Final Report

OPTN Heart Committee | Descriptive Data Request

Three-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 allows 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. The policy change was implemented on July 14, 2022 and will expire on July 13, 2023 without further action.

This report examines the impact of the modifications to adult heart policy to address patient safety following device recall at three months post-implementation, and will be followed by two more monitoring reports at six months and 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 October 13, 2022
- 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 October 13, 2022
- 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 October 2022
- Adult (age >= 18) candidates added to the heart waiting list between July 14, 2022 and October 13, 2022
- Adult (age >= 18) heart transplants performed between July 14, 2022 and October 13, 2022

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 October 13, 2022. 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 04, 2022. Data subject to change based on future data submission or correction.

Results

There were a total of 3357 adult heart registrations ever waiting and 893 adult waitlist additions between July 14, 2022 and October 13, 2022. 68 of all adult registrations ever waiting and 4 adult watilist additions submitted a 'device recall exception'. The 'device recall exception' submissions accounted for 2.03% of all adult registrations ever waiting, and 0.45% of adult waitlist additions. Moreover, of the 945 adult heart transplants performed between July 14, 2022 and October 13, 2022, 29 submitted a 'device recall exception'. This accounted for 3.07% of adult heart transplants between July 14, 2022 and October 13, 2022.

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

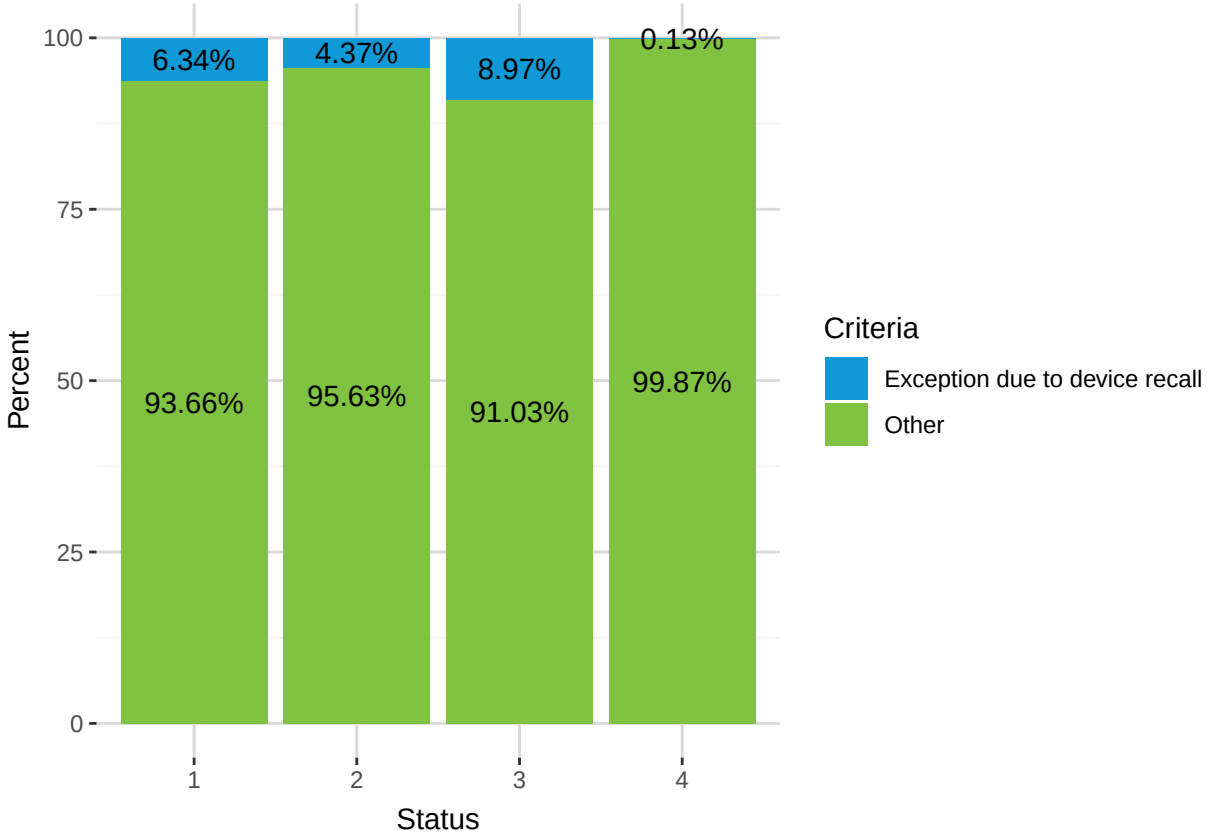

Figure 1 summarizes the percent of adult registrations ever waiting by medical urgency status and criteria within medical urgency status (including 'device recall exception') at their most recent point. Adult Status 3 represents the largest percentage of registrations by status that submitted a 'device recall exception', while Adult Status 4 had the lowest percentage.

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

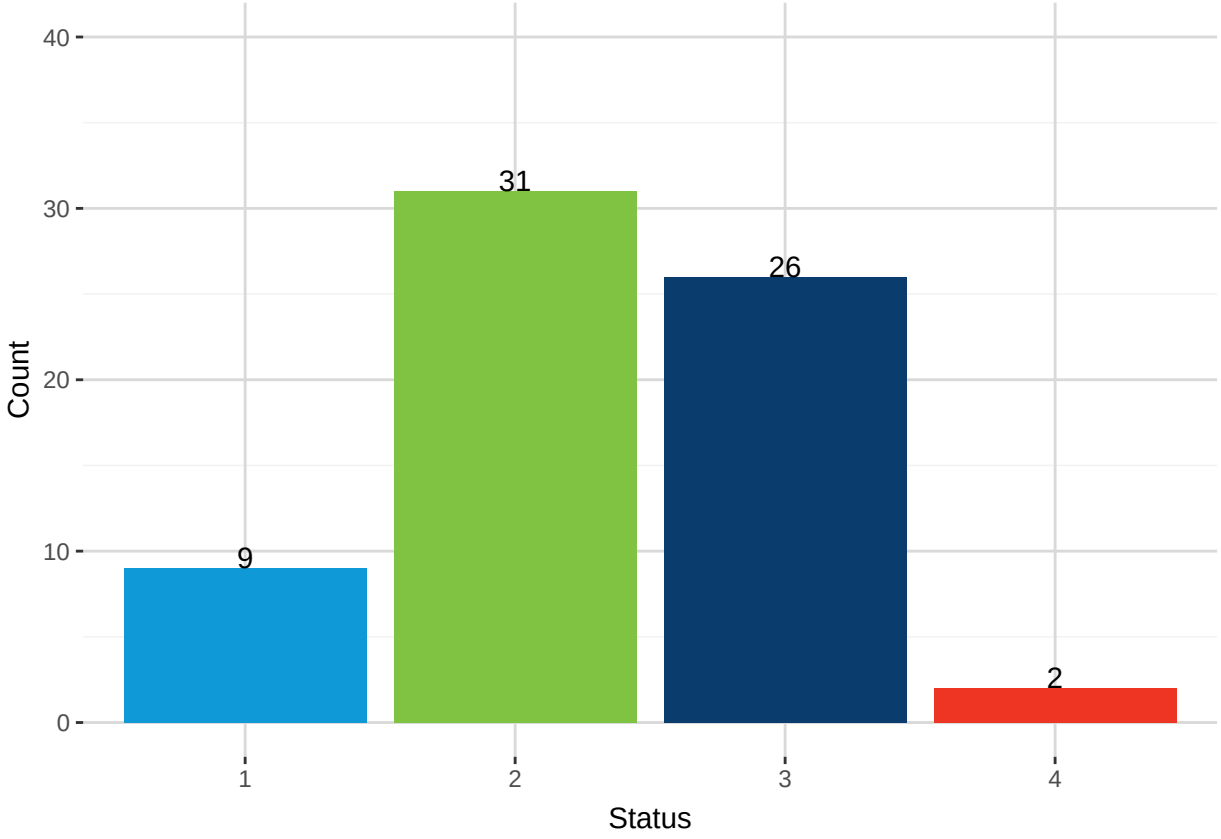

Figure 2 shows the number of adult registrations that submitted a 'device recall exception'. A total of 68 registrations submitted a 'device recall exception', which accounted for 2.03 % of all adult heart registrations between July 14, 2022 and October 13, 2022. Overall, Adult Status 2 had the largest 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	14	9.86
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	0.70
	Exception	**63**	**44.37**
	Exception due to device recall	9	6.34
	Intra-aortic ballon pump - Hemodynamic Values obtained	1	0.70
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	9	6.34
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	24	16.90
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	21	14.79
Adult Status 2	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	0.14
	Exception	**352**	**49.58**
	Exception due to device recall	31	4.37
	Intra-aortic ballon pump - Hemodynamic Values not obtained	5	0.70
	Intra-aortic ballon pump - Hemodynamic Values obtained	179	25.21
	Mechanical circulatory support device(MCSD) with malfunction	22	3.10
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	7	0.99
	Percutaneous endovascular circulatory support device after 14 days	1	0.14
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	11	1.55
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	86	12.11
	Retransplant	1	0.14
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	9	1.27
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	1	0.14
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	4	0.56
	Congenital heart disease	1	0.34
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	51	17.59
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	6	2.07
	Exception	**71**	**24.48**
	Exception due to device recall	26	8.97
	Intra-aortic ballon pump - Hemodynamic Values obtained	1	0.34
	Intra-aortic balloon pump after 14 days	2	0.69
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	11	3.79
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	40	13.79

	Mechanical circulatory support device (MCSD) with device infection - Debridement	19	6.55
	Mechanical circulatory support device (MCSD) with device infection - Erythema	10	3.45
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	6	2.07
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	4	1.38
	Mechanical circulatory support device (MCSD) with device infection - Recurrent Debridement	3	1.03
	Mechanical circulatory support device (MCSD) with pump thrombosis	7	2.41
	Mechanical circulatory support device (MCSD) with right heart failure	2	0.69
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	30	10.34
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	93	6.24
	Congenital heart disease	108	7.24
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	7	0.47
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	945	63.38
	Exception	**115**	**7.71**
	Exception due to device recall	2	0.13
	Inotropes without hemodynamic monitoring	106	7.11
	Intra-aortic ballon pump - Hemodynamic Values obtained	1	0.07
	Ischemic heart disease with intractable angina	35	2.35
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	0.07
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	0.07
	Retransplant	77	5.16
Adult Status 5	No criteria for this status	116	100.00
Adult Status 6	No criteria for this status	608	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)

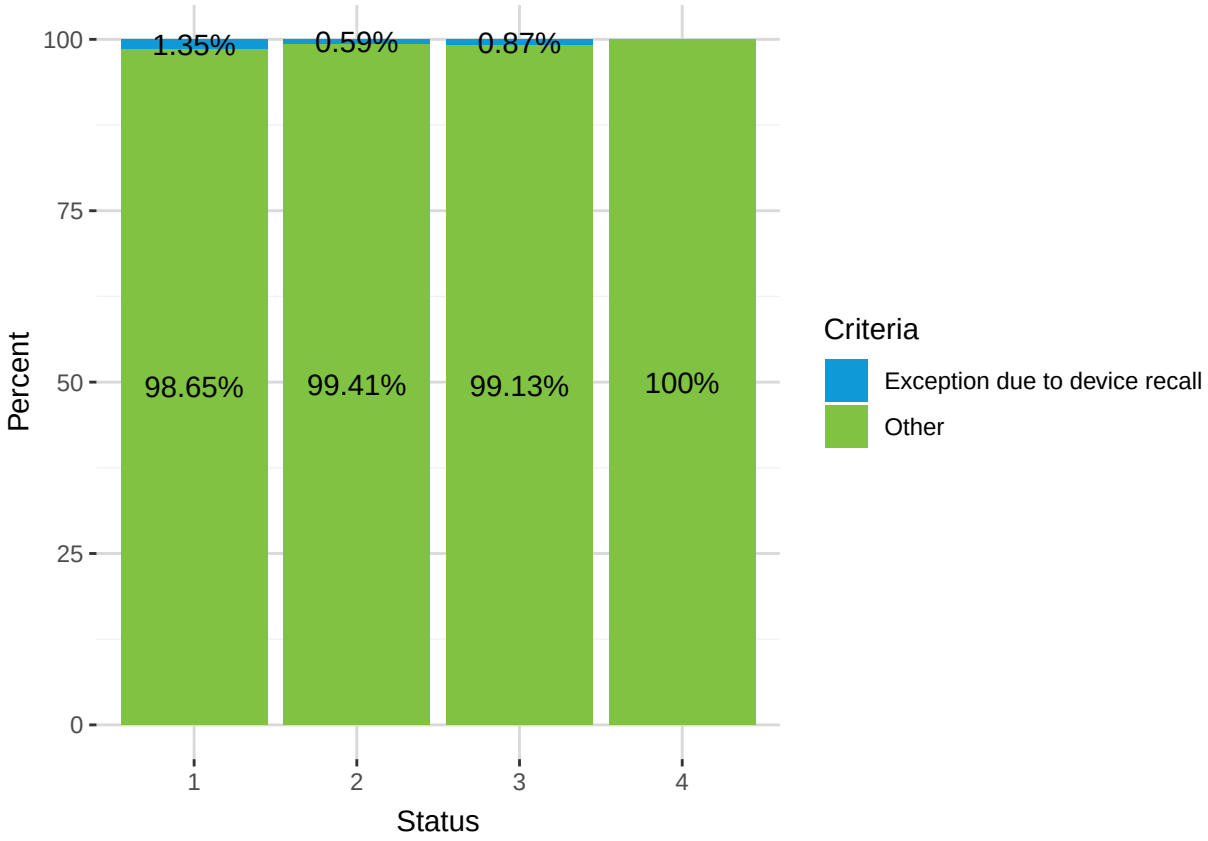

Figure 3 summarizes the percent of adult waitlist additions by medical urgency status and criteria within medical urgency status (including 'device recall exception') between July 14, 2022 and October 13, 2022. Overall, Adult Status 1 represented the largest percentage of registrations by status that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

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

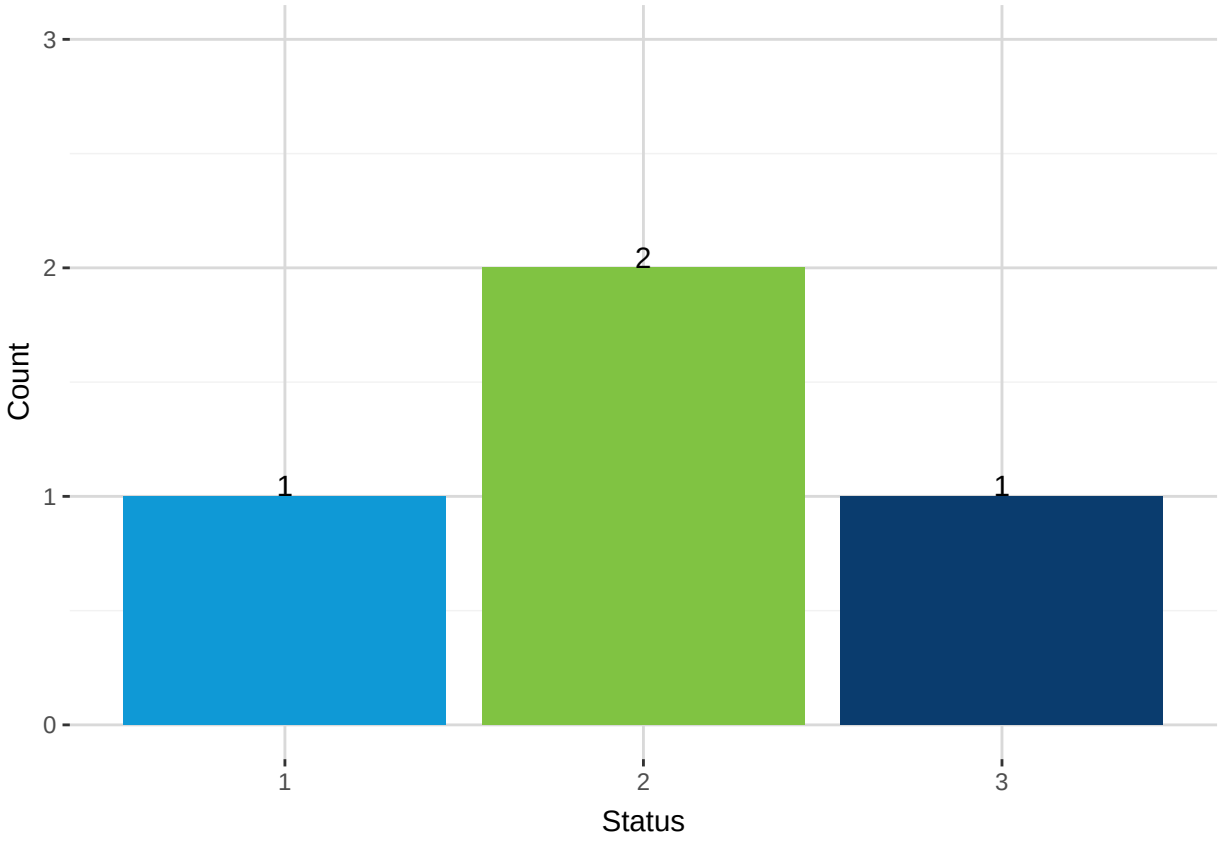

Figure 4 shows the number of adult waitlist additions that submitted a 'device recall exception' between July 14, 2022 and October 13, 2022.

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

Init_Status	Criteria Description	N	%
Adult Status 1	BIVAD/Ventricular Episodes	7	9.46
	Exception	18	24.32
	Exception due to device recall	**1**	**1.35**
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	5	6.76
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	27	36.49
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	16	21.62
Adult Status 2	Exception	135	40.06
	Exception due to device recall	**2**	**0.59**
	Intra-aortic ballon pump - Hemodynamic Values not obtained	5	1.48
	Intra-aortic ballon pump - Hemodynamic Values obtained	123	36.50
	Mechanical circulatory support device(MCSD) with malfunction	3	0.89
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	6	1.78
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	3	0.89
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	50	14.84
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	6	1.78
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	4	1.19
Adult Status 3	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	18	15.65
	Exception	38	33.04
	Exception due to device recall	**1**	**0.87**
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	8	6.96
	Mechanical circulatory support device (MCSD) with device infection - Debridement	7	6.09
	Mechanical circulatory support device (MCSD) with device infection - Erythema	3	2.61
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	2	1.74
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	1.74
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	36	31.30
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	34	9.26
	Congenital heart disease	37	10.08
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	132	35.97
	Exception	38	10.35
	Inotropes without hemodynamic monitoring	95	25.89
	Ischemic heart disease with intractable angina	12	3.27

	Retransplant	19	5.18
Adult Status 5	No criteria for this status	33	100.00
Adult Status 6	No criteria for this status	176	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 October 13, 2022.

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

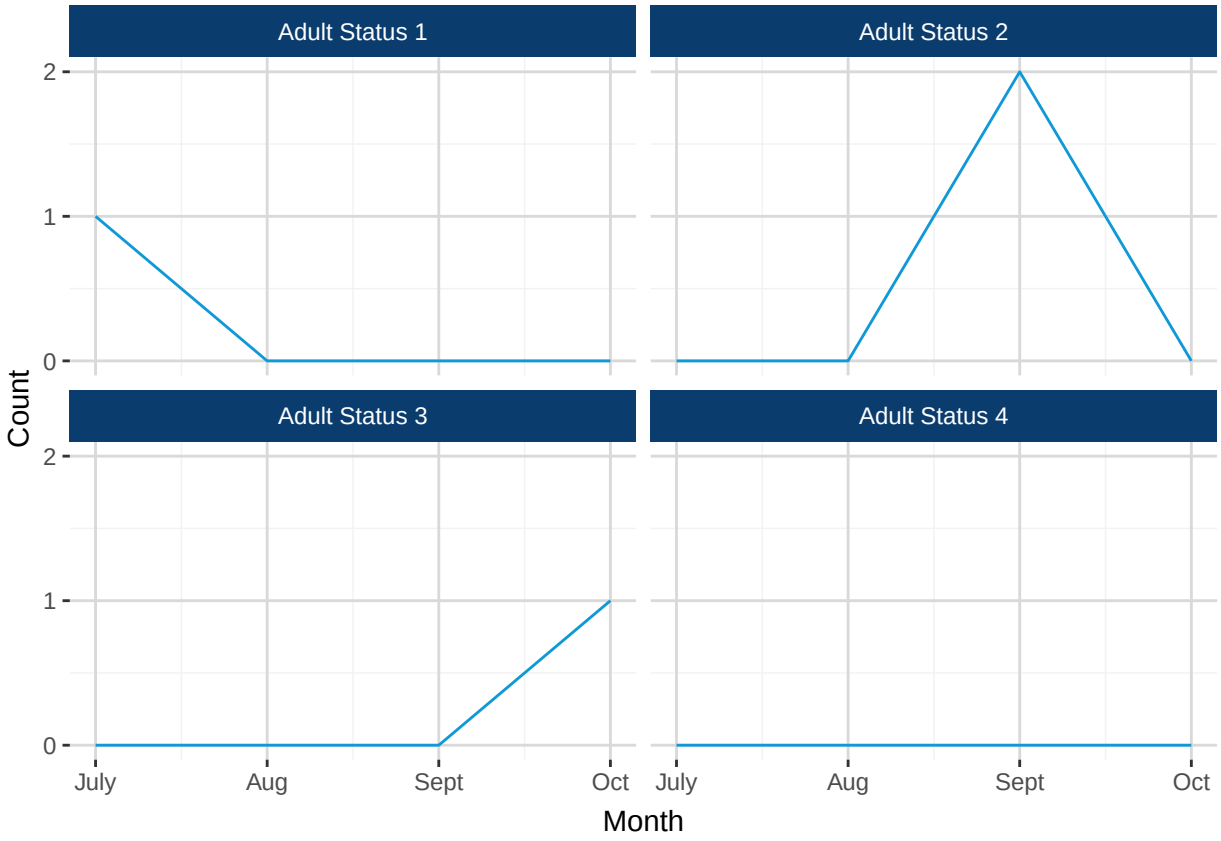

Figure 5 shows the number of adult waitlist additions per month that submitted a 'device recall exception' between July 14, 2022 and October 13, 2022. Note: July 2022 and October 2022 appear as incomplete months due to the timing of project implementation.

Table 3. Number of Waitlist Additions by Medical Urgency Status and Criteria within Medical Urgency Status (including 'device recall exception') and by Month

Initial Status	Registration Month	Criteria Description	N	%
Adult Status 1	July	BIVAD/Ventricular Episodes	1	1.351
		Exception	2	2.703
		Exception due to device recall	**1**	**1.351**
		Non-dischargeable, surgically implanted, non-endovascular biventricular support device	1	1.351
		Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	6	8.108
		Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	4	5.405
	August	BIVAD/Ventricular Episodes	2	2.703
		Exception	5	6.757
		Non-dischargeable, surgically implanted, non-endovascular biventricular support device	2	2.703
		Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	9	12.162
		Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	5	6.757
	September	BIVAD/Ventricular Episodes	4	5.405
		Exception	9	12.162
		Non-dischargeable, surgically implanted, non-endovascular biventricular support device	1	1.351
		Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	7	9.459
		Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	5	6.757
	October	Exception	2	2.703
		Non-dischargeable, surgically implanted, non-endovascular biventricular support device	1	1.351
		Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	5	6.757
		Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	2	2.703
	July	Exception	23	6.825
		Intra-aortic ballon pump - Hemodynamic Values obtained	22	6.528
		Mechanical circulatory support device(MCSD) with malfunction	1	0.297
		Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.297
		Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	0.297
		Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	12	3.561
		Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	0.593
		Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	0.593
		Exception	44	13.056
		Intra-aortic ballon pump - Hemodynamic Values not obtained	2	0.593

Adult Status 2	August	Intra-aortic ballon pump - Hemodynamic Values obtained	49	14.540
		Mechanical circulatory support device(MCSD) with malfunction	1	0.297
		Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	2	0.593
		Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	14	4.154
		Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	0.593
		Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	1	0.297
	September	Exception	52	15.430
		Exception due to device recall	**2**	**0.593**
		Intra-aortic ballon pump - Hemodynamic Values not obtained	3	0.890
		Intra-aortic ballon pump - Hemodynamic Values obtained	39	11.573
		Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	3	0.890
		Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	2	0.593
		Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	20	5.935
		Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	0.593
		Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	1	0.297
	October	Exception	16	4.748
		Intra-aortic ballon pump - Hemodynamic Values obtained	13	3.858
		Mechanical circulatory support device(MCSD) with malfunction	1	0.297
		Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	4	1.187
	July	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	6	5.217
		Exception	7	6.087
		Mechanical circulatory support device (MCSD) with device infection - Bacteremia	1	0.870
		Mechanical circulatory support device (MCSD) with device infection - Erythema	1	0.870
		Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	0.870
		Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	8	6.957
	August	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	7	6.087
		Exception	14	12.174
		Mechanical circulatory support device (MCSD) with device infection - Bacteremia	3	2.609
		Mechanical circulatory support device (MCSD) with device infection - Debridement	3	2.609
		Mechanical circulatory support device (MCSD) with device infection - Erythema	1	0.870
		Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	0.870
		Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	10	8.696
		Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	4	3.478
		Exception	15	13.043

September	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	3	2.609
	Mechanical circulatory support device (MCSD) with device infection - Debridement	3	2.609
	Mechanical circulatory support device (MCSD) with device infection - Erythema	1	0.870
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	0.870
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	0.870
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	15	13.043
October	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	1	0.870
	Exception	2	1.739
	Exception due to device recall	**1**	**0.870**
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	1	0.870
	Mechanical circulatory support device (MCSD) with device infection - Debridement	1	0.870
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	3	2.609
July	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	1	0.272
	Congenital heart disease	3	0.817
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	16	4.360
	Exception	5	1.362
	Inotropes without hemodynamic monitoring	22	5.995
	Ischemic heart disease with intractable angina	2	0.545
	Retransplant	2	0.545
August	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	14	3.815
	Congenital heart disease	9	2.452
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	53	14.441
	Exception	8	2.180
	Inotropes without hemodynamic monitoring	26	7.084
	Ischemic heart disease with intractable angina	5	1.362
	Retransplant	6	1.635
September	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	18	4.905
	Congenital heart disease	17	4.632
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	45	12.262
	Exception	17	4.632
	Inotropes without hemodynamic monitoring	32	8.719
	Ischemic heart disease with intractable angina	1	0.272
	Retransplant	7	1.907

	October	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	1	0.272
		Congenital heart disease	8	2.180
		Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	18	4.905
		Exception	8	2.180
		Inotropes without hemodynamic monitoring	15	4.087
		Ischemic heart disease with intractable angina	4	1.090
		Retransplant	4	1.090
Adult Status 5	July	No criteria for this status	4	12.121
	August	No criteria for this status	14	42.424
	September	No criteria for this status	12	36.364
	October	No criteria for this status	3	9.091
Adult Status 6	July	No criteria for this status	27	15.341
	August	No criteria for this status	62	35.227
	September	No criteria for this status	70	39.773
	October	No criteria for this status	17	9.659

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

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

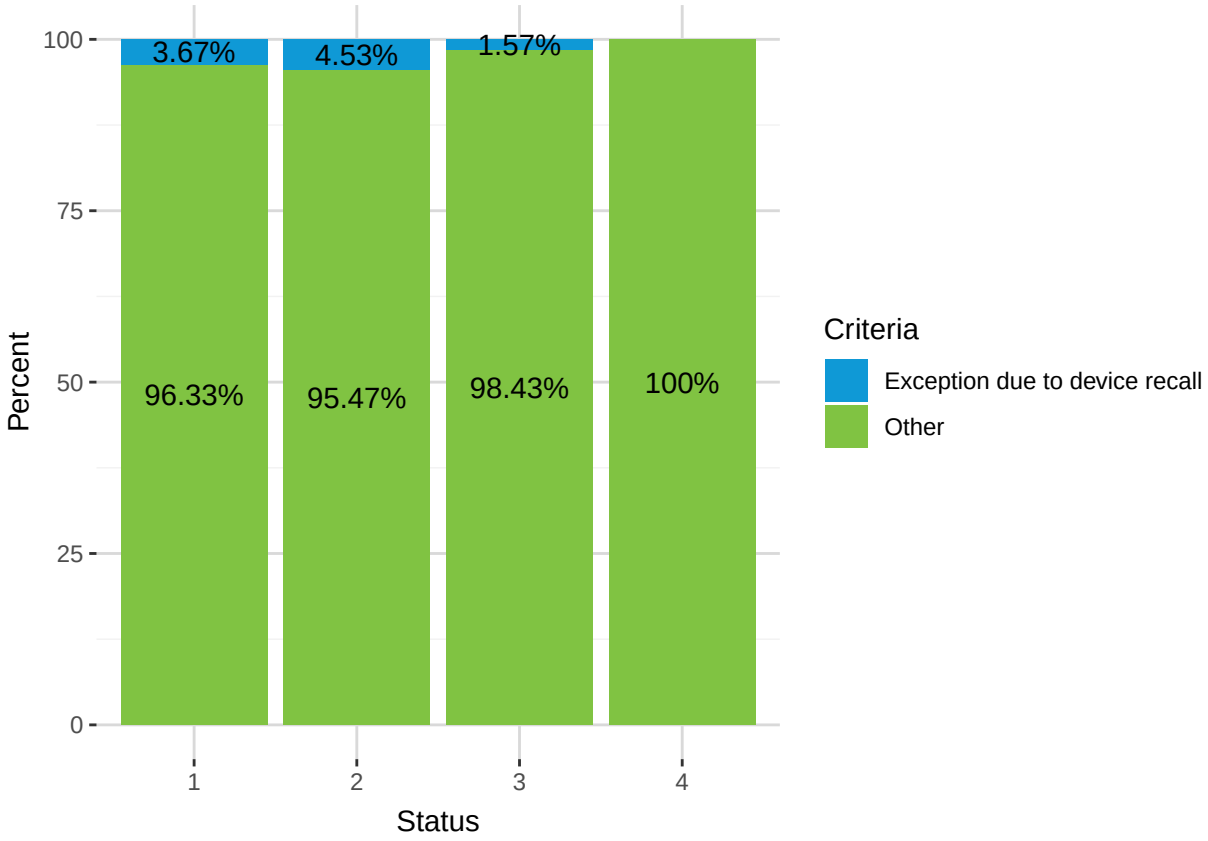

Figure 6 summarizes the percent of adult transplants by medical urgency status and criteria within medical urgency status (including 'device recall exception') between July 14, 2022 and October 13, 2022. Overall, Adult Status 2 represented the largest percentage of transplants by status that submitted a 'device recall exception'.

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

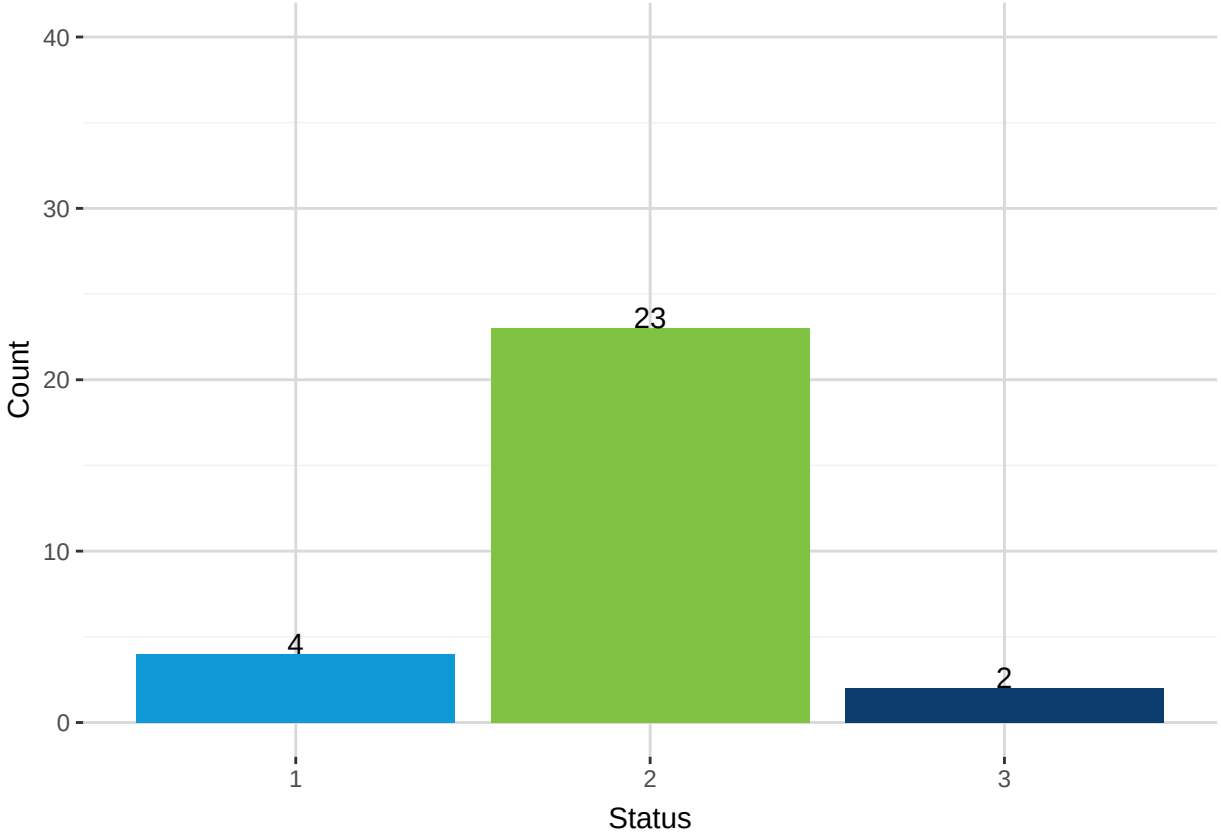

Figure 7 shows the number of adult transplants that submitted a 'device recall exception'. A total of 29 transplants submitted a 'device recall exception', which accounted for 3.07 % of adult heart transplants between July 14, 2022 and October 15, 2022. Overall, Adult Status 2 represents the largest 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	11	10.09
	Exception	47	43.12
	Exception due to device recall	**4**	**3.67**
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	8	7.34
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	21	19.27
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	18	16.51
Adult Status 2	Exception	231	45.47
	Exception due to device recall	**23**	**4.53**
	Intra-aortic ballon pump - Hemodynamic Values not obtained	5	0.98
	Intra-aortic ballon pump - Hemodynamic Values obtained	149	29.33
	Mechanical circulatory support device(MCSD) with malfunction	16	3.15
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	5	0.98
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	6	1.18
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	65	12.80
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	4	0.79
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	4	0.79
Adult Status 3	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	25	19.69
	Exception	42	33.07
	Exception due to device recall	**2**	**1.57**
	Intra-aortic balloon pump after 14 days	1	0.79
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	2	1.57
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	12	9.45
	Mechanical circulatory support device (MCSD) with device infection - Debridement	8	6.30
	Mechanical circulatory support device (MCSD) with device infection - Erythema	3	2.36
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	4	3.15
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	0.79
	Mechanical circulatory support device (MCSD) with pump thrombosis	4	3.15
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	23	18.11
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	22	15.83
	Congenital heart disease	9	6.47
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	56	40.29

Adult Status 4			
	Exception	22	15.83
	Inotropes without hemodynamic monitoring	17	12.23
	Ischemic heart disease with intractable angina	4	2.88
	Retransplant	9	6.47
Adult Status 5	No criteria for this status	12	100.00
Adult Status 6	No criteria for this status	49	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 October 13, 2022. Moreover, since the implementation of this policy, 'device recall exception' submissions have not increased over time. Status 2 represents the largest number of adult registrations ever waiting and adult transplants that submitted a 'device recall exception'.