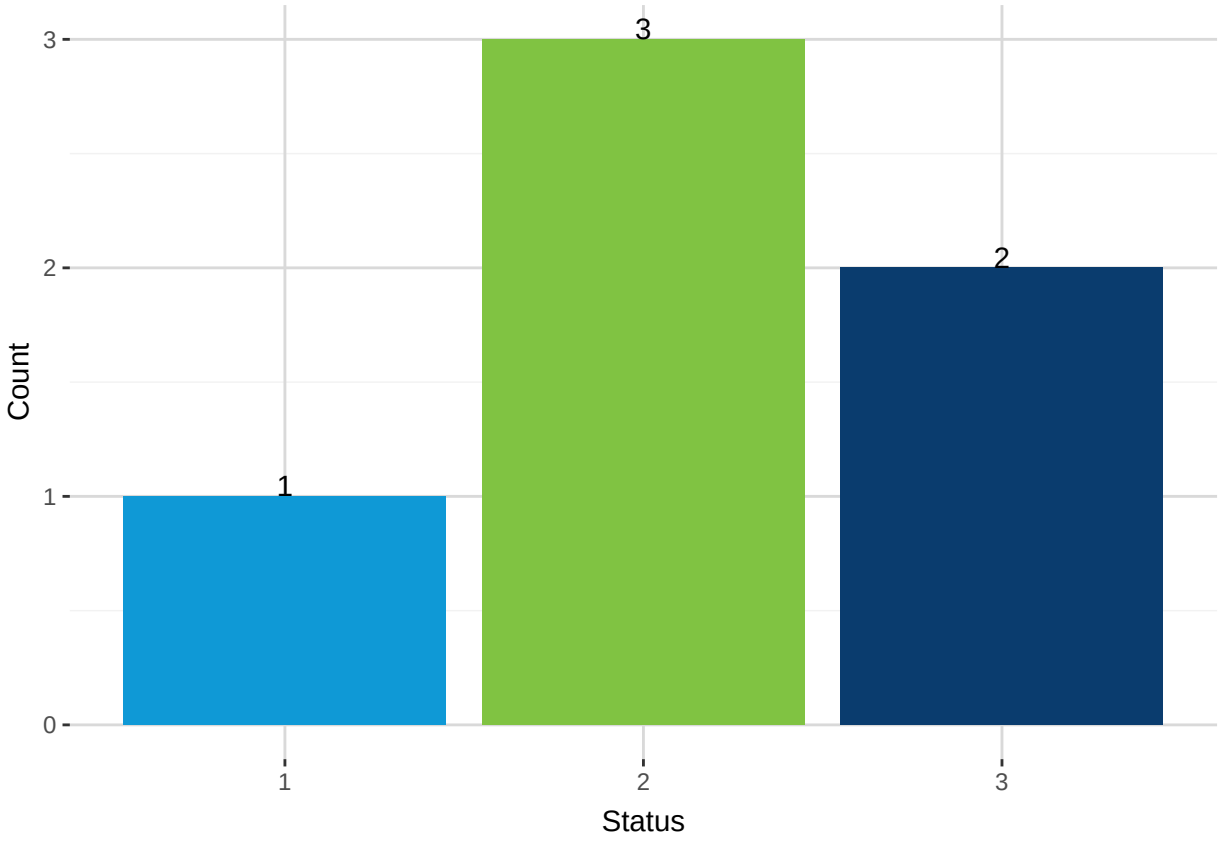

Figure 4 shows the number of adult waitlist additions that submitted a 'device recall exception' between July 14, 2022 and January 13, 2023. Overall, Adult Status 2 had the largest number of waitlist additions with 'exception due to device recall' criteria.

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	9	5.73
	Exception	56	35.67
	Exception due to device recall	**1**	**0.64**
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	9	5.73
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	49	31.21
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	33	21.02
Adult Status 2	Exception	278	39.89
	Exception due to device recall	**3**	**0.43**
	Intra-aortic ballon pump - Hemodynamic Values not obtained	9	1.29
	Intra-aortic ballon pump - Hemodynamic Values obtained	237	34.00
	Mechanical circulatory support device(MCSD) with malfunction	6	0.86
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	16	2.30
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	18	2.58
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	111	15.93
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	8	1.15
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	11	1.58
Adult Status 3	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	42	19.00
	Exception	74	33.48
	Exception due to device recall	**2**	**0.90**
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	0.45
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	14	6.33
	Mechanical circulatory support device (MCSD) with device infection - Debridement	11	4.98
	Mechanical circulatory support device (MCSD) with device infection - Erythema	3	1.36
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	2	0.90
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	3	1.36
	Mechanical circulatory support device (MCSD) with device infection - Recurrent Debridement	3	1.36
	Mechanical circulatory support device (MCSD) with right heart failure	1	0.45
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	65	29.41
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	89	11.93
	Congenital heart disease	76	10.19
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	254	34.05

Adult Status 4			
	Exception	80	10.72
	Inotropes without hemodynamic monitoring	190	25.47
	Ischemic heart disease with intractable angina	18	2.41
	Retransplant	39	5.23
Adult Status 5	No criteria for this status	76	100.00
Adult Status 6	No criteria for this status	385	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 January 13, 2023.

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

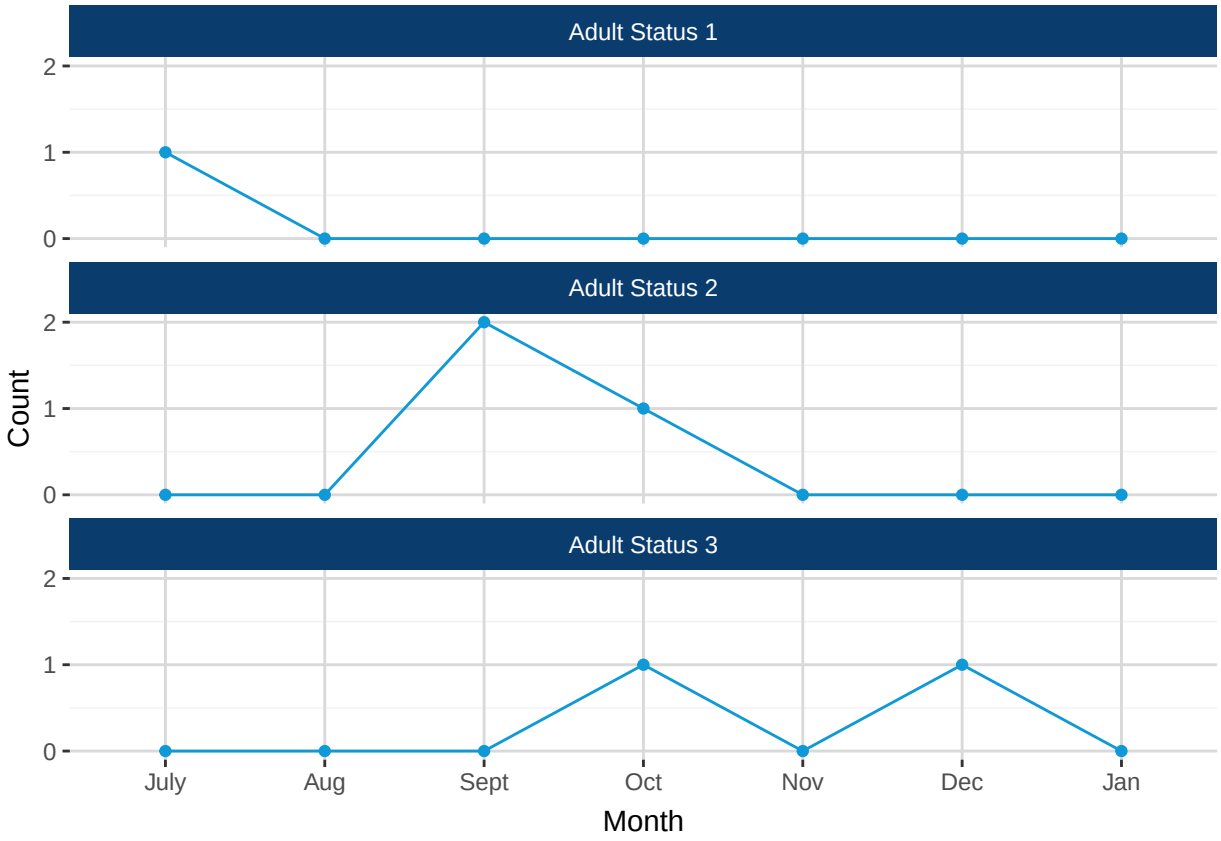

Figure 5 shows the number of adult waitlist additions per month that submitted a 'device recall exception' between July 14, 2022 and January 13, 2023 . Note: July 2022 and January 2023 appear as incomplete months due to the timing of project implementation.

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
Adult Status 1	August	0	0.000
	December	0	0.000
	January	0	0.000
	July	**1**	**0.637**
	November	0	0.000
	October	0	0.000
	September	0	0.000
Adult Status 2	August	0	0.000
	December	0	0.000
	January	0	0.000
	July	0	0.000
	November	0	0.000
	October	0	0.000
	October	**1**	**0.143**
	September	**2**	**0.287**
	September	0	0.000
Adult Status 3	August	0	0.000
	December	0	0.000
	December	**1**	**0.452**
	January	0	0.000
	July	0	0.000
	November	0	0.000
	October	**1**	**0.452**
	October	0	0.000
	September	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 January 13, 2023.

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

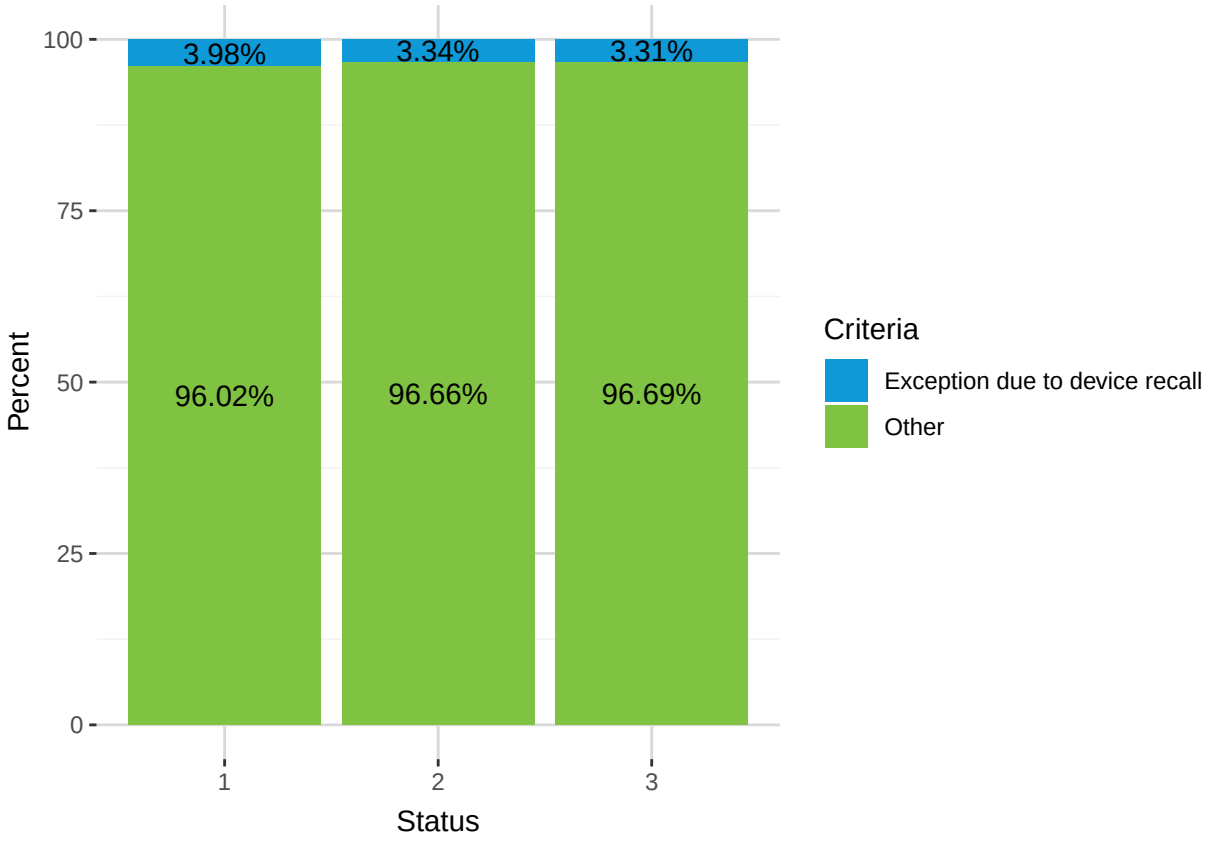

Figure 6 summarizes the percent of adult transplants by medical urgency status and criteria within medical urgency status (including 'device recall exception') between July 14, 2022 and January 13, 2023. Overall, Adult Status 1 represented the largest percentage of transplants by status that submitted a 'device recall exception'.

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

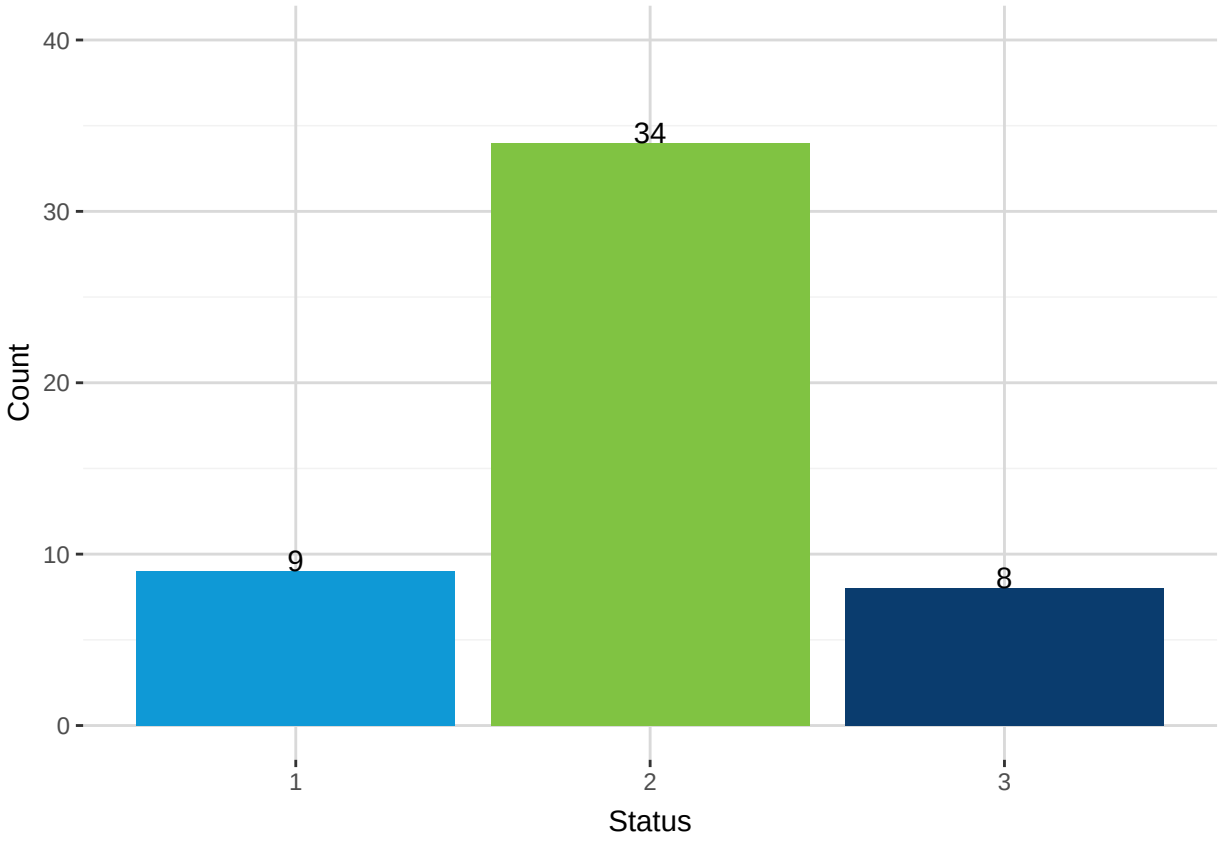

Figure 7 shows the number of adult transplants that submitted a 'device recall exception'. A total of 51 transplants submitted a 'device recall exception', which accounted for 2.65 % of adult heart transplants between July 14, 2022 and January 13, 2023. Overall, Adult Status 2 represents the largest 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	16	7.08
	Exception	102	45.13
	Exception due to device recall	**9**	**3.98**
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	14	6.19
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	46	20.35
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	39	17.26
Adult Status 2	Exception	494	48.48
	Exception due to device recall	**34**	**3.34**
	Intra-aortic ballon pump - Hemodynamic Values not obtained	8	0.79
	Intra-aortic ballon pump - Hemodynamic Values obtained	280	27.48
	Mechanical circulatory support device(MCSD) with malfunction	25	2.45
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	13	1.28
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	21	2.06
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	129	12.66
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	7	0.69
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	8	0.79
Adult Status 3	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	63	26.03
	Exception	83	34.30
	Exception due to device recall	**8**	**3.31**
	Intra-aortic balloon pump after 14 days	1	0.41
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	3	1.24
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	17	7.02
	Mechanical circulatory support device (MCSD) with device infection - Debridement	10	4.13
	Mechanical circulatory support device (MCSD) with device infection - Erythema	3	1.24
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	5	2.07
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	0.83
	Mechanical circulatory support device (MCSD) with device infection - Recurrent Debridement	2	0.83
	Mechanical circulatory support device (MCSD) with pump thrombosis	5	2.07
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	39	16.12
	Percutaneous endovascular circulatory support device after 14 days	1	0.41
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	34	11.45

	Congenital heart disease	20	6.73
Adult Status 4	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	123	41.41
	Exception	44	14.81
	Inotropes without hemodynamic monitoring	47	15.82
	Ischemic heart disease with intractable angina	10	3.37
	Retransplant	19	6.40
Adult Status 5	No criteria for this status	25	100.00
Adult Status 6	No criteria for this status	113	100.00

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

Conclusion

Early monitoring shows that 'device recall exception' submissions account for a very small percentage of adult heart registrations ever waiting, adult heart wait-list additions, and adult heart transplants between July 14, 2022, and January 13, 2023. Moreover, since the implementation of this policy, 'device recall exception' submissions have not increased over time. Status 2 represents the largest number of adult waitlist additions and adult transplants that submitted a 'device recall exception'.