

Guidance for Multivisceral Transplant Candidates One-Year Monitoring Report

DHHS Contract No. 250-2019-00001C
Date Completed: February 2025

Prepared for:
Liver & Intestinal Transplantation Committee
Committee Meeting
Date of Meeting: February 2025

By:
Alina Martinez, MS
Benjamin Schumacher, PhD
UNOS Research Department

Contents

Executive Summary	3
Background/Purpose	4
Monitoring Plan	4
Data and Methods	5
Cohorts	5
Methods	5
Results	6
OPTN Waiting List	6
Figure 1. Multivisceral Transplant Registrations Ever-Waiting in each Guidance Era by Multiple-Organ Registration Type	7
Table 1. Multivisceral Transplant Registrations Ever-Waiting in each Guidance Era by Organ Registration Type	7
Figure 2. Number and Proportion of Multivisceral Transplant Registrations Ever-Waiting in each Guidance Era who Applied for at Least One Exception during the Era	8
Table 2. Number and Proportion of Multivisceral Transplant Registrations Ever-Waiting in each Guidance Era who Applied for at Least One Exception during the Era	8
Figure 3. Number and Proportion of Multivisceral Transplant Registration Exception Request Forms by Outcome based on Form Type	9
Table 3. Number and Proportion of Multivisceral Transplant Registration Exception Request Forms by Outcome based on Form Type	10
Figure 4. Number and Proportion of Approved Exception Forms for Multivisceral Transplant Registrations by Primary Exception Diagnosis Provided based on Form Type	12
Table 4. Number and Proportion of Approved Exception Forms for Multivisceral Transplant Registrations by Primary Exception Diagnosis Provided based on Form Type	13

Figure 5. Number and Proportion of Multivisceral Transplant Registrations Ever-Waiting in each Guidance Era with an Approved Exception during the Era	14
Table 5. Number and Proportion of MVT Registrations Ever-Waiting in each Guidance Era with an Approved Exception during the Era	14
Figure 6. The Distribution of Lab MELD Scores at Listing for Multivisceral Transplant Registrations Ever-Waiting in each Guidance Era with an Approved Exception during the Era	15
Table 6. The Distribution of Lab MELD Scores at Listing for Multivisceral Transplant Registrations Ever-Waiting in each Guidance Era with an Approved Exception during the Era	15
Waiting List Removals	16
Figure 7. Number and Proportion of Multivisceral Transplant Registrations Removed from the OPTN Waiting List by Removal Reason, Exception Status at Removal and Guidance Era .	17
Table 7. Number and Proportion of Multivisceral Transplant Registrations Removed from the OPTN Waiting List by Removal Reason, Exception Status at Removal and Guidance Era .	18
Transplants	19
Figure 8. Number and Proportion of Multivisceral Transplants by Exceptions Status at Transplant	19
Table 8. Number and Proportion of Multivisceral Transplants by Exceptions Status at Transplant	19

Executive Summary

This report provides a review of the first year under the National Liver Review Board (NLRB) Guidance for Multivisceral Transplant Candidates. The current number of multivisceral candidates and transplants remains small, so results should be taken with caution. That being noted, after implementation of this guidance:

- A greater number of multivisceral candidates applied for and received a liver exception
- The number of multivisceral candidates with an exception removed due to death or too sick increased by three
- The number of multivisceral candidates without an exception removed due to death or too sick decreased by six
- Multivisceral transplants increased by two transplants and more recipients were transplanted with a liver exception

Background/Purpose

Multivisceral (MVT) candidates are candidates registered for liver-intestine, liver-intestine-pancreas, liver-intestine-pancreas-kidney, or liver-intestine-kidney transplant. Organ Procurement and Transplantation Network (OPTN) policy provides some additional allocation priority for these candidates automatically due to their increased urgency for transplant. For example, OPTN Policy 9.1.F provides adult MVT candidates with an increase in Model for End-Stage Liver Disease (MELD) points equivalent to a 10% increase in 90-day waiting list mortality; pediatric MVT candidates are provided with a flat 23 point increase in Pediatric End-Stage Liver Disease (PELD) score. OPTN Policy 9.8.I also provides additional priority to MVT candidates when liver-intestine combinations are offered from the same adult donor. More specifically, liver-intestine donor organs are first offered to liver-alone and liver-intestine transplant candidates with MELD scores of at least 29 who are registered at transplant hospitals within 500 nautical miles (NM) of the donor hospital; if these offers are not accepted, the organs will then be offered to any liver-intestine candidate across the nation, regardless of MELD or PELD score, before being offered to any liver-alone candidates with MELD or PELD scores below 29.

Despite these policies, research suggests that MVT candidates experienced a decrease in access to transplant and an increase in waiting list mortality after implementation of the acuity circles policy in 2020. To address these issues, on July 27, 2023, the OPTN implemented the “National Liver Review Board (NLRB) Guidance for Multivisceral Transplant Candidates”. This guidance recommends that adult MVT candidates who submit a MELD score exception be considered for an initial MELD exception score equivalent to median MELD at Transplant (MMaT) plus 6, with an additional 3 point increase every 90 days. This guidance did not impact priority for pediatric MVT candidates. For more details on this guidance, please see the National Liver Review Board (NLRB) Guidance for Multivisceral Transplant Candidates briefing paper.

The purpose of this report is to evaluate whether the new NLRB Guidance for Multivisceral Transplant Candidates improved access to transplant and decreased waiting list mortality for adult MVT candidates.

Monitoring Plan

The following metrics are evaluated in this report:

For a cohort of adult multivisceral (to include Liver-Intestine-Pancreas, Liver-Intestine, Liver-Intestine-Pancreas-Kidney, and Liver-Intestine-Kidney, MVT) candidates stratified by pre- and post-guidance:

- Number and proportion of MVT candidates who apply for at least one exception
- Number and proportion of exception request forms by case outcome (approved, withdrawn, denied, etc.)
- Number and proportion of MVT candidates listed with approved exceptions
 - If listed with an exception, the distribution of lab MELD at listing
- Number and proportion of MVT candidates transplanted with approved exceptions
 - If transplanted with an exception, the distribution of exception points relative to MMaT
 - If transplanted with an exception, time-to-transplant (in days)
- Number and proportion of MVT candidates removed from the OPTN waiting list due to death or too sick by exception status

Due to small numbers, the 1-year monitoring report only includes the number and proportion of MVT candidates transplanted with approved exceptions.

Data and Methods

Data Sources:

These analyses use data from the OPTN Waiting List, Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), Transplant Recipient Followup (TRF), and Deceased Donor Registration (DDR) forms. The report also summarizes liver exception requests including liver MELD exception request forms submitted during the timeframes noted below. Analyses are based on OPTN data as of February 21, 2025 and are subject to change based on future data submission or correction.

Cohorts

This report includes cohorts of adult multivisceral (to include Liver-Intestine-Pancreas, Liver-Intestine, Liver-Intestine-Pancreas-Kidney, and Liver-Intestine-Kidney, MVT) registrations ever-waiting or removed from the OPTN waiting list during 07/26/2022 - 07/26/2023 (pre-guidance) and 07/27/2023 - 07/26/2024 (post-guidance). All MVT registrations used in these analyses were 18 years of age or older at time of listing for their liver registration. MVT candidates were identified based on their liver registration, and were considered MVT if they ever had an overlapping intestine registration at any point in their OPTN Waiting List history, regardless of whether the intestine registration occurred before or after their liver registration. MVT registrations were grouped into pre- and post-guidance eras based on whether they were ever-waiting for both a liver and intestine during the guidance era (i.e., MVT registrations ever-waiting between 07/26/2022 - 07/26/2023 were grouped into the pre-guidance era, whereas MVT registrations ever-waiting between 07/27/2023 - 07/26/2024 were grouped into the post-guidance era). The use of an ever-waiting cohort allows us to better capture the key measures of interest (application and approval of exceptions during each guidance era), however, this implies MVT registrations may appear in both eras. We then looked at whether each liver registration was also listed for intestine with a kidney, and/or pancreas to determine the appropriate MVT category.

MVT OPTN Waiting List removals consider registrations removed during 07/26/2022 - 07/26/2023 (pre-guidance) and 07/27/2023 - 07/26/2024 (post-guidance) for liver registrations overlapping with an intestine registration at any point during the guidance era of removal. Removals are based on the removal date of the MVT candidate's liver registration.

This report also includes MVT exception request forms submitted during 07/26/2022 - 07/26/2023 (pre-guidance) and 07/27/2023 - 07/26/2024 (post-guidance). Multiple exception request forms can be submitted for a registration throughout a single or both guidance era(s).

Deceased donor, adult MVT transplant cohorts are defined as 07/26/2022 - 07/26/2023 (pre-guidance) and 07/27/2023 - 07/26/2024 (post-guidance). Recipients under 18 at the time of their liver listing were excluded. MVT transplant recipients were identified based on liver transplant and were considered MVT if they also received an intestine. Recipients may or may not have also received a kidney and/or pancreas transplant with the liver-intestine transplant. MVT transplant recipients were grouped into pre- and post-guidance eras based on liver transplant date (i.e., MVT recipients with liver transplant dates between 07/26/2022 - 07/26/2023 were grouped into the pre-guidance era, whereas MVT recipients with liver transplant dates between 07/27/2023 - 07/26/2024 were grouped into the post-guidance era).

Methods

Counts and percentages were used to summarize categorical variables or characteristics, while density curves and distribution summaries (minimum, maximum, median, percentiles) were provided for continuous characteristics.

All MVT exception forms approved were for diagnosis reasons not indicated to be in the nine main liver standard exception diagnoses and therefore classified as "Other" diagnosis. Exception requests categorized as "Other" diagnosis forms require a free-text entry of the diagnosis justifying the need for an exception. This implies some entries may have indicated multiple diagnoses in the free-text field. This free-text field was evaluated and forms were grouped based on the primary diagnosis provided.

Results

OPTN Waiting List

This section reviews MVT registrations grouped into pre-guidance (07/26/2022 - 07/26/2023) and post-guidance (07/27/2023 - 07/26/2024) eras based on whether they were ever-waiting for both a liver and intestine during the guidance era. MVT registrations were listed for a liver registration as well as an intestine, and may or may not be listed for a kidney, and/or pancreas registration as well. As the section considers MVT registrations ever-waiting in the pre- and post-guidance era, some MVT registrations may appear in both eras.

Figure 1 and table 1 shows the number of ever-waiting MVT registrations in each guidance era by their multiple-organ registration type. The number of MVT registrations increased slightly in the post-guidance era (Pre: 87, Post: 97). The majority of ever-waiting MVT registrations in both eras were liver-intestine-pancreas registrations (Pre: 76 (87.36%), Post: 82 (84.54%)).

Figure 1. Multivisceral Transplant Registrations Ever-Waiting in each Guidance Era by Multiple-Organ Registration Type

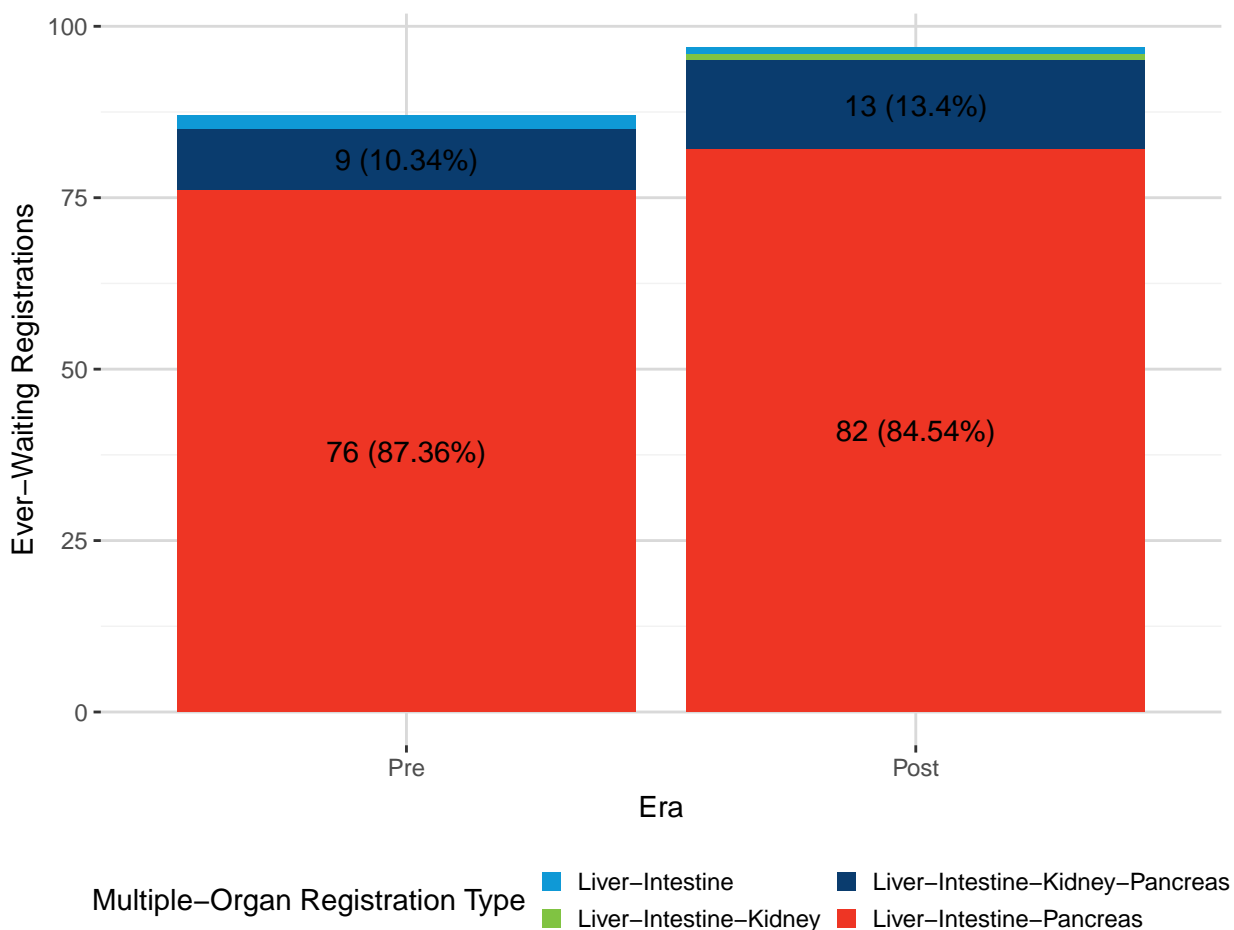


Table 1. Multivisceral Transplant Registrations Ever-Waiting in each Guidance Era by Organ Registration Type

Multiple-Organ Registration Type	Guidance Era	
	Pre	Post
Liver-Intestine	2 (2.30%)	1 (1.03%)
Liver-Intestine-Kidney	0 (0.00%)	1 (1.03%)
Liver-Intestine-Kidney-Pancreas	9 (10.34%)	13 (13.40%)
Liver-Intestine-Pancreas	76 (87.36%)	82 (84.54%)
Total	87 (100.00%)	97 (100.00%)

Figure 2 and table 2 shows the number of ever-waiting MVT registrations in each guidance era based on whether the registration applied for at least one exception during the era. A greater number and proportion of MVT registrations ever-waiting applied for at least one exception in the post-guidance era (Pre: 27 (31.03%), Post: 65 (67.01%)).

Figure 2. Number and Proportion of Multivisceral Transplant Registrations Ever-Waiting in each Guidance Era who Applied for at Least One Exception during the Era

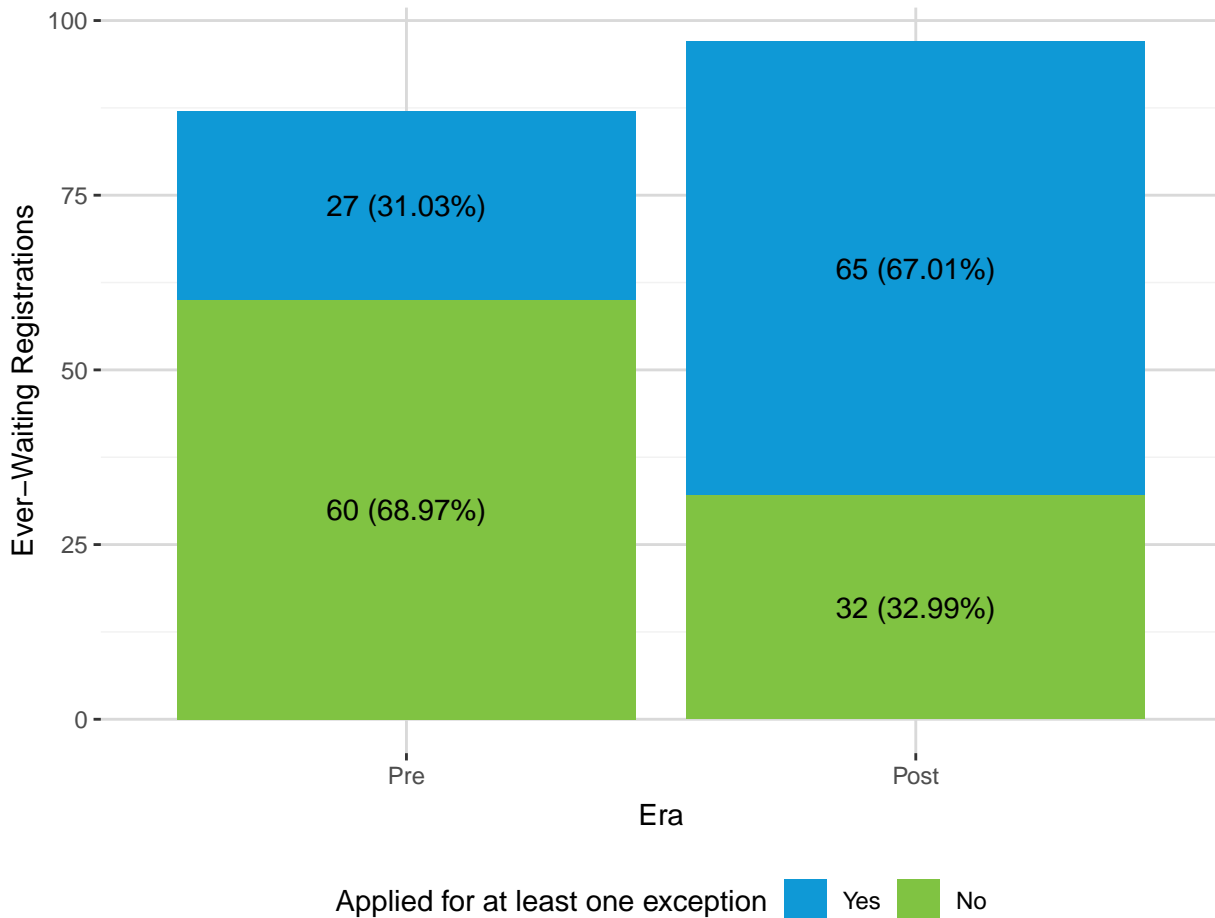


Table 2. Number and Proportion of Multivisceral Transplant Registrations Ever-Waiting in each Guidance Era who Applied for at Least One Exception during the Era

Applied for at Least One Exception	Guidance Era	
	Pre	Post
Yes	27 (31.03%)	65 (67.01%)
No	60 (68.97%)	32 (32.99%)
Total	87 (100.00%)	97 (100.00%)

Figure 3 and table 3 shows the number of exception request forms submitted by MVT registrations in each guidance era based on the outcome of the request and form type. Registrations can submit multiple exception request forms throughout each era. All request forms are reviewed by the National Liver Review Board Adult Other Diagnosis Board. There was an increase in the number of initial (Pre: 48, Post: 99) and extension (Pre: 30, Post: 67) forms submitted in the post-guidance era. Initial forms saw the greatest increase in the post-guidance era, with the majority of forms being approved (Pre: 23 (47.92%), Post: 84 (84.85%)). Furthermore, the majority of extension forms in both the pre- and post-guidance era were approved by the NLRB (Pre: 29 (96.67%), Post: 66 (98.51%)).

Figure 3. Number and Proportion of Multivisceral Transplant Registration Exception Request Forms by Outcome based on Form Type

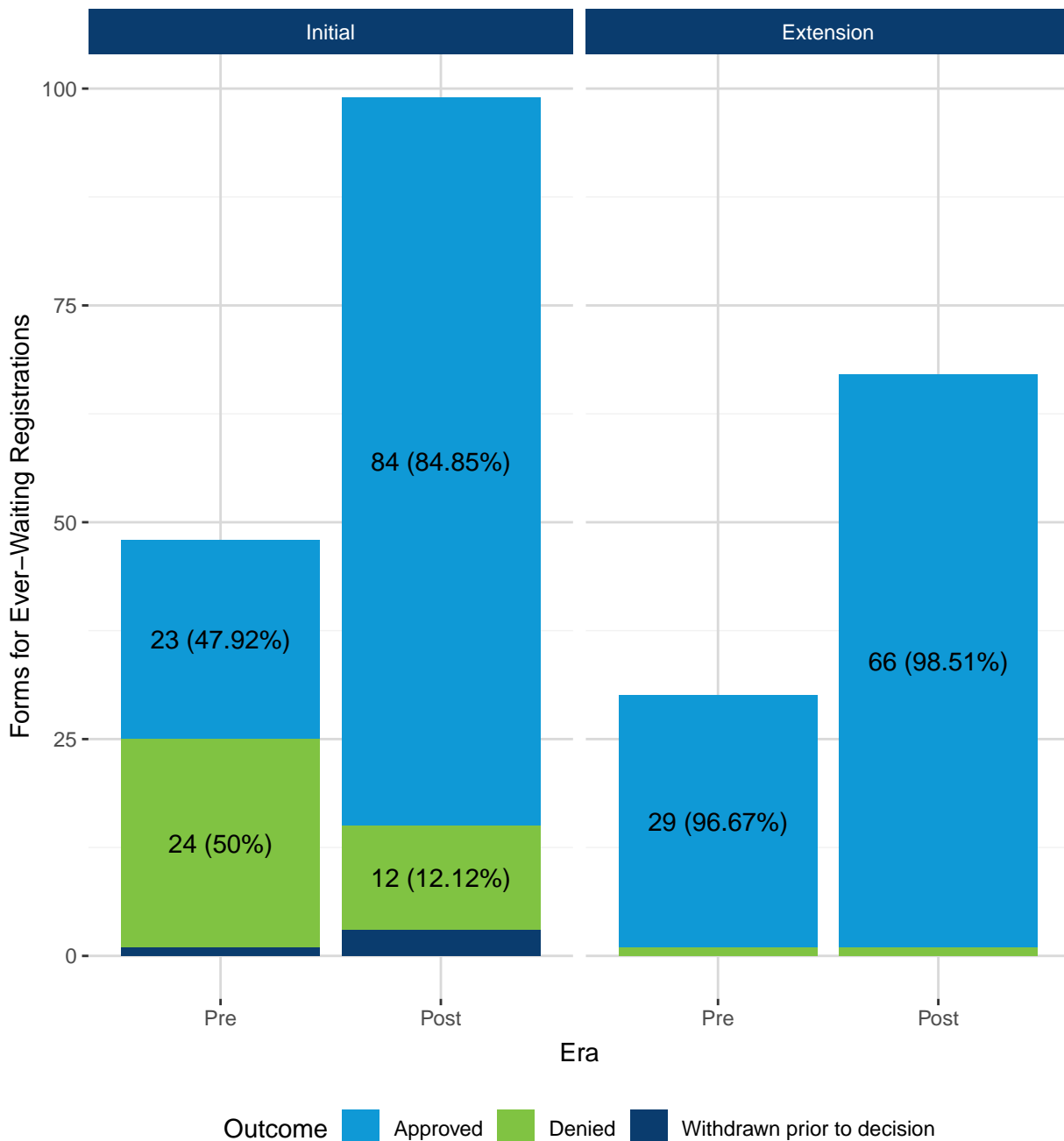


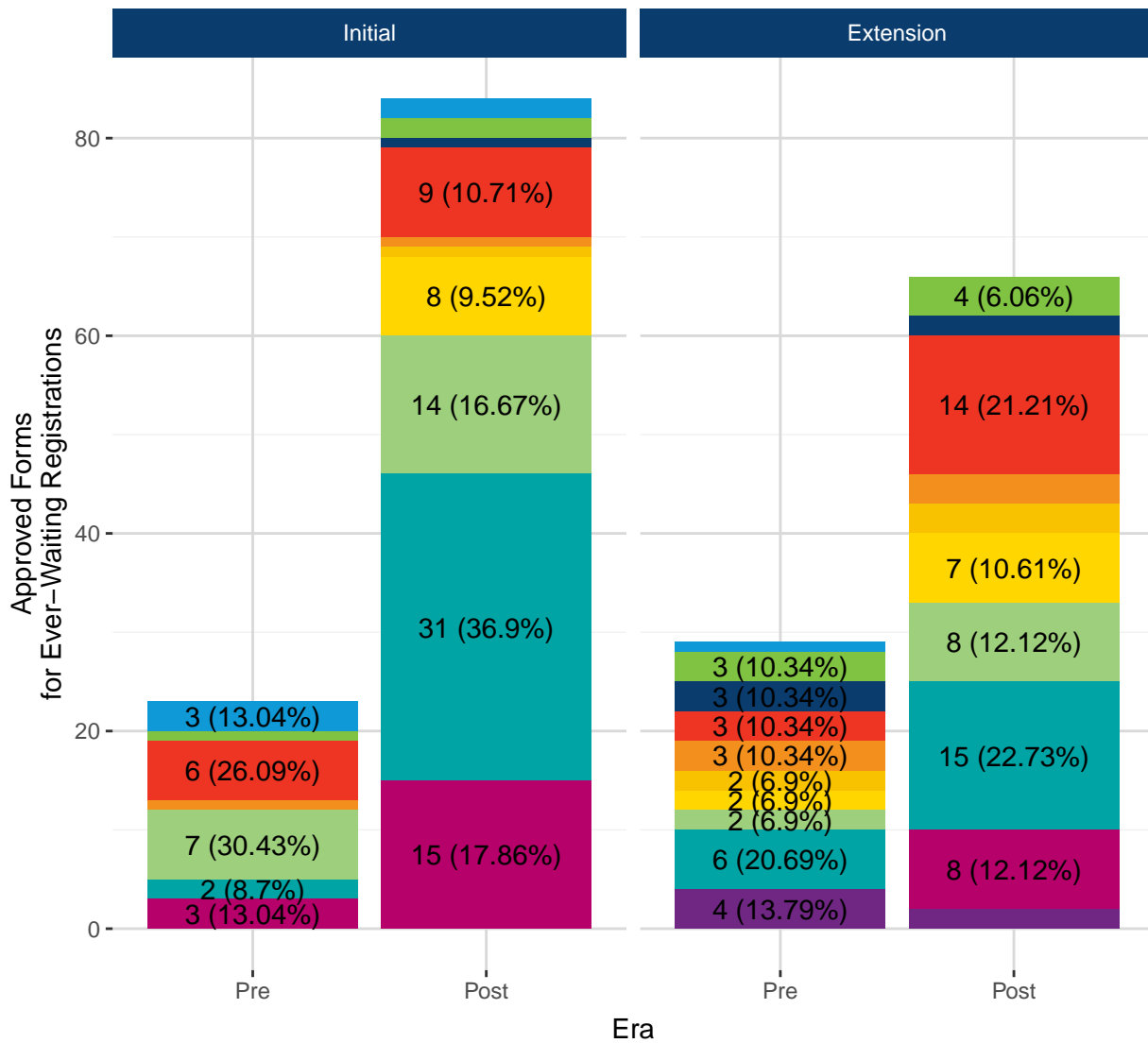
Table 3. Number and Proportion of Multivisceral Transplant Registration Exception Request Forms by Outcome based on Form Type

Form Type	Outcome	Guidance Era	
		Pre	Post
Initial	Approved	23 (47.92%)	84 (84.85%)
	Denied	24 (50%)	12 (12.12%)
	Withdrawn prior to decision	1 (2.08%)	3 (3.03%)
	Total	48 (100%)	99 (100%)
Extension	Approved	29 (96.67%)	66 (98.51%)
	Denied	1 (3.33%)	1 (1.49%)
	Total	30 (100%)	67 (100%)

Figure 4 and table 4 show the number and proportion of approved exception request forms for multivisceral registrations based on the primary exception diagnosis indicated and form type. All multivisceral forms were approved by the Adult Other Diagnosis review board. Diagnosis for other exception forms are indicated by a free-text field and summarized below by primary diagnosis indicated. Primary exception diagnoses with 5 or less forms over both guidance eras were categorized as “Other” due to small number of events. Multiple forms can be submitted and approved for a single registration throughout a single or both guidance era(s).

For initial forms, most approved exceptions were for registrations with an indicated primary exception diagnosis of portal vein thrombosis in the pre-guidance era and portomesenteric venous thrombosis in the post-guidance era. For approved extension exceptions in the pre- and post-guidance era most forms had an indicated portomesenteric venous thrombosis to be the primary exception diagnosis.

Figure 4. Number and Proportion of Approved Exception Forms for Multivisceral Transplant Registrations by Primary Exception Diagnosis Provided based on Form Type



Primary Exception Diagnosis Group

- Bowel Obstruction
- Gastrointestinal Bleeding
- Highly Sensitized Intestine Candidate
- Intestinal Failure
- Malformation of gastrointestinal tract
- Non-cirrhotic Portal Hypertension
- Other
- Portal Vein Thrombosis
- Portomesenteric Venous Thrombosis
- Short Bowel Syndrome
- Total Parenteral Nutrition Induced Liver Failure

*If the total number of approved forms for any primary exception diagnosis group was 5 or less across both guidance eras, the forms were categorized as 'Other' due to small numbers.

**Primary exception diagnoses with less than 5% of approved forms in an era are not labelled here, but provided in the corresponding table.

Table 4. Number and Proportion of Approved Exception Forms for Multivisceral Transplant Registrations by Primary Exception Diagnosis Provided based on Form Type

Form Type	Primary Exception Diagnosis Group	Guidance Era	
		Pre	Post
Initial	Bowel Obstruction	3 (13.04%)	2 (2.38%)
	Gastrointestinal Bleeding	1 (4.35%)	2 (2.38%)
	Highly Sensitized Intestine Candidate	0 (0.00%)	1 (1.19%)
	Intestinal Failure	6 (26.09%)	9 (10.71%)
	Malformation of gastrointestinal tract	1 (4.35%)	1 (1.19%)
	Non-cirrhotic Portal Hypertension	0 (0.00%)	1 (1.19%)
	Other	0 (0.00%)	8 (9.52%)
	Portal Vein Thrombosis	7 (30.43%)	14 (16.67%)
	Portomesenteric Venous Thrombosis	2 (8.70%)	31 (36.90%)
	Short Bowel Syndrome	3 (13.04%)	15 (17.86%)
Total	-	23 (100.00%)	84 (100.00%)
Extension	Bowel Obstruction	1 (3.45%)	0 (0.00%)
	Gastrointestinal Bleeding	3 (10.34%)	4 (6.06%)
	Highly Sensitized Intestine Candidate	3 (10.34%)	2 (3.03%)
	Intestinal Failure	3 (10.34%)	14 (21.21%)
	Malformation of gastrointestinal tract	3 (10.34%)	3 (4.55%)
	Non-cirrhotic Portal Hypertension	2 (6.90%)	3 (4.55%)
	Other	2 (6.90%)	7 (10.61%)
	Portal Vein Thrombosis	2 (6.90%)	8 (12.12%)
	Portomesenteric Venous Thrombosis	6 (20.69%)	15 (22.73%)
	Short Bowel Syndrome	0 (0.00%)	8 (12.12%)
Total Parenteral Nutrition Induced Liver Failure	4 (13.79%)	2 (3.03%)	
Total	-	29 (100.00%)	66 (100.00%)

If the total number of approved forms for any primary exception diagnosis group was 5 or less across both guidance eras, the forms were categorized as 'Other' due to small numbers.

Figure 5 and table 5 shows the number of ever-waiting MVT registrations in each guidance era based on whether the registration had at least one exception request form approved in the era. Registrations can submit multiple exception request forms throughout an era. A greater number and proportion of ever-waiting MVT registrations in the post-guidance era had at least one exception form approved (Pre: 22 (25.29%), Post: 63 (64.95%)).

Figure 5. Number and Proportion of Multivisceral Transplant Registrations Ever-Waiting in each Guidance Era with an Approved Exception during the Era

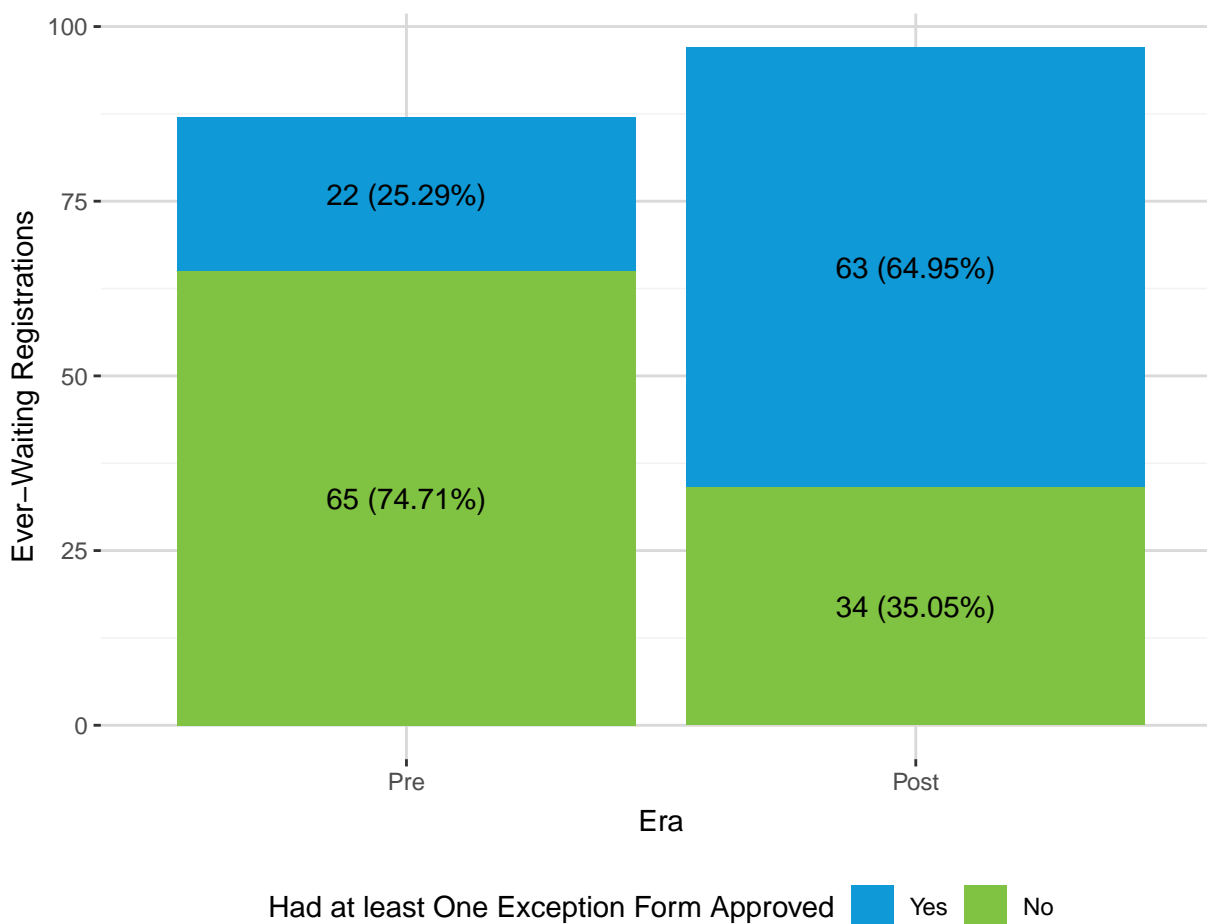
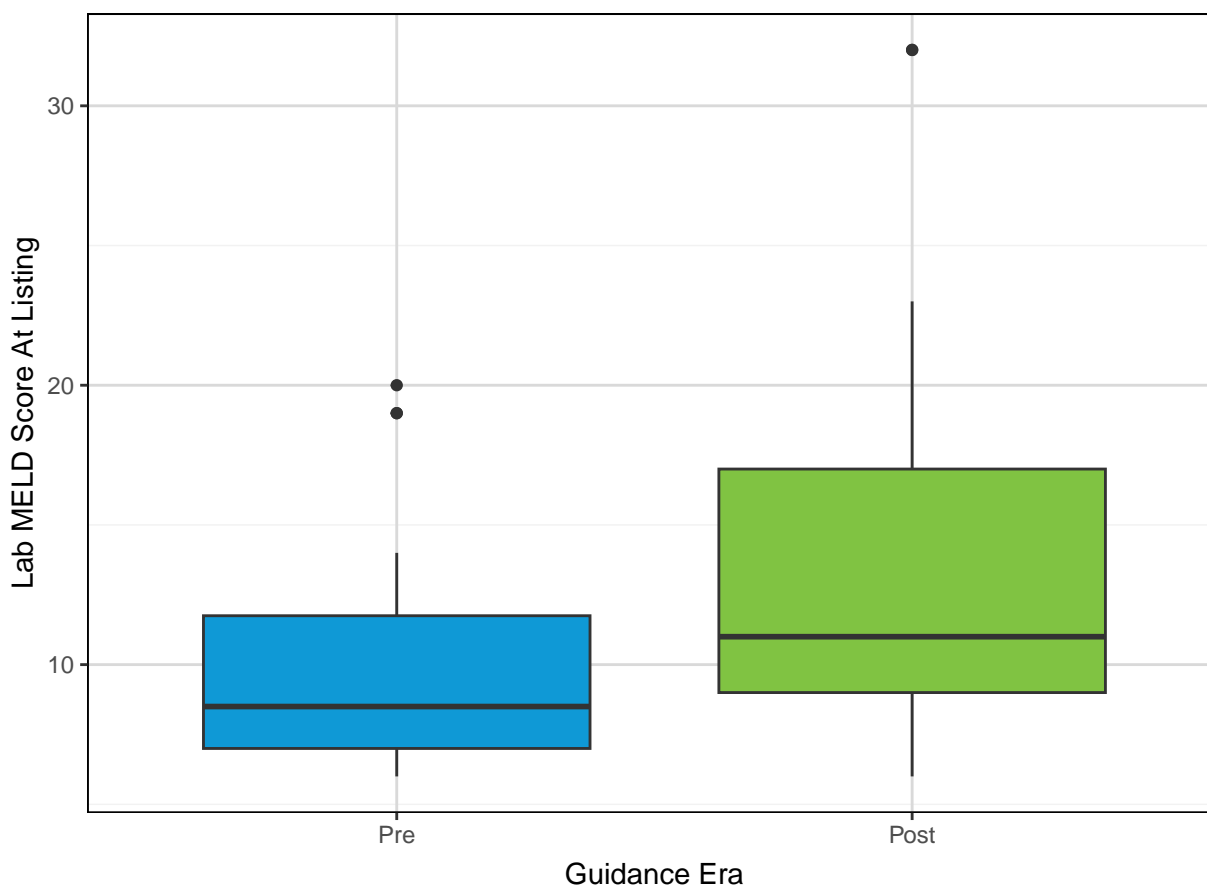


Table 5. Number and Proportion of MVT Registrations Ever-Waiting in each Guidance Era with an Approved Exception during the Era

Had at least One Exception Form Approved	Guidance Era	
	Pre	Post
Yes	22 (25.29%)	63 (64.95%)
No	65 (74.71%)	34 (35.05%)
Total	87 (100.00%)	97 (100.00%)

Figure 6 and table 6 shows the distribution of MELD lab scores at liver registration listing for ever-waiting MVT registrations with an approved exception during the era. As we are considering ever-waiting registrations, registrations can appear in both eras. In the post-guidance era, ever-waiting MVT registrations with an exception had a higher median MELD lab score at listing, and were generally more medically urgent (Pre: 8.5, Post: 11).

Figure 6. The Distribution of Lab MELD Scores at Listing for Multivisceral Transplant Registrations Ever-Waiting in each Guidance Era with an Approved Exception during the Era



Critical to note, the implementation of the MVT guidance on 7/27/2023 was closely aligned with the implementation of MELD 3.0 on 7/13/2023 and such policy change could impact or confound lab MELD trends seen in this figure.

Table 6. The Distribution of Lab MELD Scores at Listing for Multivisceral Transplant Registrations Ever-Waiting in each Guidance Era with an Approved Exception during the Era

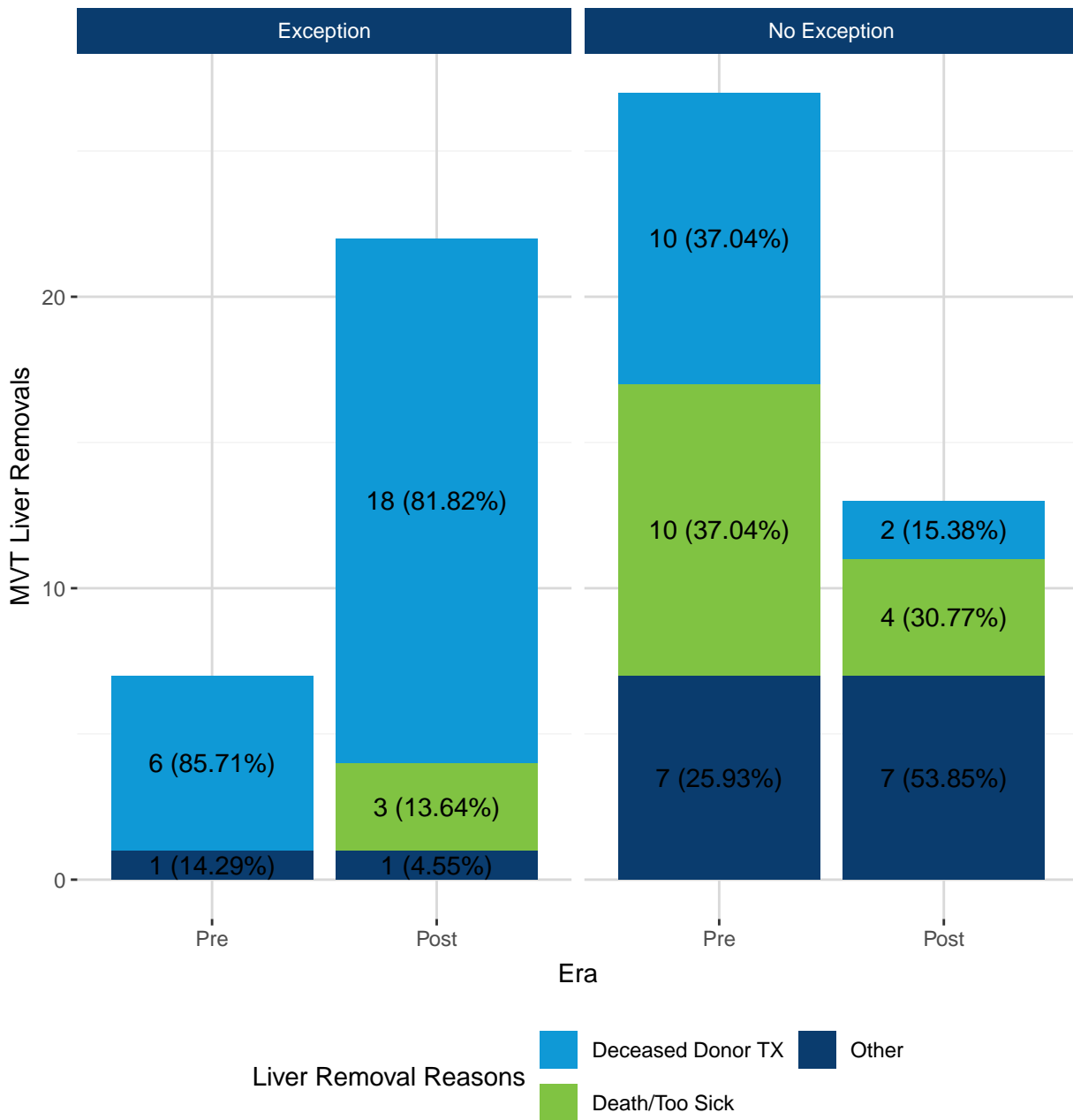
Era	Minimum	25th Percentile	Median	75th Percentile	Maximum	Interquartile Range	Number of Registrations With Approved Exceptions
Pre	6	7	8.5	11.75	20	4.75	22
Post	6	9	11.0	17.00	32	8.00	63

Critical to note the implementation of the MVT guidance on 7/27/2023 was closely aligned with the implementation of MELD 3.0 on 7/13/2023 and such policy change could impact/confound MELD trends seen in this figure.

Waiting List Removals

Figure 7 and table 7 show the MVT liver registrations removed from the OPTN waiting list by removal reason and exception status at removal. Removal reasons are based on the reason provided with the removal of the MVT liver registration. For liver registrations to be considered MVT candidates, registrations must have been ever-waiting in the pre- or post-guidance with a liver registrations that overlapped in time with an intestine registration. The number of MVT liver registrations with an exception at removal removed for the reason of death or too sick increased in the post-guidance era (Pre: 0, Post: 3). The number of MVT liver registrations with an exception at removal removed for the reason of deceased donor transplant also increased in the post-guidance era (Pre: 6, Post: 18). Conversely, the number of MVT liver registrations with no exception at removal removed for the reason of death or too sick decreased in the post-guidance era (Pre: 10, Post: 4). The number of MVT liver registrations with no exception at removal removed for the reason of deceased donor transplant also decreased in the post-guidance era (Pre: 10, Post: 2).

Figure 7. Number and Proportion of Multivisceral Transplant Registrations Removed from the OPTN Waiting List by Removal Reason, Exception Status at Removal and Guidance Era



*Removals for deceased donor transplant include liver-alone and liver multiple organ transplants.

Table 7. Number and Proportion of Multivisceral Transplant Registrations Removed from the OPTN Waiting List by Removal Reason, Exception Status at Removal and Guidance Era

Liver Removal Reason	Exception Status At Removal	Guidance Era	
		Pre	Post
Exception	Deceased Donor TX	6 (85.71%)	18 (81.82%)
	Death/Too Sick	0 (0.00%)	3 (13.64%)
	Other	1 (14.29%)	1 (4.55%)
	Still Waiting	0 (0.00%)	0 (0.00%)
Total	-	7 (100.00%)	22 (100.00%)
No Exception	Deceased Donor TX	10 (37.04%)	2 (15.38%)
	Death/Too Sick	10 (37.04%)	4 (30.77%)
	Other	7 (25.93%)	7 (53.85%)
	Still Waiting	0 (0.00%)	0 (0.00%)
Total	-	27 (100.00%)	13 (100.00%)

*Removals for deceased donor transplant include liver-alone and liver multiple organ transplants.

Transplants

Figure 8 and table 8 shows multivisceral transplants by exception status at transplant and guidance era. There was an increase in MVT transplants in the post-guidance era (Pre: 16, Post: 18). Furthermore, most MVTs had a liver exception at the time of transplant. Further evaluation of multivisceral exception transplants is not available at this time due to the small number of transplants.

Figure 8. Number and Proportion of Multivisceral Transplants by Exceptions Status at Transplant

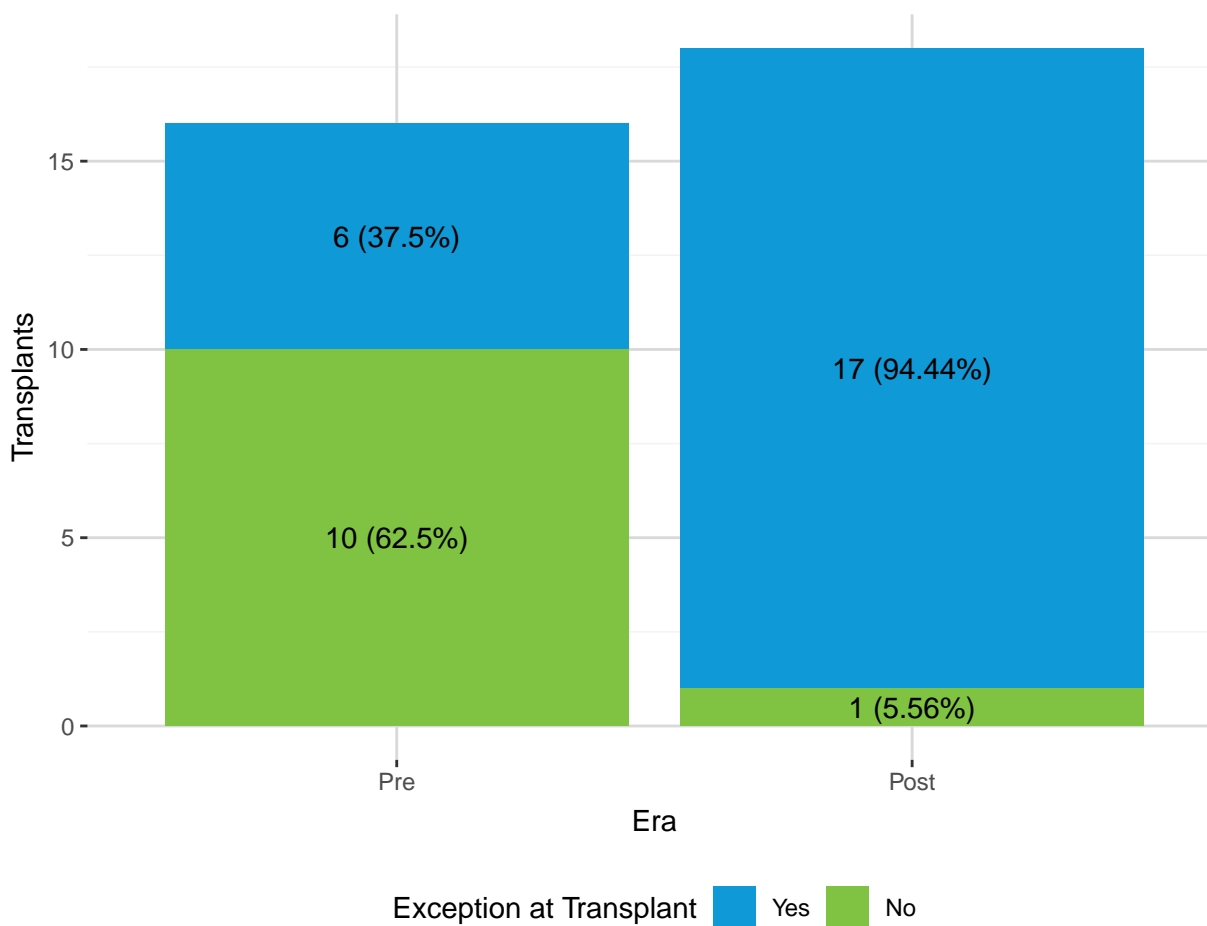


Table 8. Number and Proportion of Multivisceral Transplants by Exceptions Status at Transplant

Exception at Transplant	Guidance Era	
	Pre	Post
No	10 (62.50%)	1 (5.56%)
Yes	6 (37.50%)	17 (94.44%)
Total	16 (100.00%)	18 (100.00%)