



SCIENTIFIC  
REGISTRY OF  
TRANSPLANT  
RECIPIENTS

# MELD Exception Score: LSAM modeling of a fixed floor rather than an elevator

Authors: J Heimbach,<sup>1</sup> R Hirose,<sup>2</sup> D Schladt,<sup>3</sup> J Pyke,<sup>3</sup> A Harper,<sup>4</sup> J Zeglin,<sup>3</sup> S Leppke,<sup>3</sup> J Lake,<sup>5</sup> WR Kim<sup>6</sup>

<sup>1</sup>Mayo Clinic, Rochester, US; <sup>2</sup>University of California San Francisco, San Francisco, US; <sup>3</sup>Scientific Registry of Transplant Recipients, Minneapolis, US; <sup>4</sup>United Network for Organ Sharing, Richmond, US; <sup>5</sup>University of Minnesota, Minneapolis, US; <sup>6</sup>Stanford University, Stanford, US.

# Disclosures

**Julie Heimbach, MD**

**Director, Liver Transplantation**

**Mayo Clinic, Rochester MN, United States**

I have no financial relationships to disclose within the past 12 months relevant to my presentation. The ACCME defines 'relevant' financial relationships as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

My presentation does not include discussion of off-label or investigational use. I do not intend to reference unlabeled/unapproved uses of drugs or products in my presentation

This work was supported wholly or in part by HRSA contract HHS-250-2015-00009C. The content is the responsibility of the authors alone and does not necessarily reflect the views or policies of the Department of HHS, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.



SCIENTIFIC REGISTRY OF  
TRANSPLANT RECIPIENTS

# Overview

- Why a National Liver Review Board (NLRB)?
- Challenges for the NLRB
- Concept: Fixed score based on median MELD at transplant
  - Modeling study design
  - Modeling results
- Current NLRB proposal and next steps



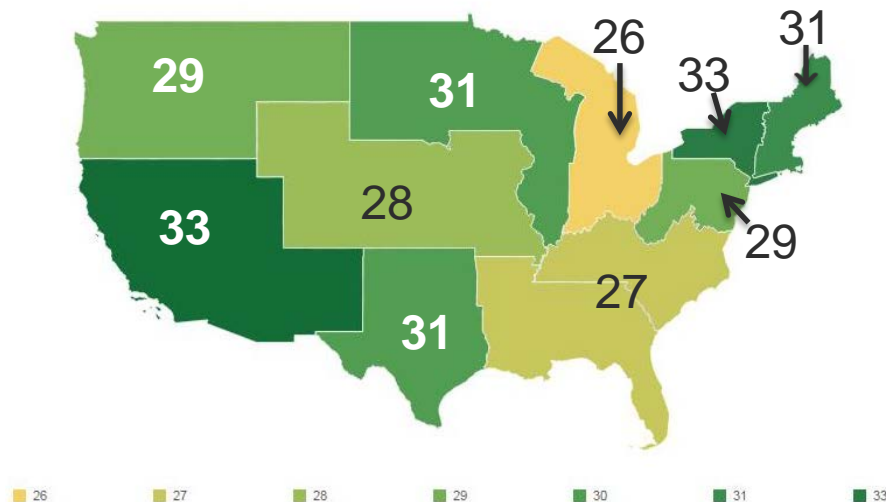
# Why a National Liver Review Board?

- Variation in rates of standard and non-standard exceptions across the country (range of exceptions 20.9% to 49.7% of LT performed in each region in 2016).
- Different regional agreements for HCC outside of Milan, and for other types of exceptions.
- Lack of efficiency of current exception system.

# Challenges for the NLRB

- Currently, most **standard** MELD exceptions begin at 22 and increase every three months, 25, 28, 29, 31, 33, 34... **"MELD elevator."**
- HCC begins at 28 after a 6-month delay, and oxalosis patients begin at 28 with no delay.
- Non-standard exceptions are **often** granted scores similar to those for standard exceptions, despite the variation in score typically needed to access LT.

Median MELD at TX for 2016,  
excluding status 1



# Potential solution: a fixed score based on Median MELD/PELD at Transplant (MMaT)

- The OPTN Liver and Intestinal Organ Transplantation Committee developed a policy concept that would assign exception candidates 1, 2, 3, or 5 points below the median MELD at transplant (MMaT) in their DSA as a fixed score.
- MMaT would be recalculated every 6 months, based on the previous 12 months of data.



# Simulated allocation modeling: study design

Analysis based on actual patient and donor data including:

- Transplant candidates listed on liver waiting lists as of December 31, 2006, and candidates added to those lists between January 1, 2007, and December 31, 2011.
  - Organs donated between January 1, 2007, and December 31, 2011.
- 5 different allocation scenarios were simulated with LSAM.
- Each simulation was repeated 10 times to provide an estimate of variability.
  - Each scenario simulated one year of transplants.
  - Allocation MELD/PELD scores were capped at 40 for all simulations.

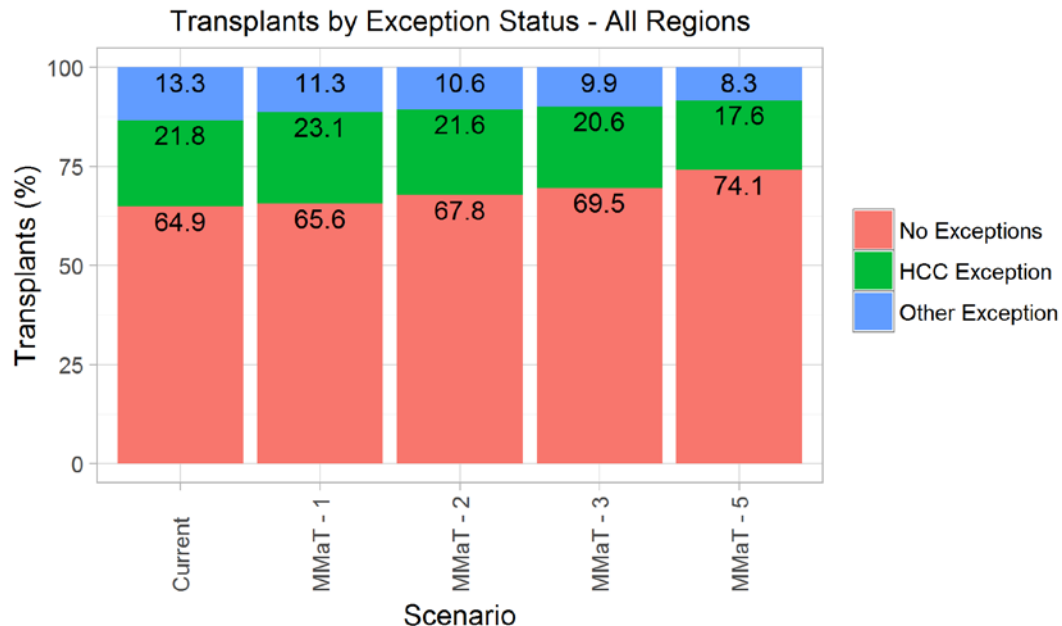


# Simulated allocation modeling: details of alternative scenarios

- No automatic increases in exception MELD/PELD scores.
- Baseline MMaT was set based on 1 year of data on all adult recipients in the DSA, and updated every 6 months.
  - A 12-month current policy simulation was used to set the initial exception scores for the proposed exception system (months 1-12). We then conducted two 6-month simulation runs (months 13-18 and months 19-24) to simulate 12 months of experience under this system, with the median MELD/PELD at transplant recalculated between the two runs.
  - For reporting results, we aggregated the data from months 13-24 to provide 1 year of comparison between the current policy and alternative exception policies.
- All exception patients received a score update at the 6 month mark.



# Proportion of transplants by exception status: all regions



# Proportion of transplants by exception status: summary

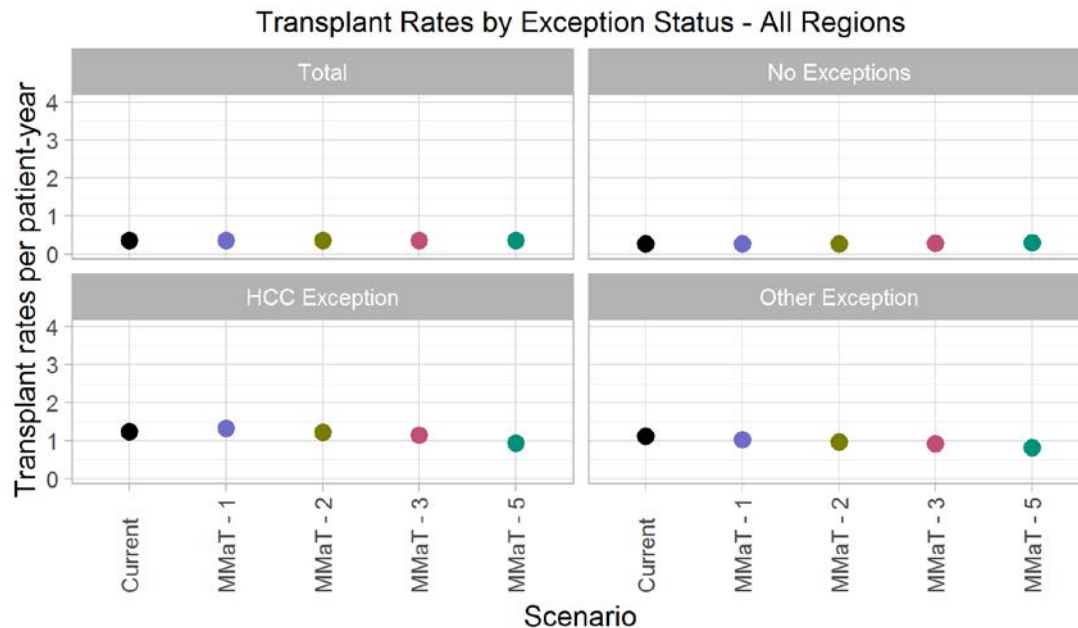
## All regions (US)

- Proportion of candidates with no exceptions undergoing transplant increases as awarded exception points decrease.
- Largest increase for candidates with no exceptions undergoing transplant is in the MMaT-5 scenario.

## Regional variation

- Most regions follow the national trend, except:
- In the MMaT-1 scenario, the proportion of candidates with no exceptions undergoing transplant decreases (compared with current policy) in regions 4, 5, 7, and 9.

# Transplant rates by exception status: all regions



# Transplant rates by exception status: summary

## All regions (US)

- Transplant rates decrease for candidates with HCC exceptions and other exceptions as awarded exception points decrease.
- Transplant rates for candidates with no exceptions are largely unaffected.
- Although transplant rates decrease for exception candidates, rates generally remain higher overall for exception candidates than for those with no exceptions.

## Regional variation

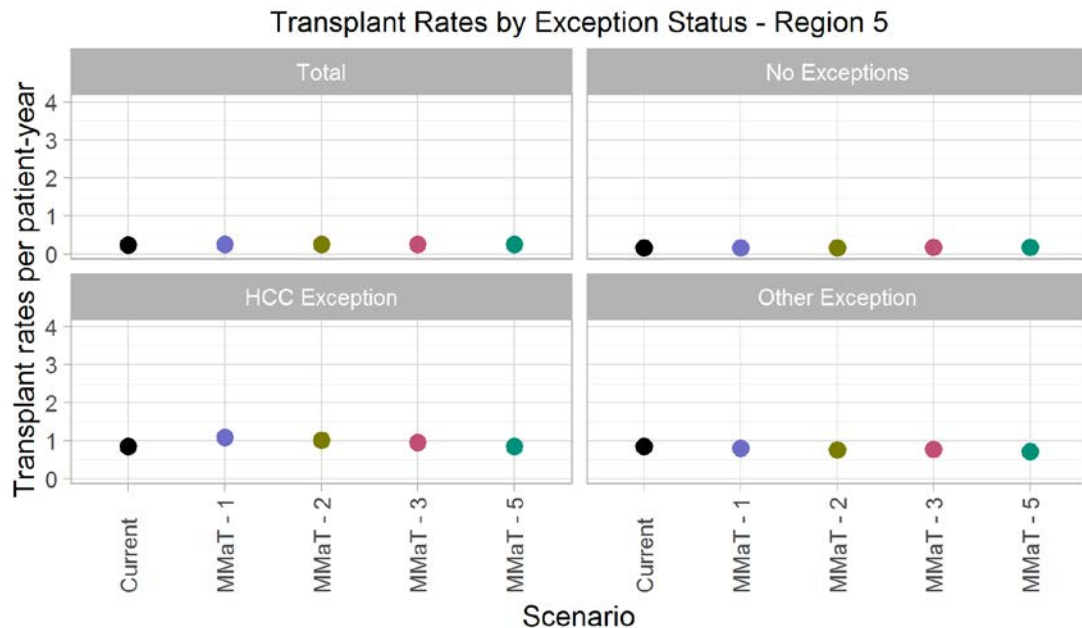
- Most regions follow the national trends.
- In the MMaT-1 scenario, transplant rates increase for HCC candidates in regions 1, 2, 4, 5, 7, and 9.
- In regions 5 and 9, transplant rates may increase for HCC candidates in the MMaT-1, -2, and -3 scenarios.

# Transplant rates by exception status: region 5

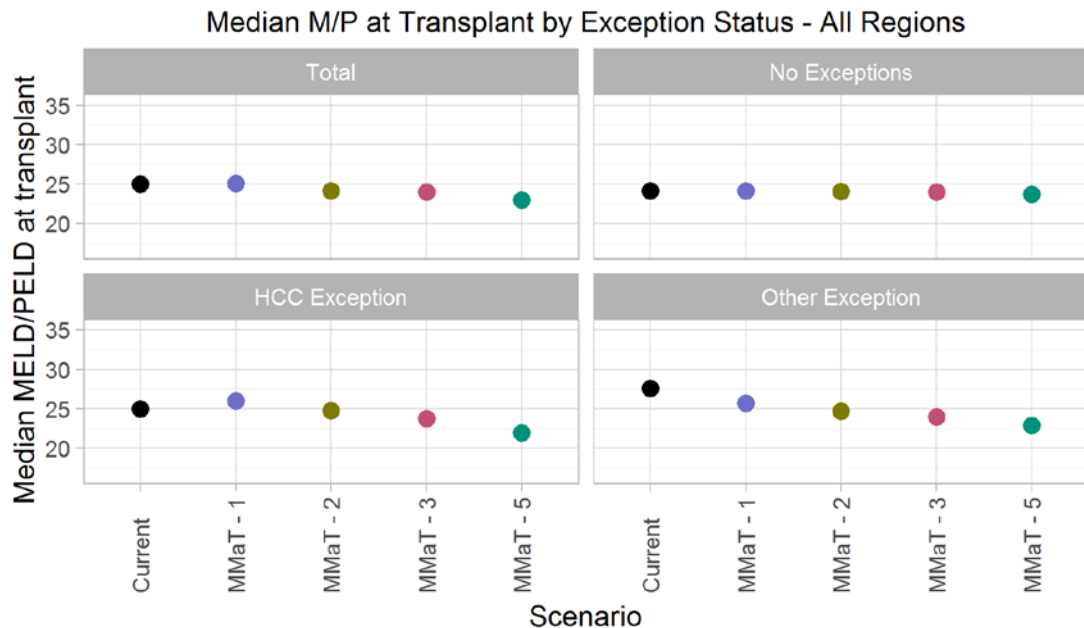
Increase in transplant rate for  
HCC exception group:

Scenario	Transplants per person year (range)
Current	0.84 (0.79, 0.89)
MMaT-1	1.08 (0.98, 1.17)
MMaT-2	1.01 (0.86, 1.12)
MMaT-3	0.95 (0.84, 1.04)
MMaT-5	0.85 (0.76, 0.94)

Similar pattern seen in region 9.



# Median MELD/PELD at transplant by exception status: all regions (data 2007-2011)



# Median MELD/PELD at transplant by exception status: summary

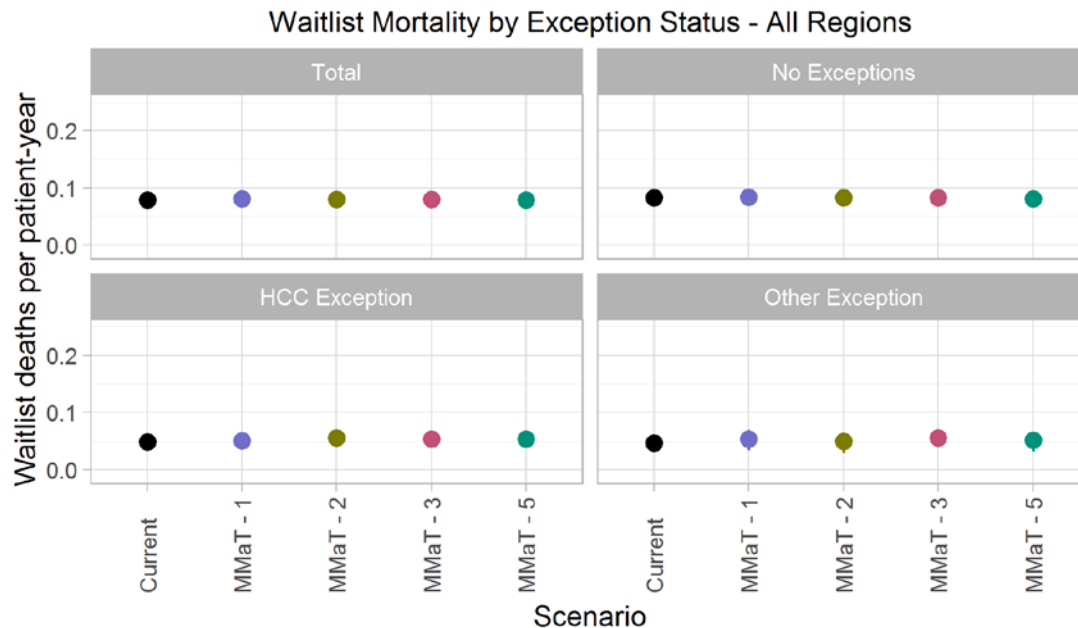
## All regions (US)

- MMaT decreases as the awarded exception points decrease, except:
  - In the MMaT-1 scenario, the HCC exception group has higher MMaT.

## Regional variation

- Some regions follow the national trend, in which MMaT decreases as exception points decrease, particularly for HCC exception and other exception patients (regions 3, 6, 8, 10, and 11).
- In other regions, MMaT increases for some candidate groups in the MMaT-1 and MMaT-2 scenarios (regions 1, 2, 4, 5, 7, and 9).

# Waitlist mortality by exception status: all regions





# Waitlist mortality by exception status: summary

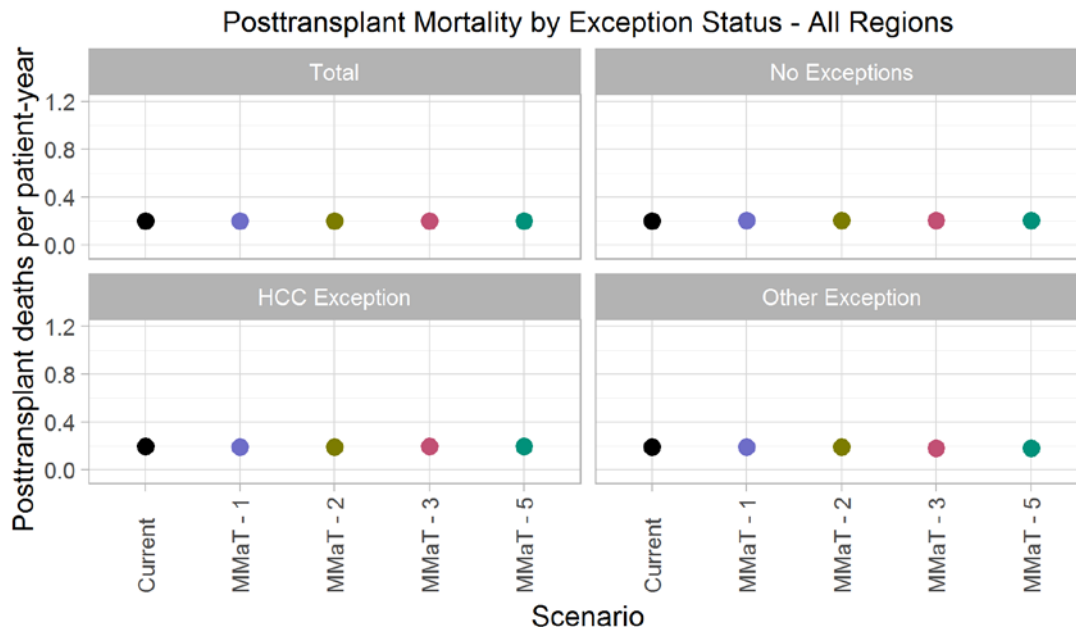
## All regions (US)

- Waitlist mortality rates for HCC exception and other exception candidates may increase slightly or remain the same in alternative exception point scenarios.
- Waitlist mortality rates for non-exception candidates are estimated to remain unchanged.

## Regional variation

- Regions echo the national trend; however, due to smaller sample sizes, ranges of estimated waitlist mortality rates are greater.

# Posttransplant mortality by exception status: all regions



# Posttransplant mortality by exception status: summary

## All regions (US)

- No projected change in posttransplant mortality between current and alternative policy scenarios.

## Regional variation

- Regions echo the national trend; however, due to smaller sample sizes ranges of estimated posttransplant mortality rates are greater.

# Current NLRB proposal and next steps

- NLRB structure (Adult, HCC, Adult Other, Pediatrics, with 5 randomly assigned reviewers per case, with a well-defined appeal process) has been out for public comment and has been well supported.
- Guidance documents for common non-standard exceptions have been created for all three boards and have been well supported in public comment.
- The score proposal for standard exceptions, which may also be used for non-standard exceptions at the discretion of the NLRB, has also been supported by 7/11 regions. Three regions supported MMaT by **region** rather than DSA, and one only supported NLRB in conjunction with broader sharing.



SCIENTIFIC  
REGISTRY OF  
TRANSPLANT  
RECIPIENTS

# Thank you!

**Contact:**

[heimbach.julie@mayo.edu](mailto:heimbach.julie@mayo.edu)

[srtr@srtr.org](mailto:srtr@srtr.org)

# Supplemental Slides

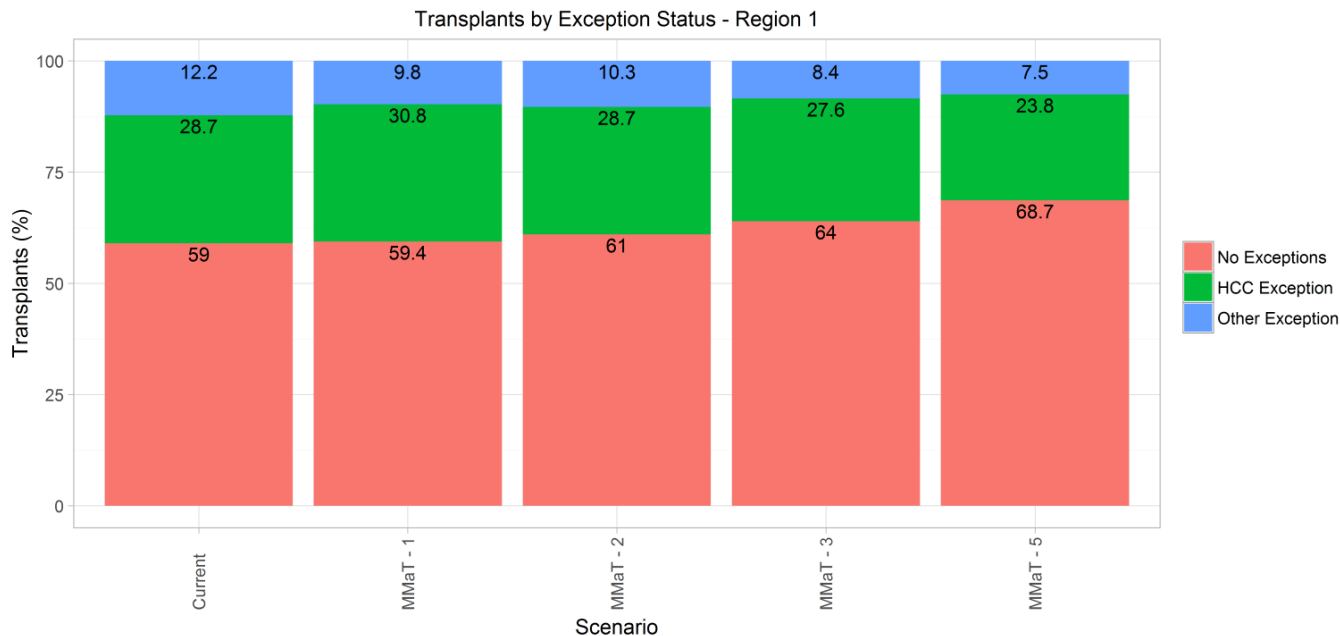


# Median Allocation MELD at Transplant, 2016

Region	Exceptional Case?	N	Median MELD	% Exception
1	No	197	29	
1	Yes	99	31	33.4%
2	No	560	30	
2	Yes	269	28	32.4%
3	No	965	25	
3	Yes	279	28	22.4%
4	No	487	32	
4	Yes	217	29	30.8%
5	No	657	37	
5	Yes	303	33	31.6%
6	No	125	31	
6	Yes	75	28	37.5%

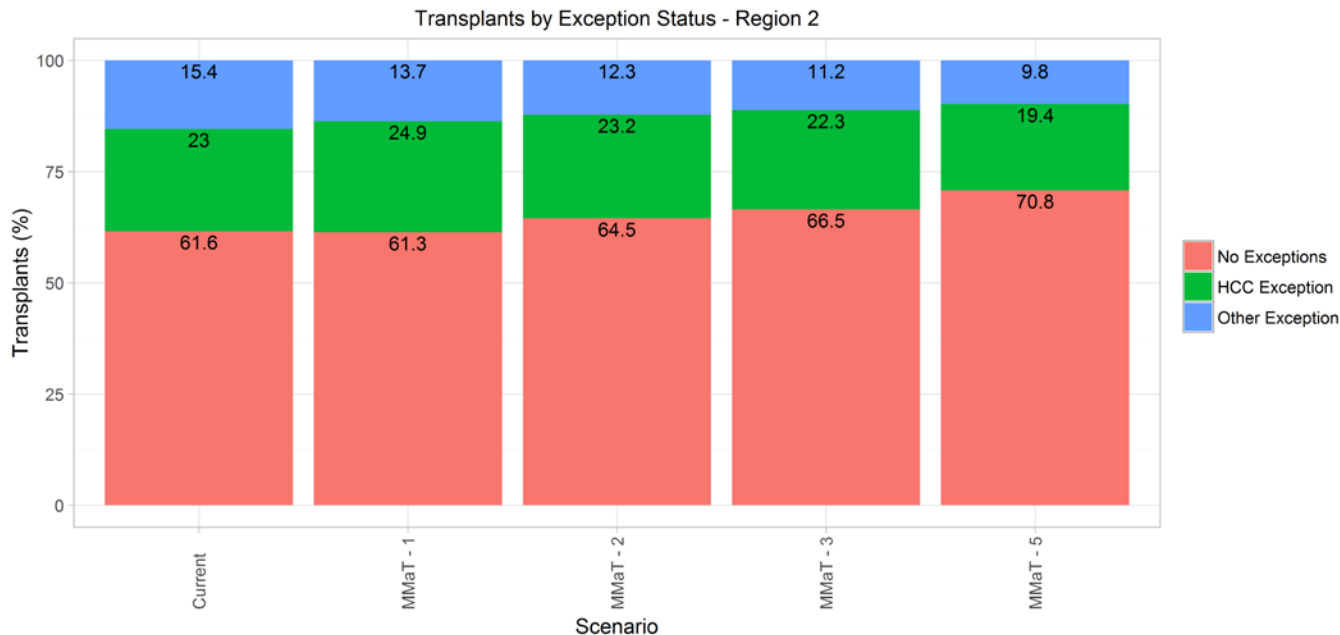
Region	Exceptional Case?	N	Median MELD	% Exception
7	No	365	32	
7	Yes	176	29	32.5%
8	No	268	26	
8	Yes	125	28	31.8%
9	No	158	33.5	
9	Yes	156	33	49.7%
10	No	501	24	
10	Yes	133	28	21.0%
11	No	544	26	
11	Yes	142	28	20.7%
US	No	4827	29	
US	Yes	1974	28	29.0%

# Proportion of transplants by exception status: region 1

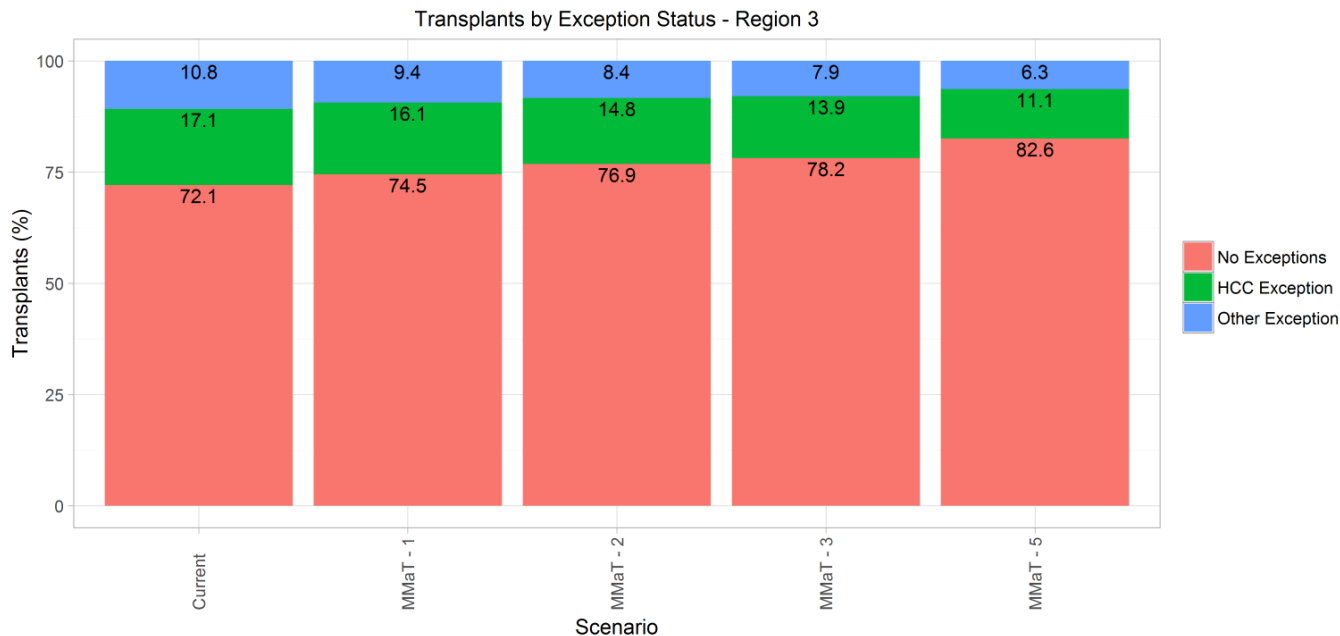




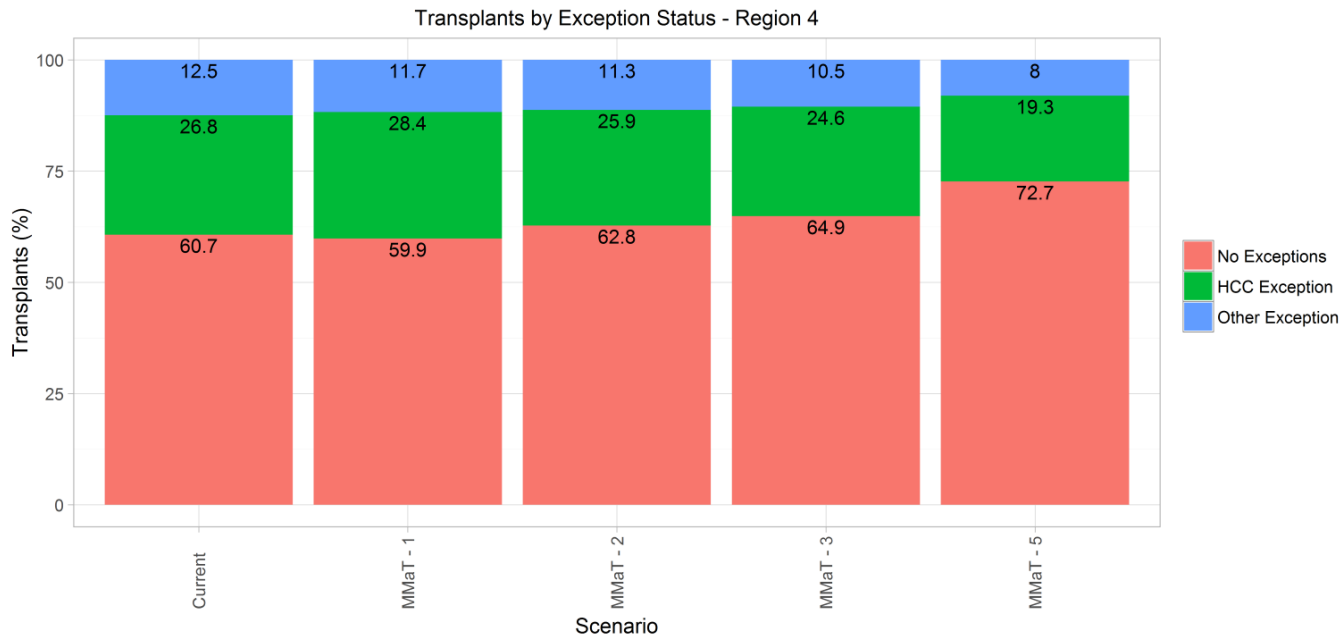
# Proportion of transplants by exception status: region 2



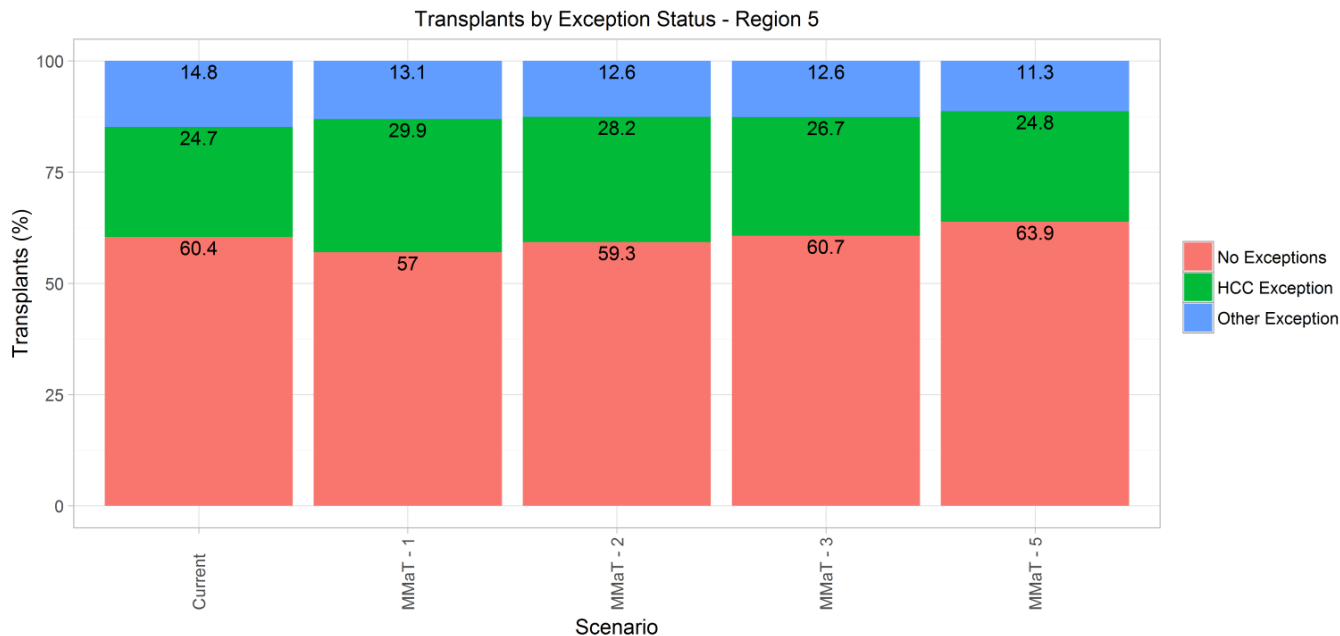
# Proportion of transplants by exception status: region 3



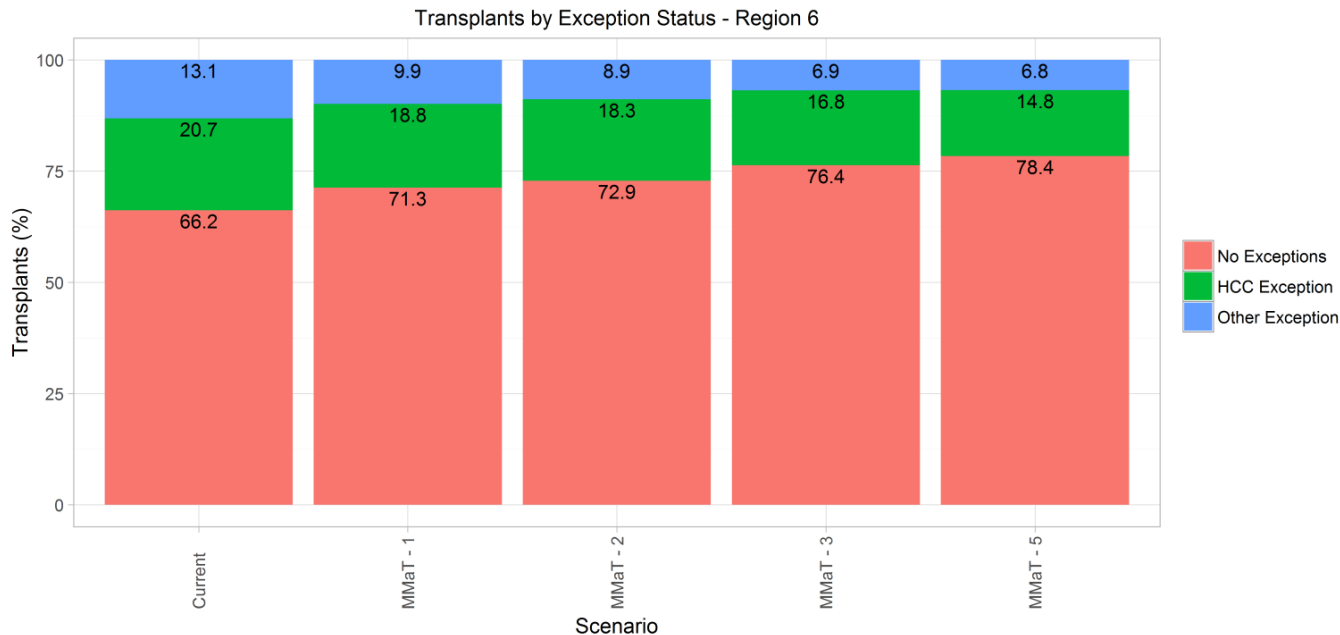
# Proportion of transplants by exception status: region 4



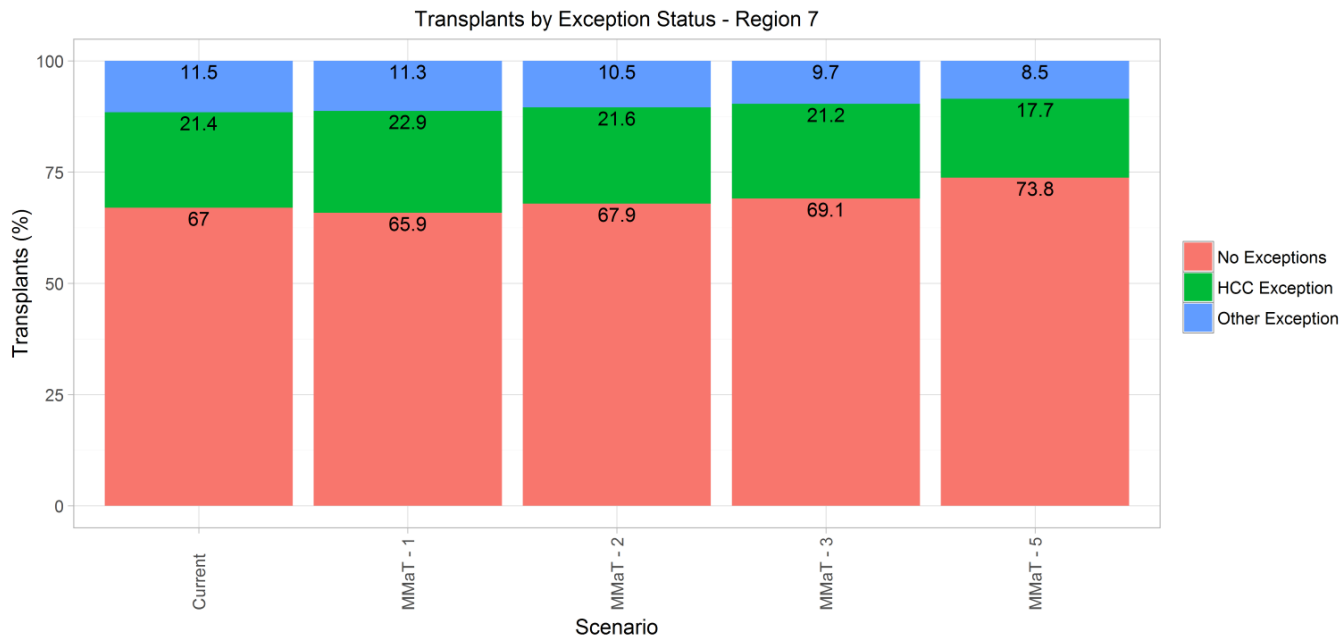
# Proportion of transplants by exception status: region 5



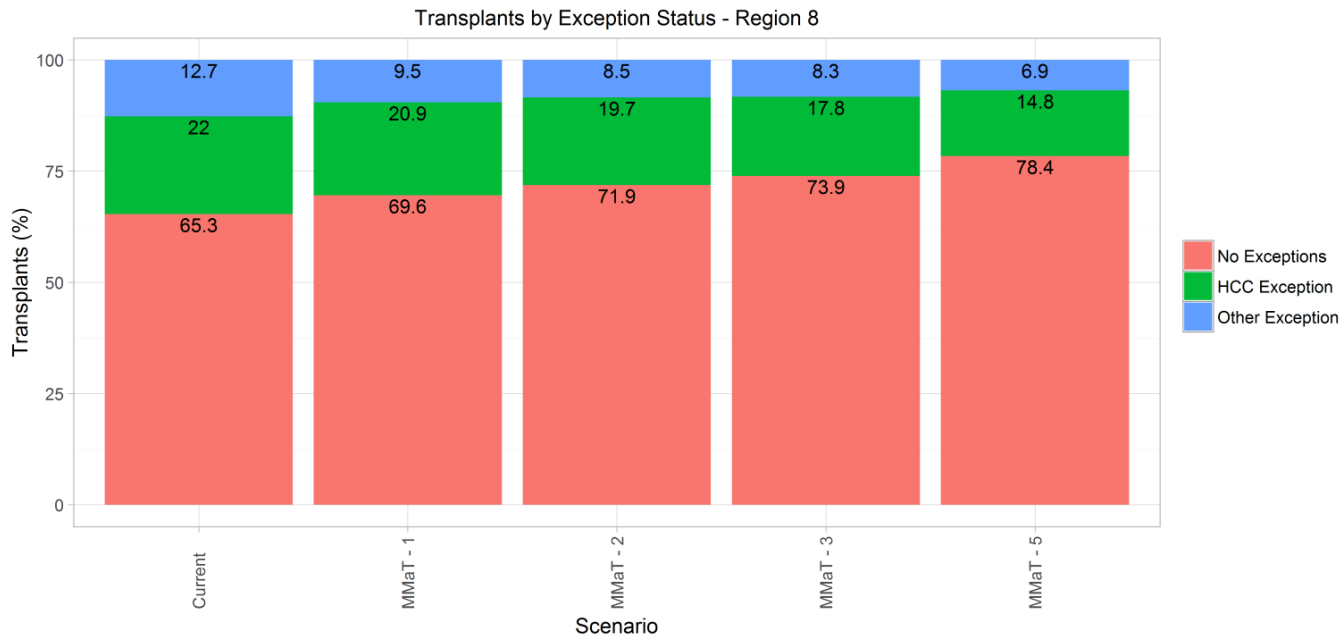
# Proportion of transplants by exception status: region 6



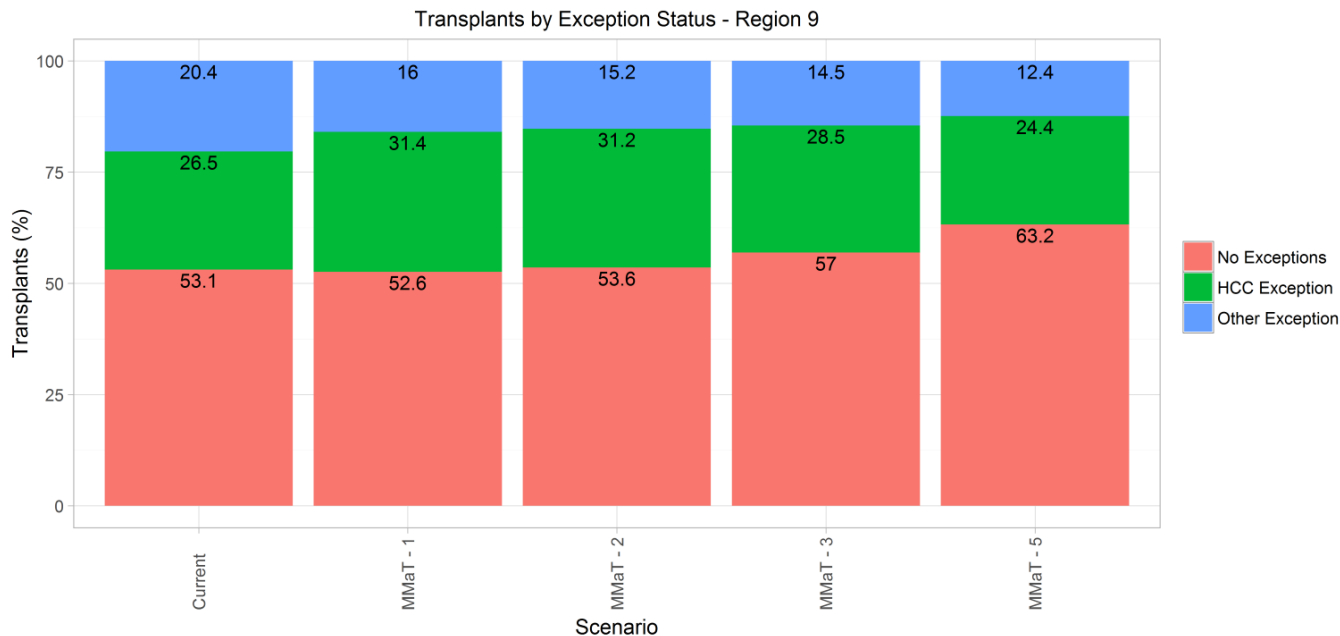
# Proportion of transplants by exception status: region 7



# Proportion of transplants by exception status: region 8

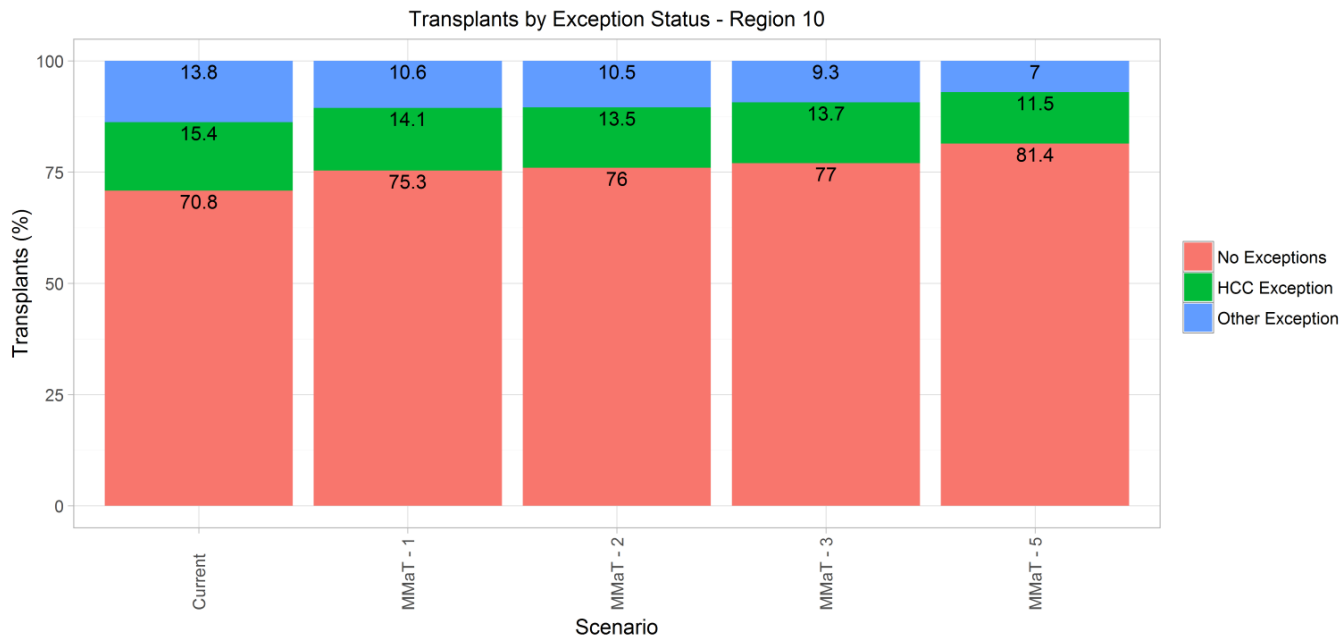


# Proportion of transplants by exception status: region 9

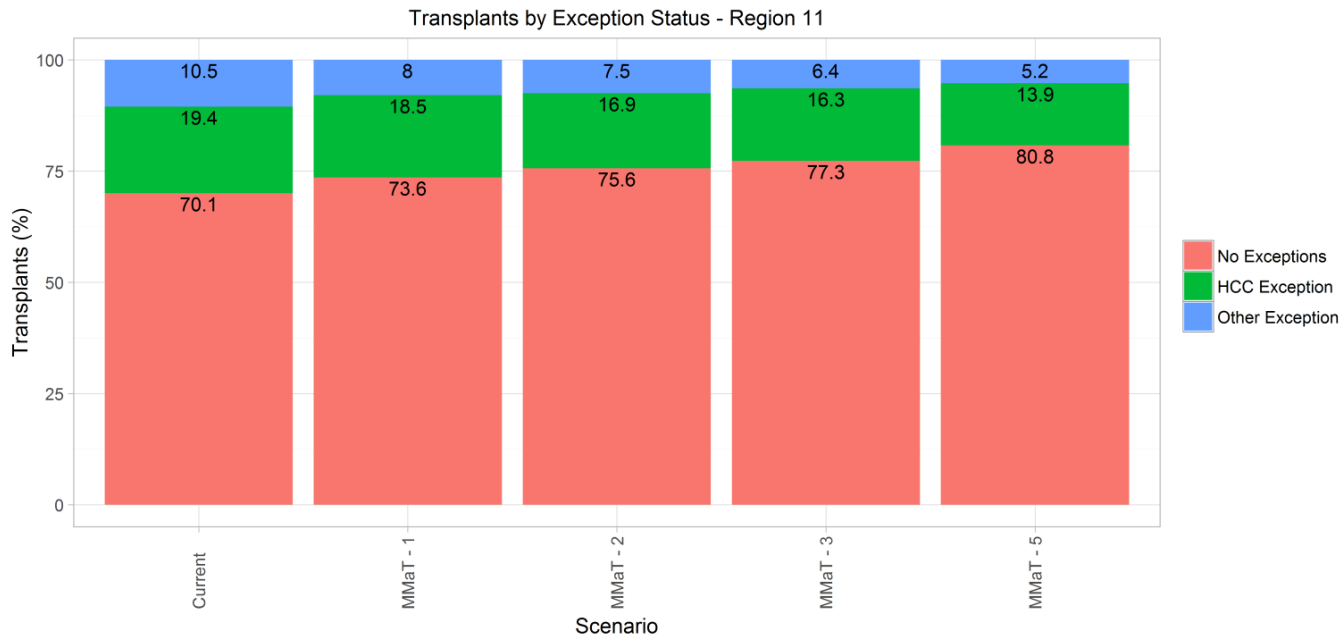




# Proportion of transplants by exception status: region 10

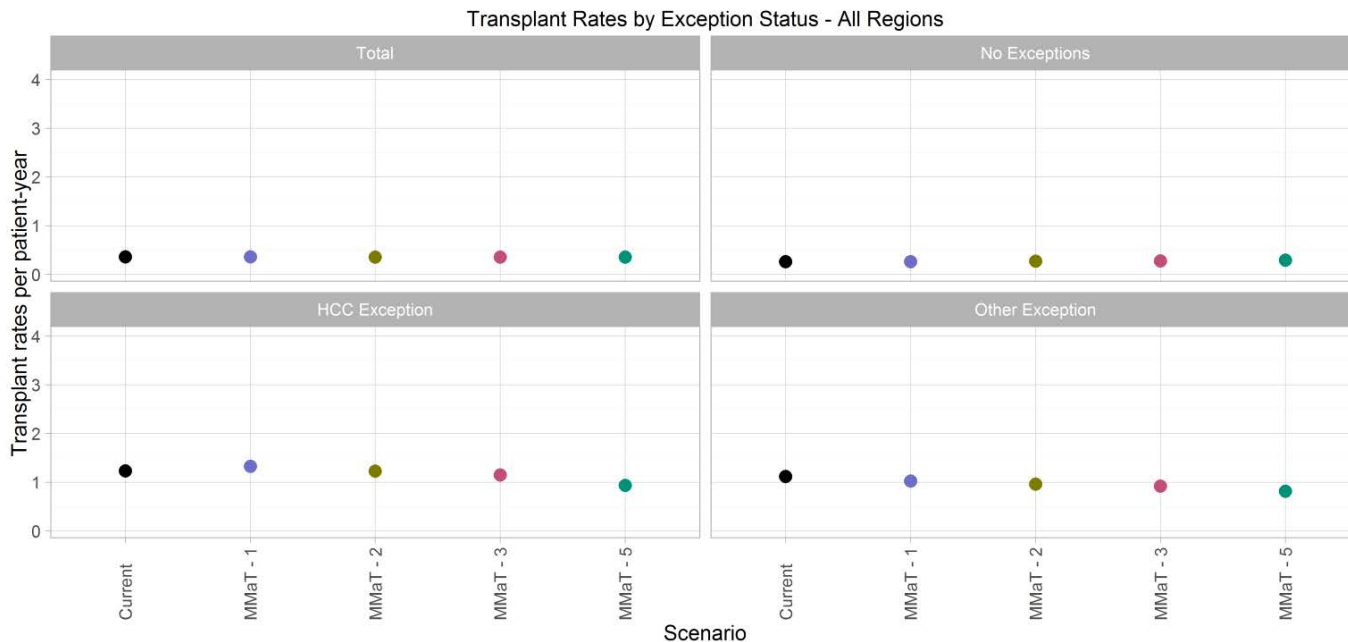


# Proportion of transplants by exception status: region 11

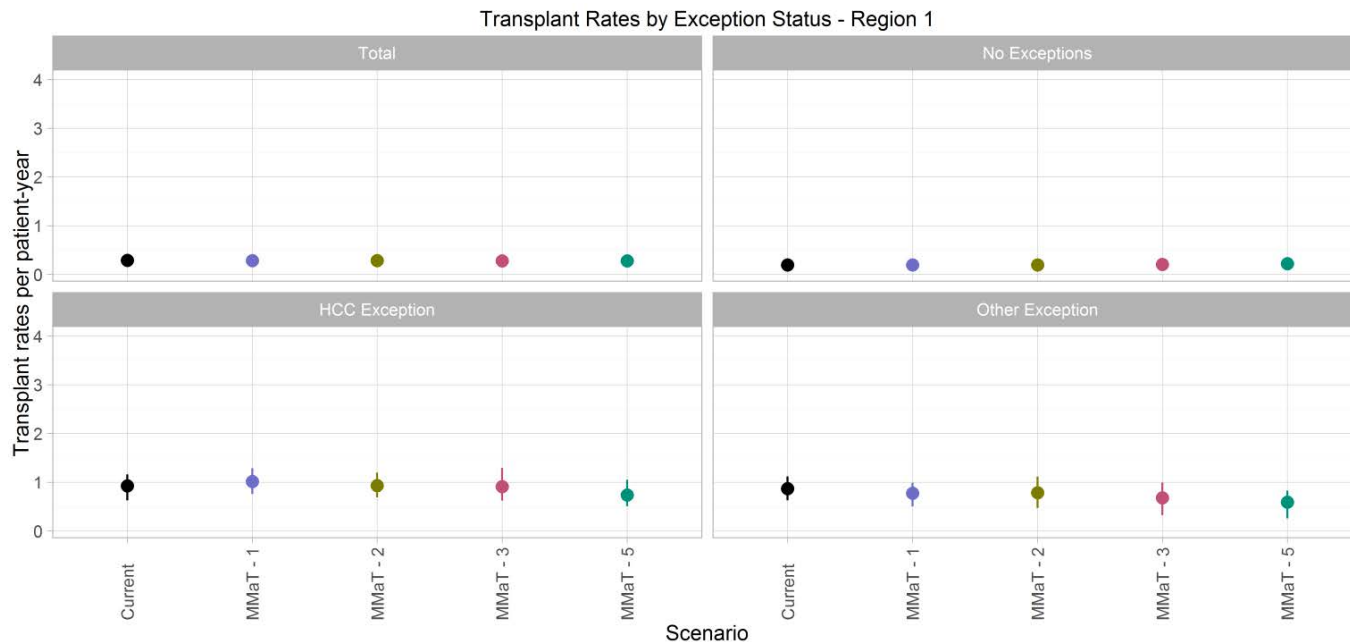


# Transplant rates by exception status

# Transplant rates by exception status: all regions



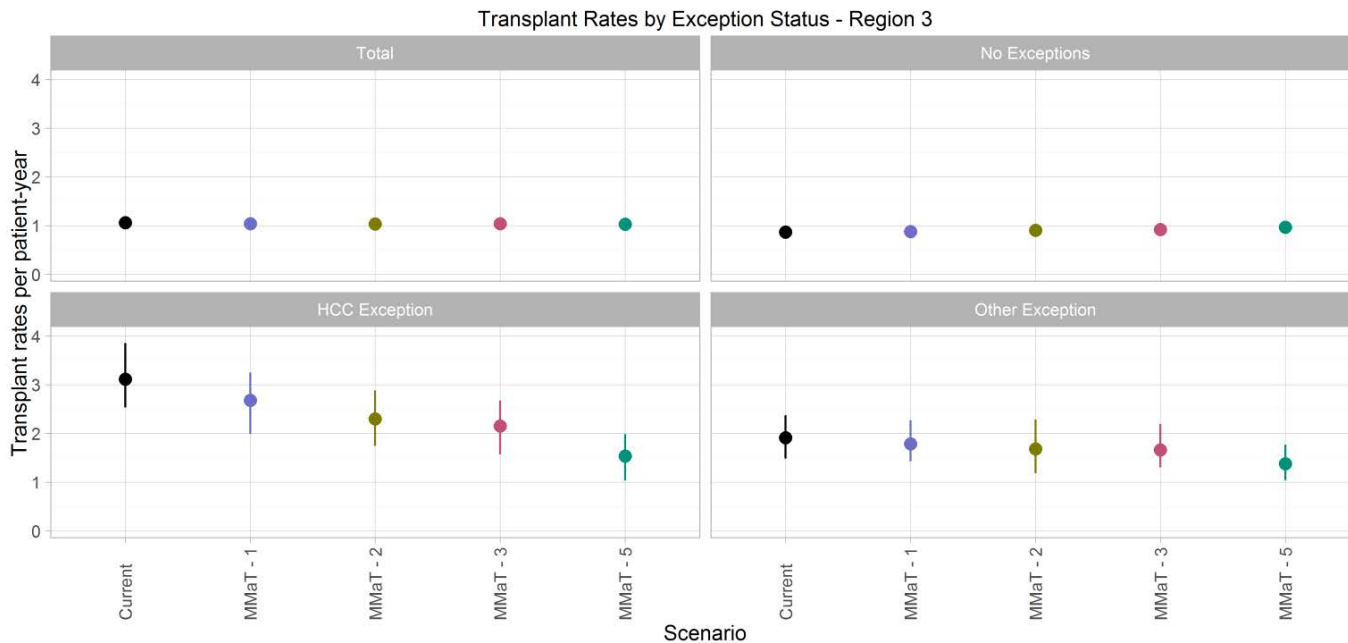
# Transplant rates by exception status: region 1



# Transplant rates by exception status: region 2



# Transplant rates by exception status: region 3



# Transplant rates by exception status: region 4

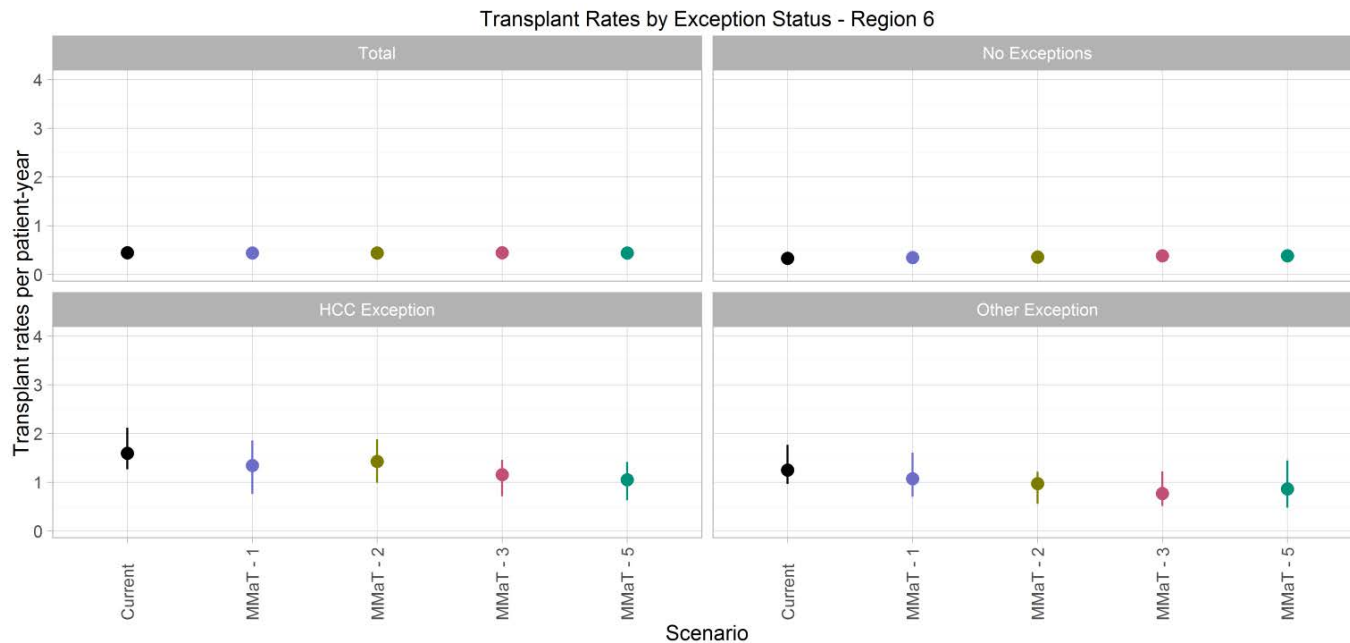




# Transplant rates by exception status: region 5



# Transplant rates by exception status: region 6



# Transplant rates by exception status: region 7



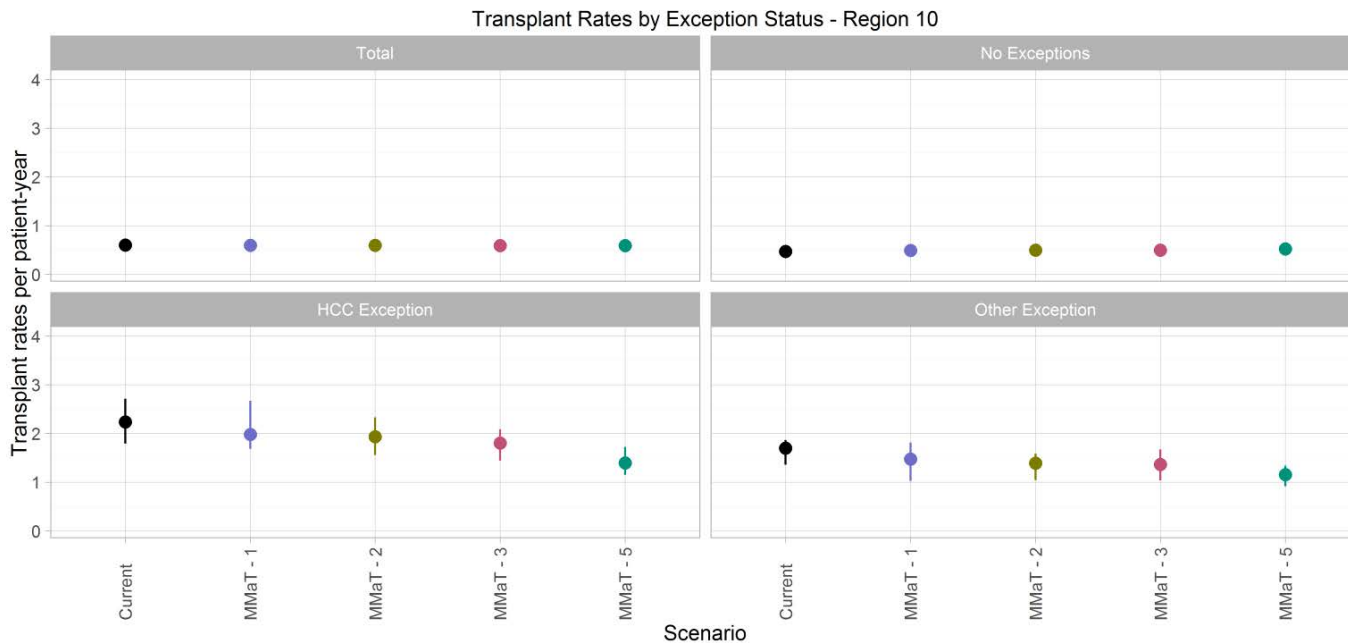
# Transplant rates by exception status: region 8



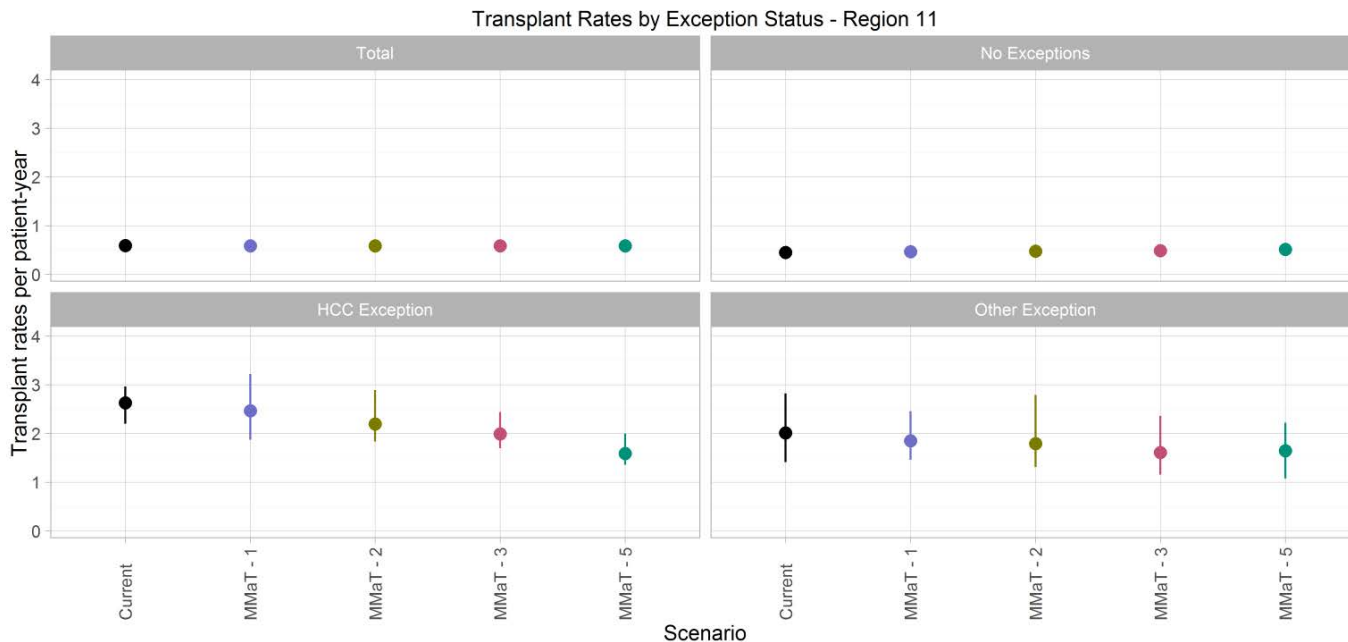
# Transplant rates by exception status: region 9



# Transplant rates by exception status: region 10



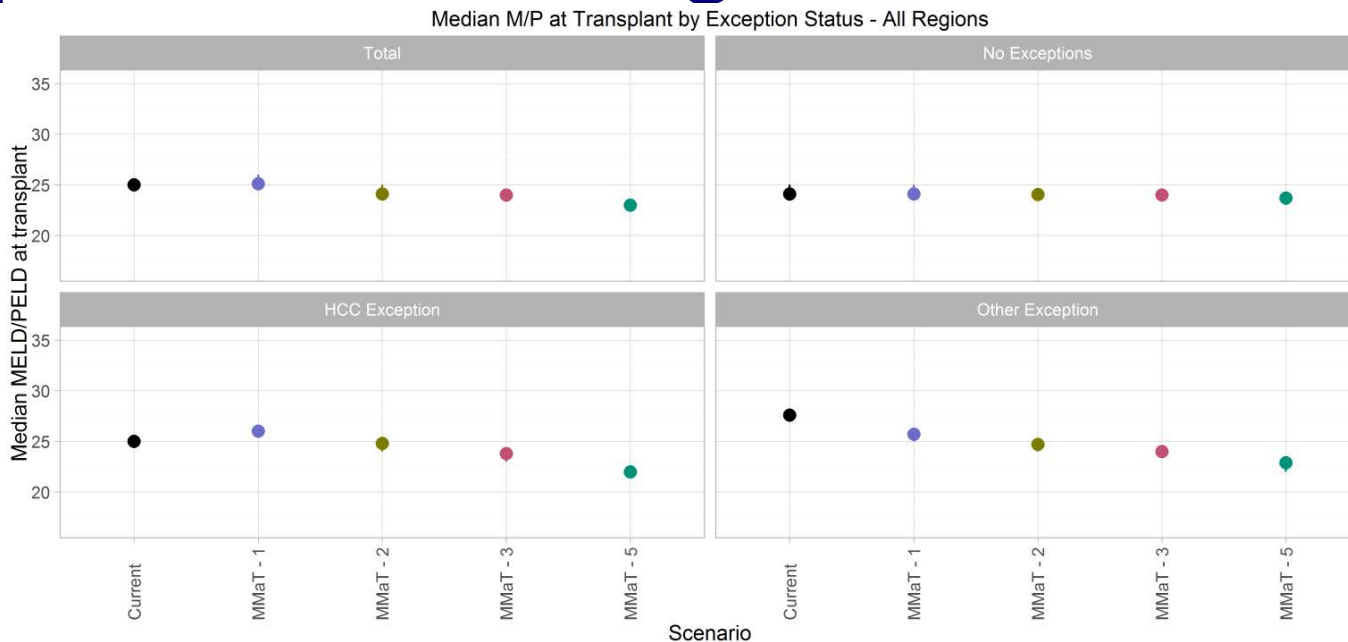
# Transplant rates by exception status: region 11



# Median MELD/PELD at transplant by exception status



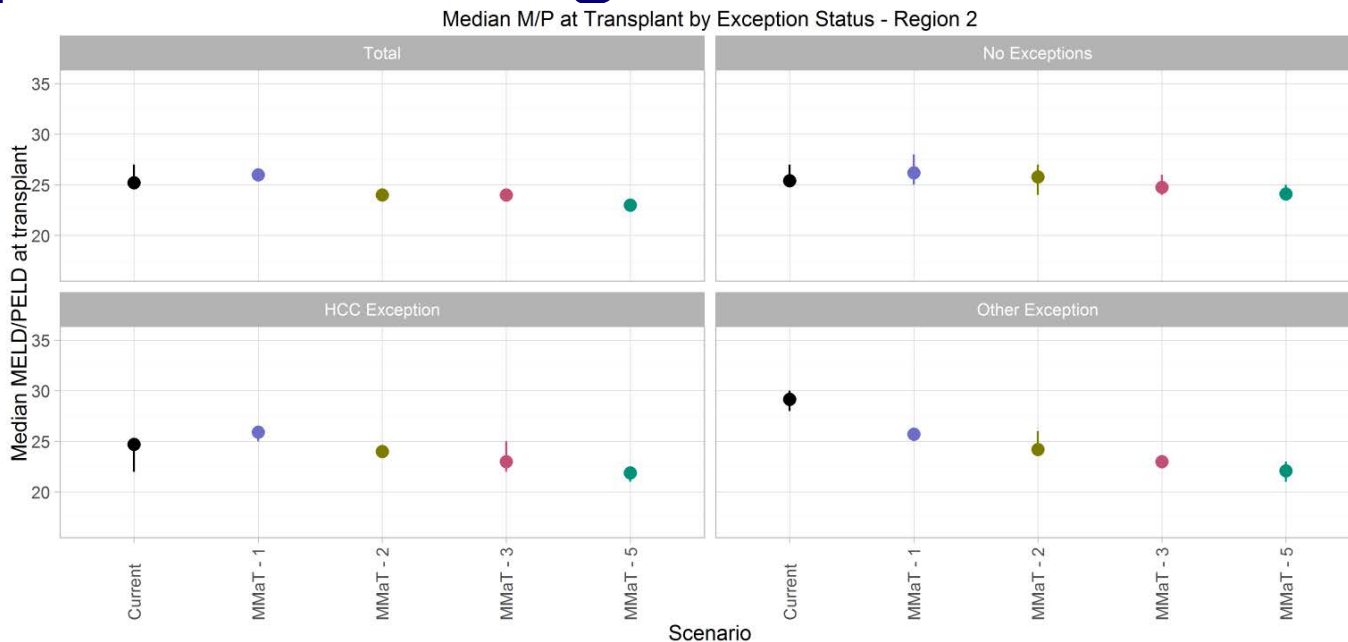
# Median MELD/PELD at transplant by exception status: all regions



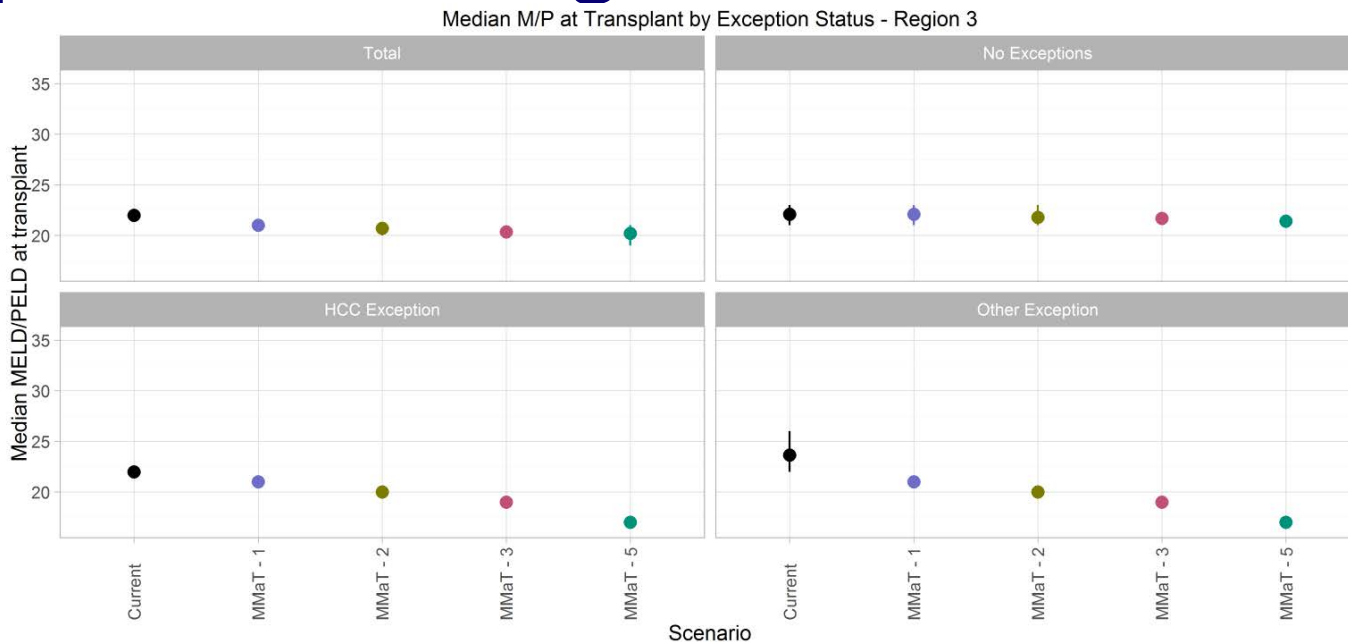
# Median MELD/PELD at transplant by exception status: region 1



# Median MELD/PELD at transplant by exception status: region 2



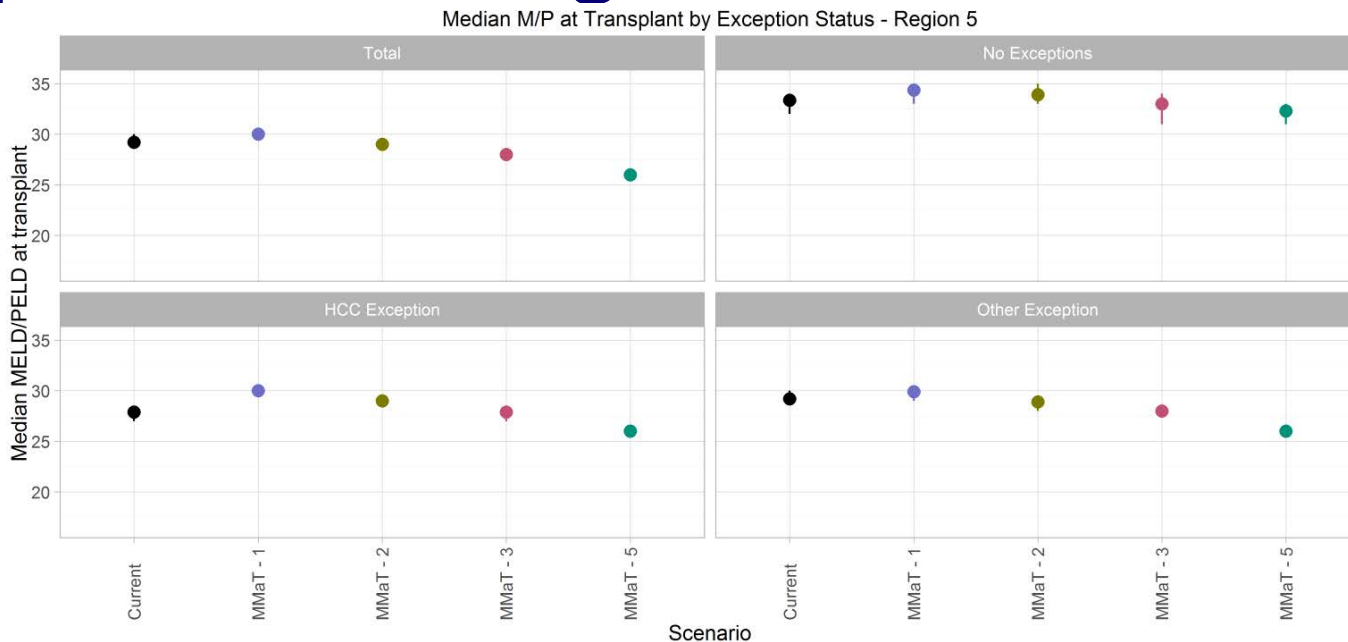
# Median MELD/PELD at transplant by exception status: region 3



# Median MELD/PELD at transplant by exception status: region 4



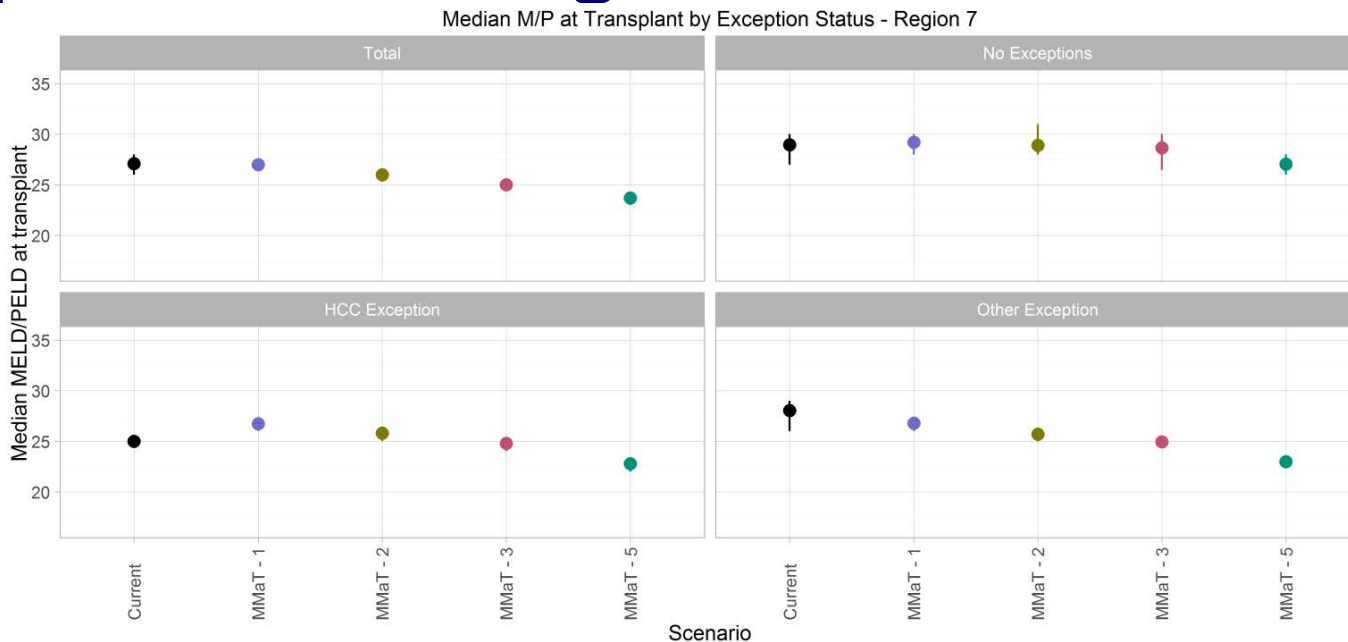
# Median MELD/PELD at transplant by exception status: region 5



# Median MELD/PELD at transplant by exception status: region 6

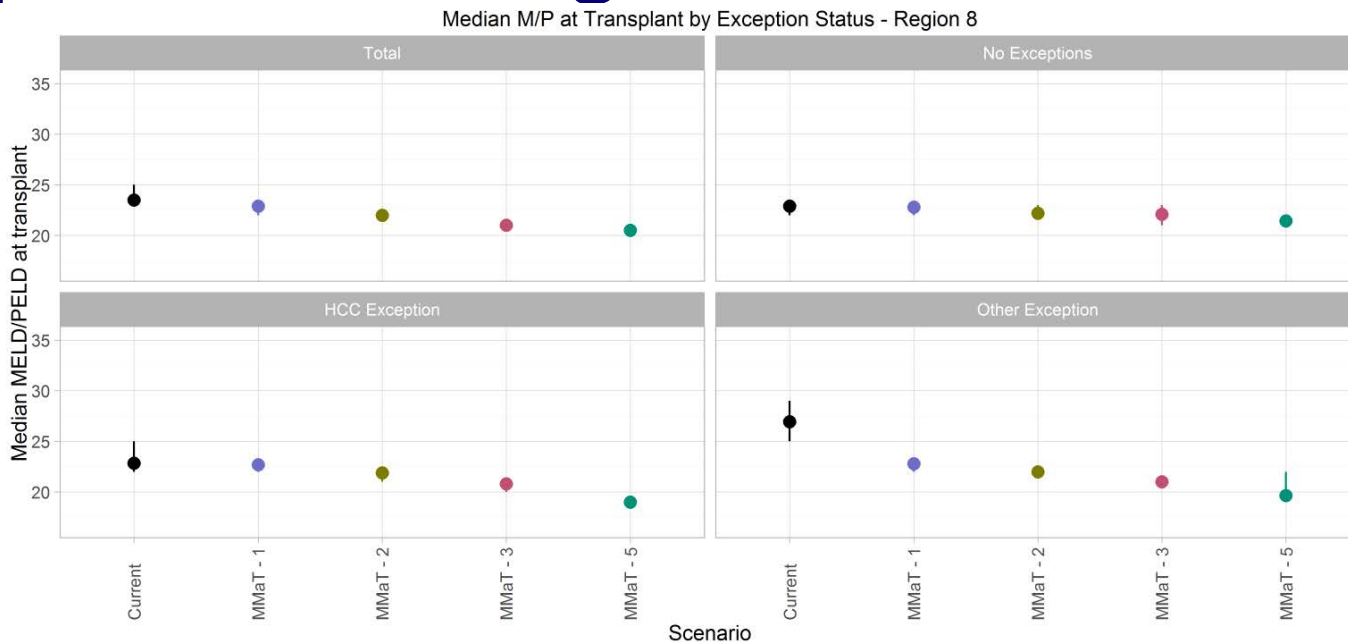


# Median MELD/PELD at transplant by exception status: region 7





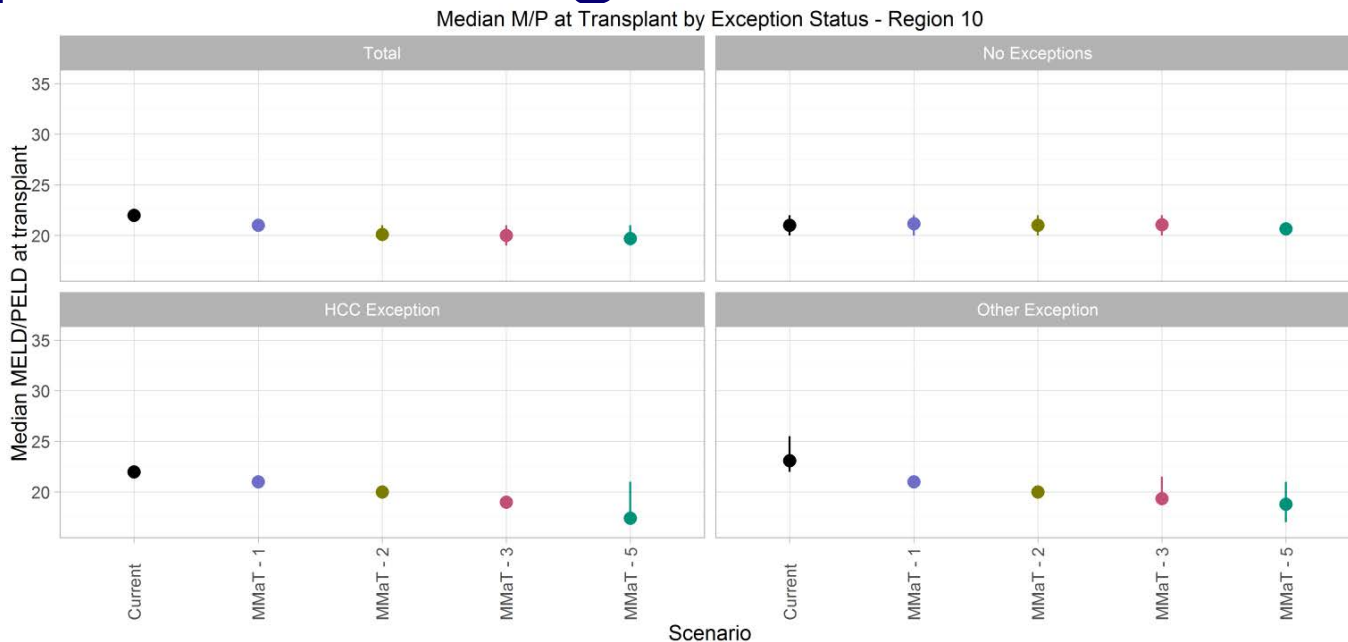
# Median MELD/PELD at transplant by exception status: region 8



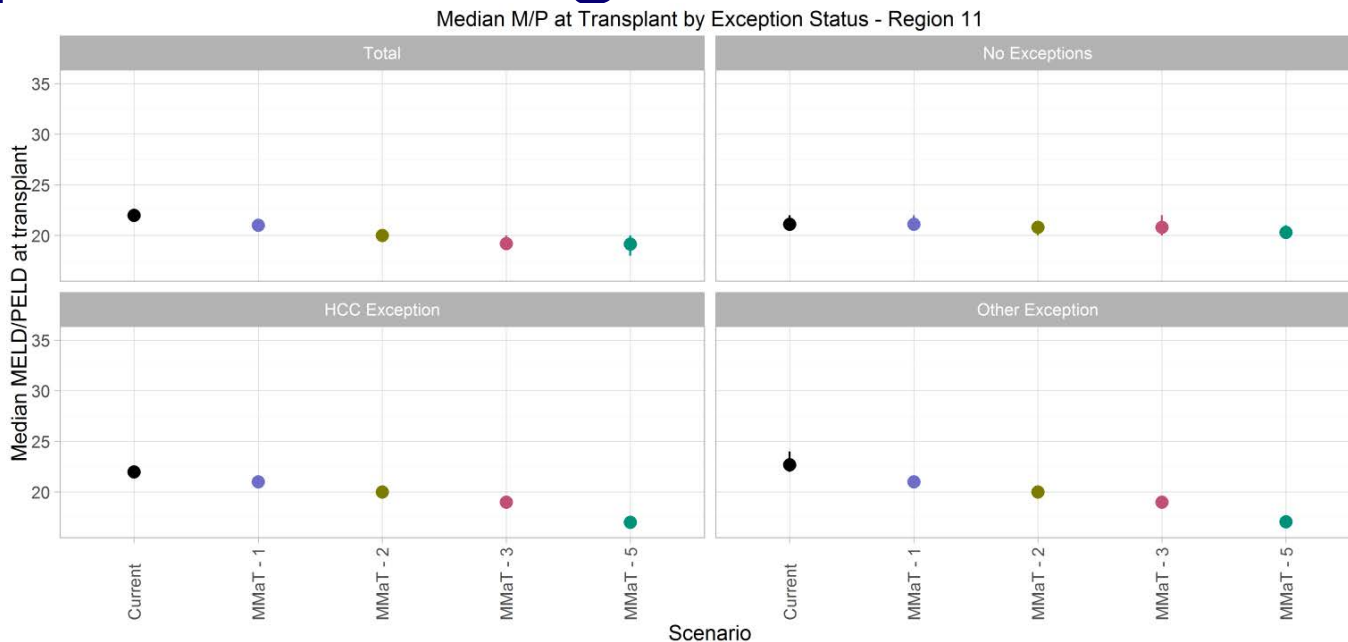
# Median MELD/PELD at transplant by exception status: region 9



# Median MELD/PELD at transplant by exception status: region 10

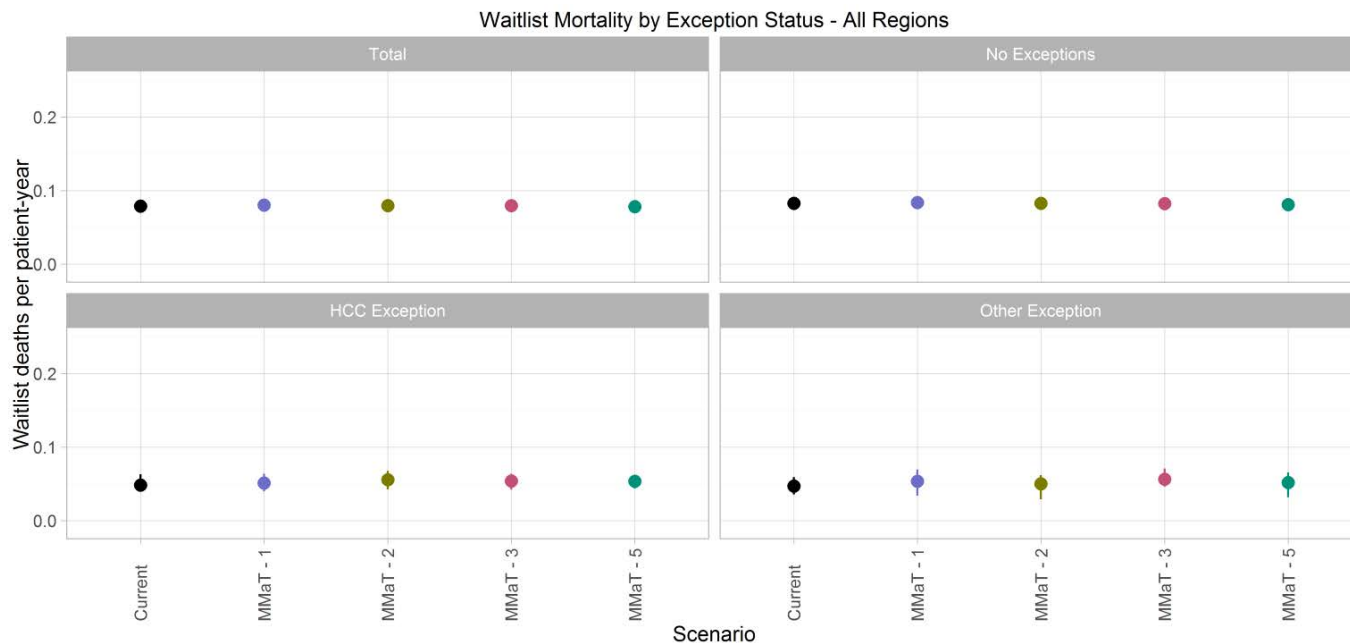


# Median MELD/PELD at transplant by exception status: region 11

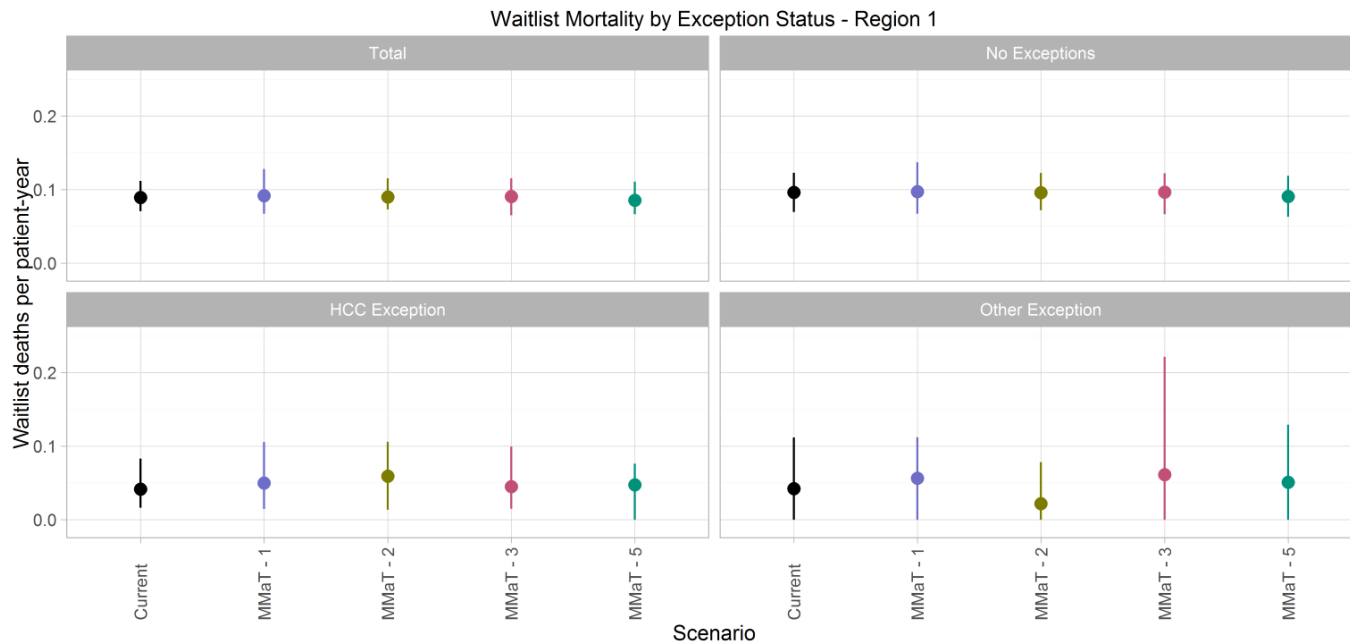


# Waitlist mortality by exception status

# Waitlist mortality by exception status: all regions



# Waitlist mortality by exception status: region 1

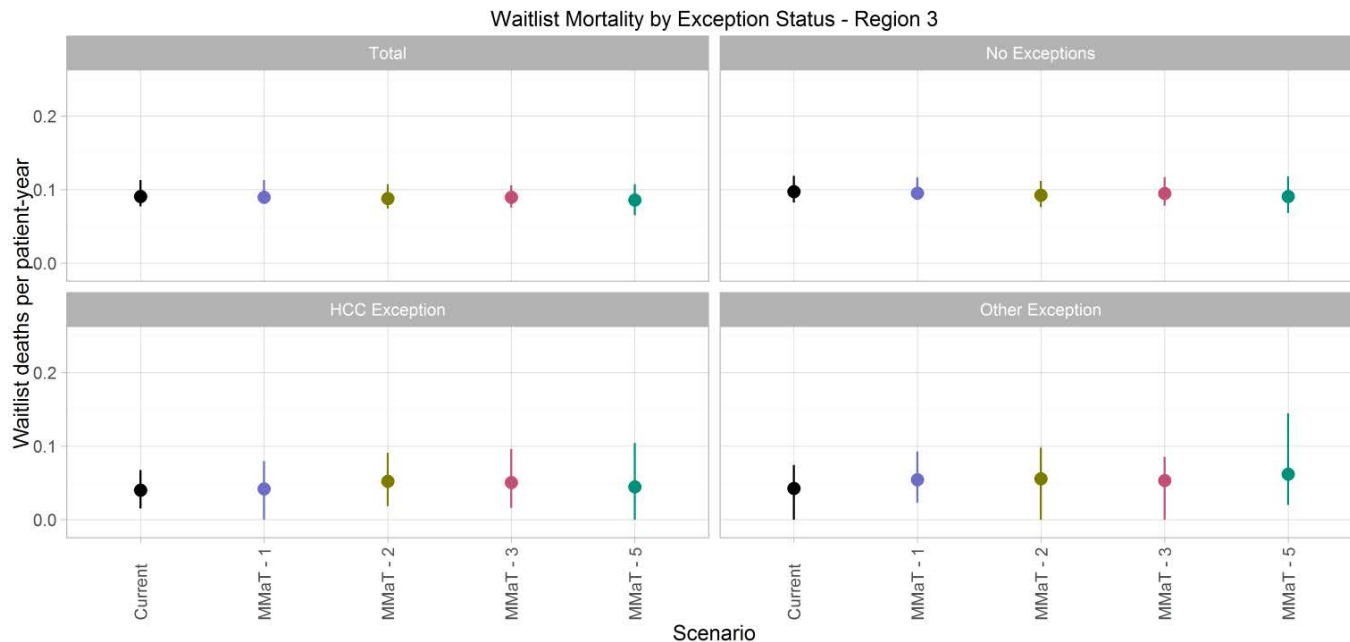


# Waitlist mortality by exception status: region 2





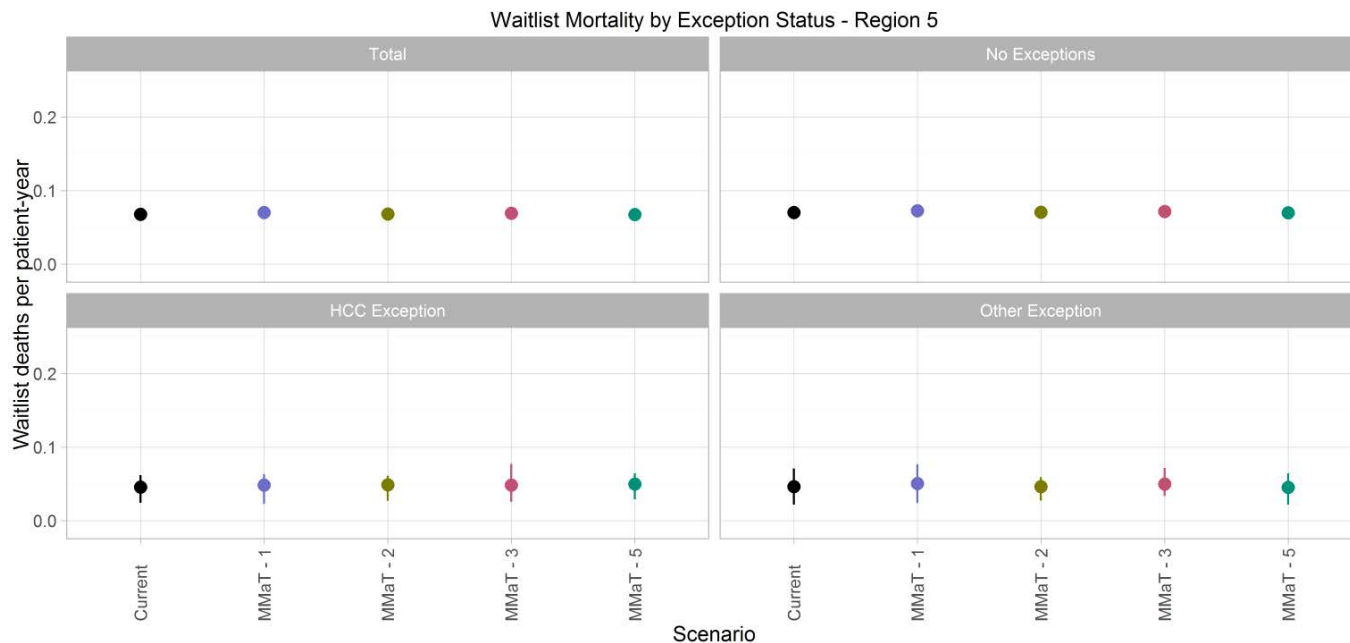
# Waitlist mortality by exception status: region 3



# Waitlist mortality by exception status: region 4



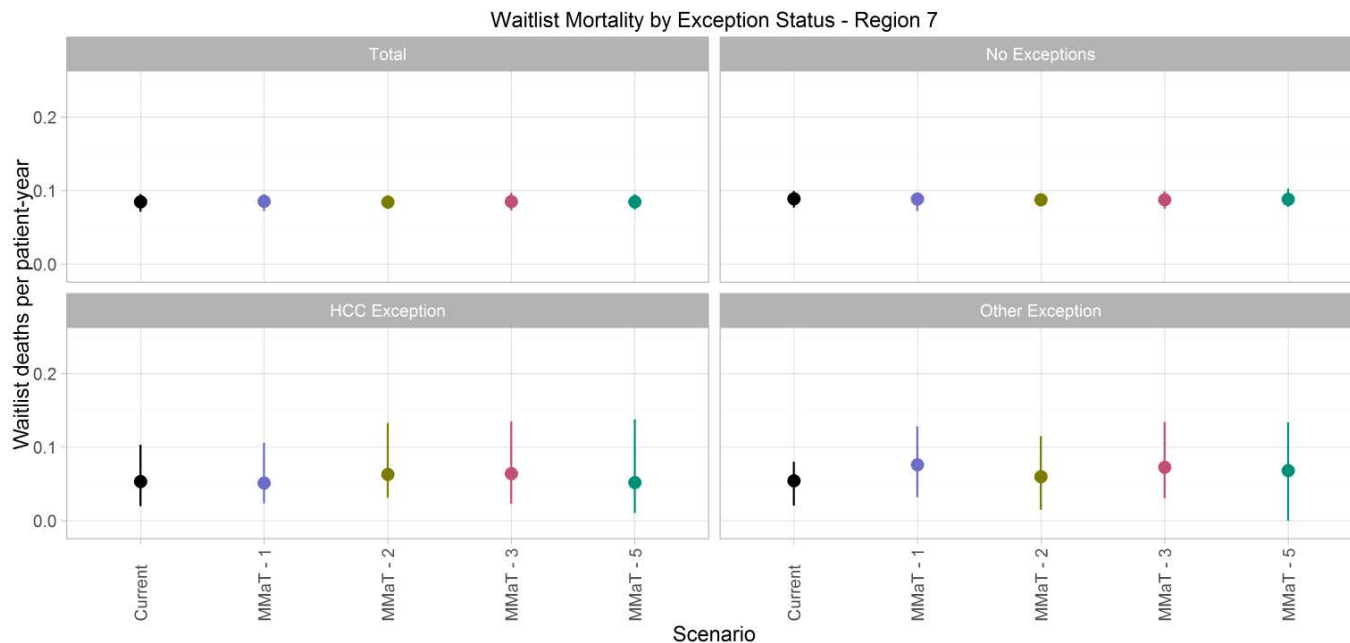
# Waitlist mortality by exception status: region 5



# Waitlist mortality by exception status: region 6



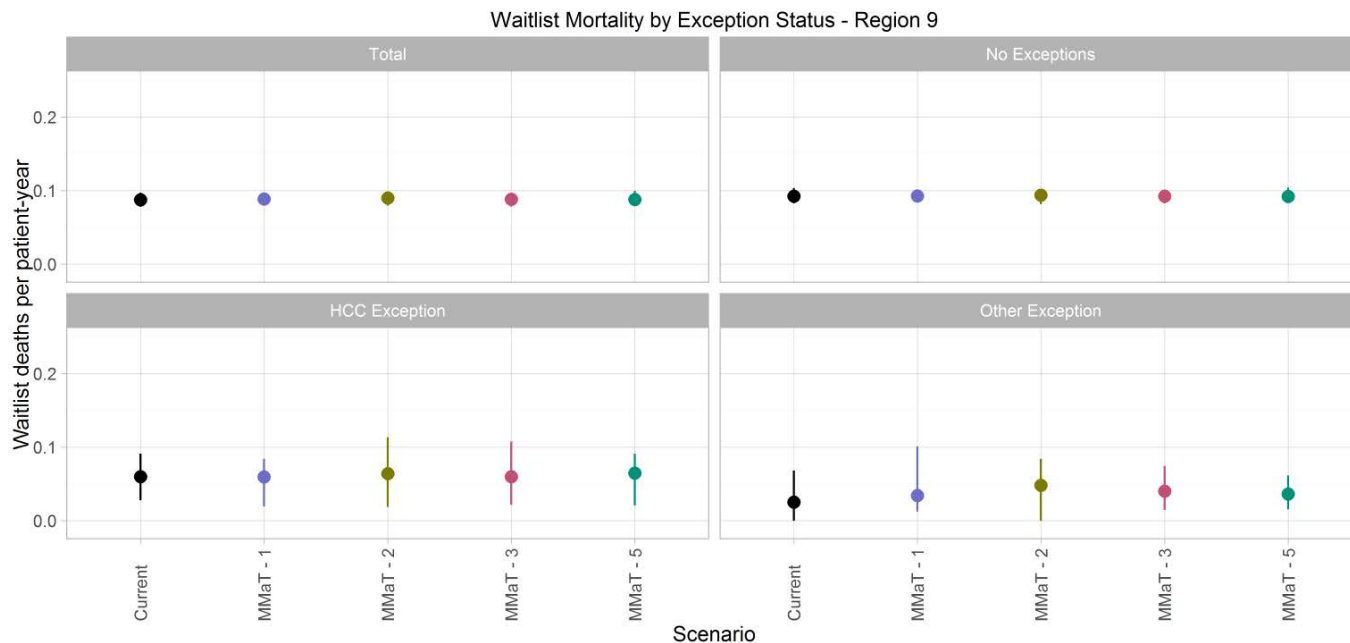
# Waitlist mortality by exception status: region 7



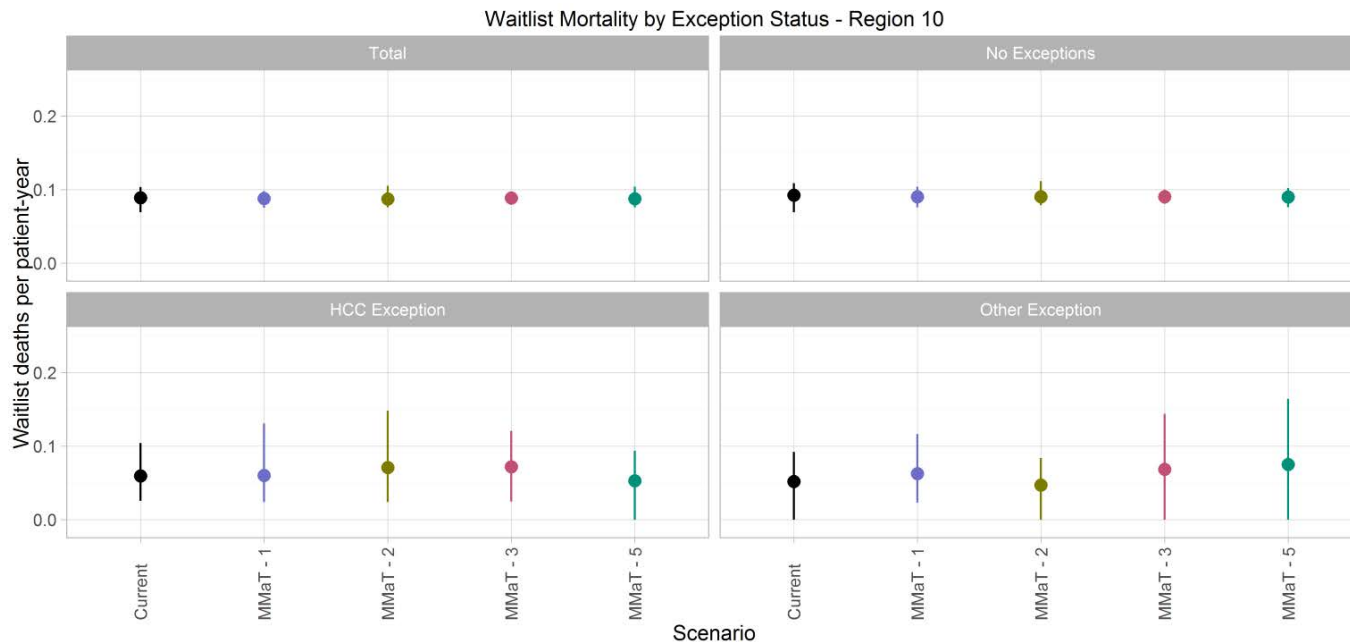
# Waitlist mortality by exception status: region 8



# Waitlist mortality by exception status: region 9



# Waitlist mortality by exception status: region 10





# Waitlist mortality by exception status: region 11

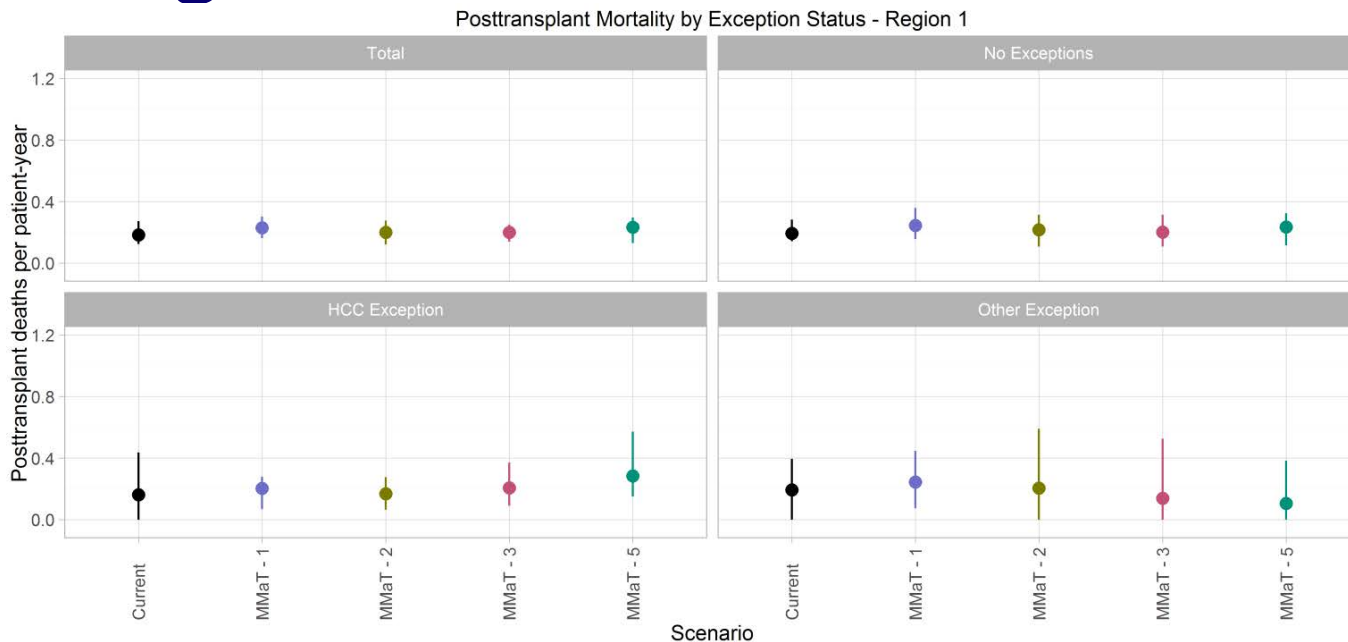


# Posttransplant mortality by exception status

# Posttransplant mortality by exception status: all regions



# Posttransplant mortality by exception status: region 1



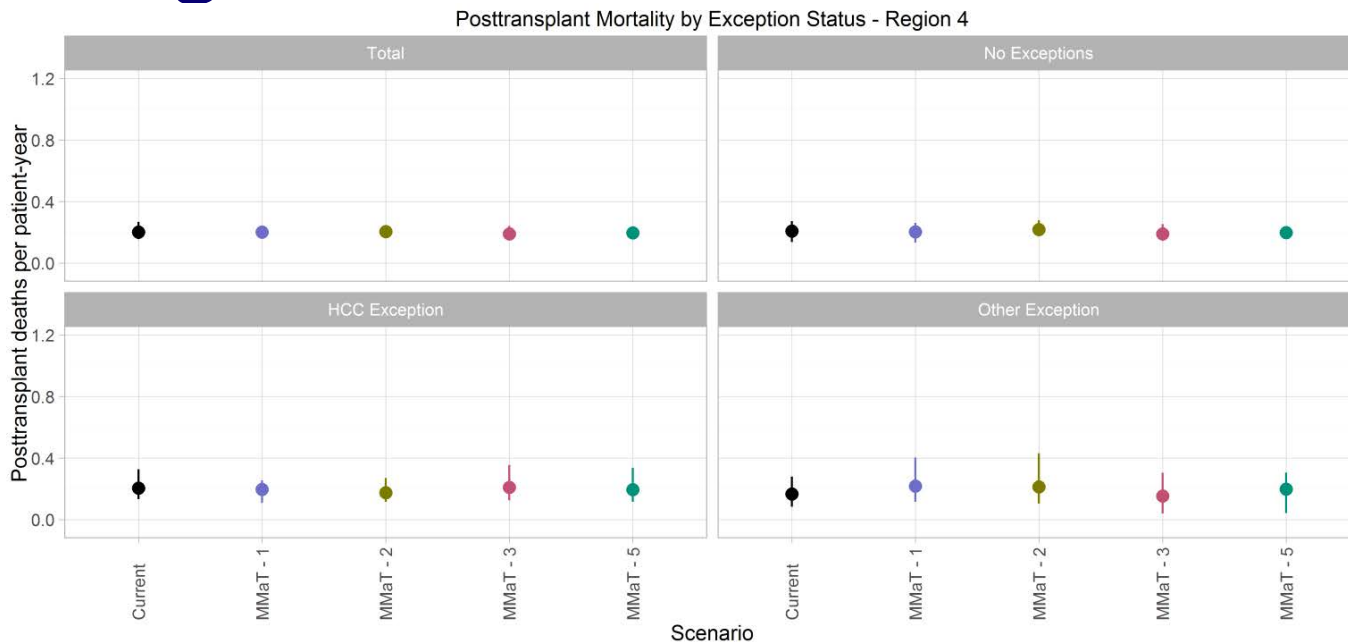
# Posttransplant mortality by exception status: region 2



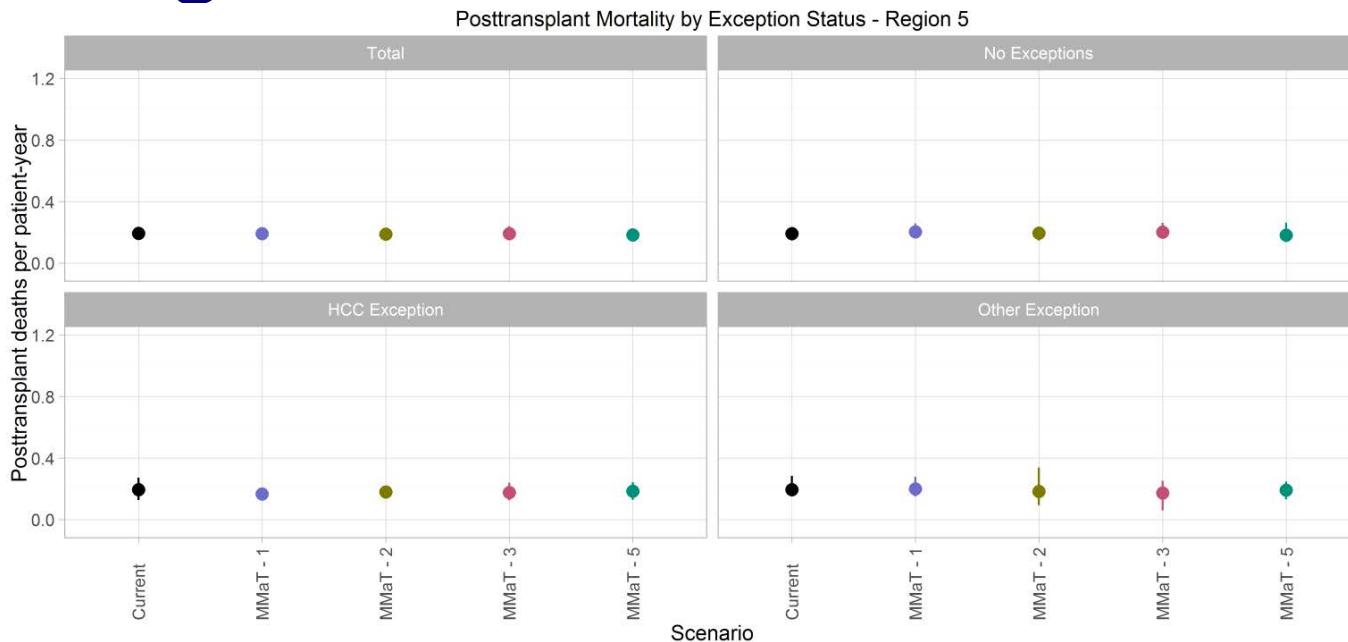
# Posttransplant mortality by exception status: region 3



# Posttransplant mortality by exception status: region 4

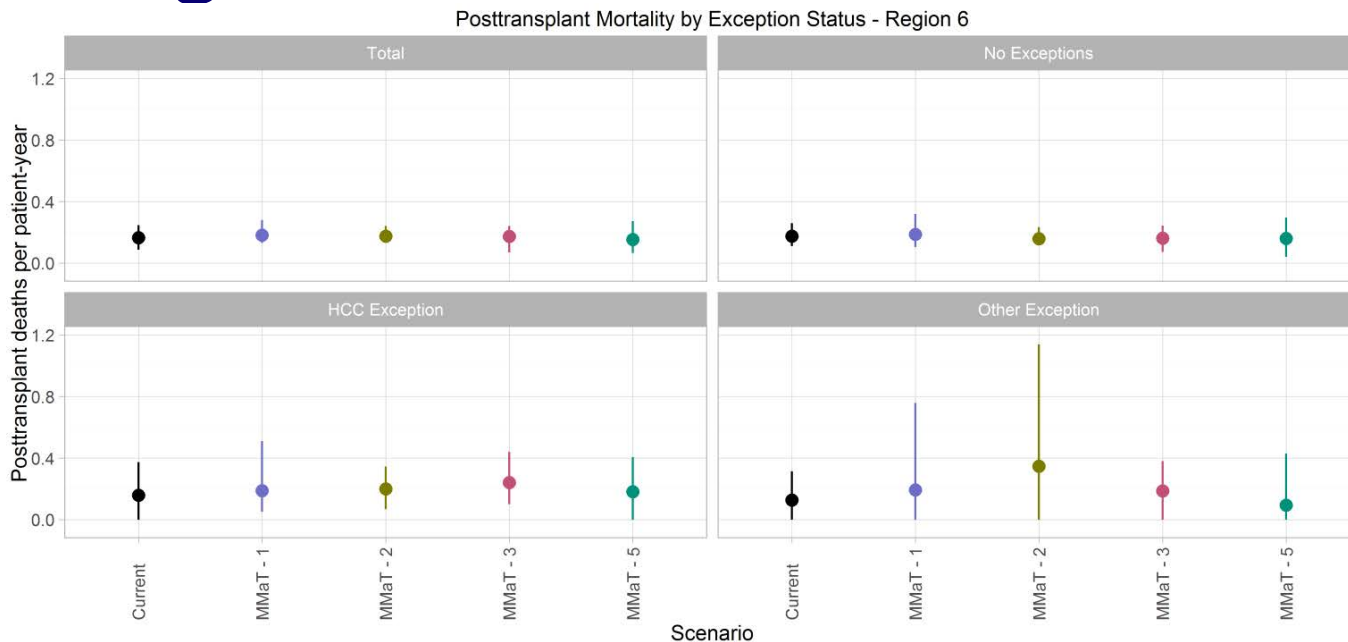


# Posttransplant mortality by exception status: region 5

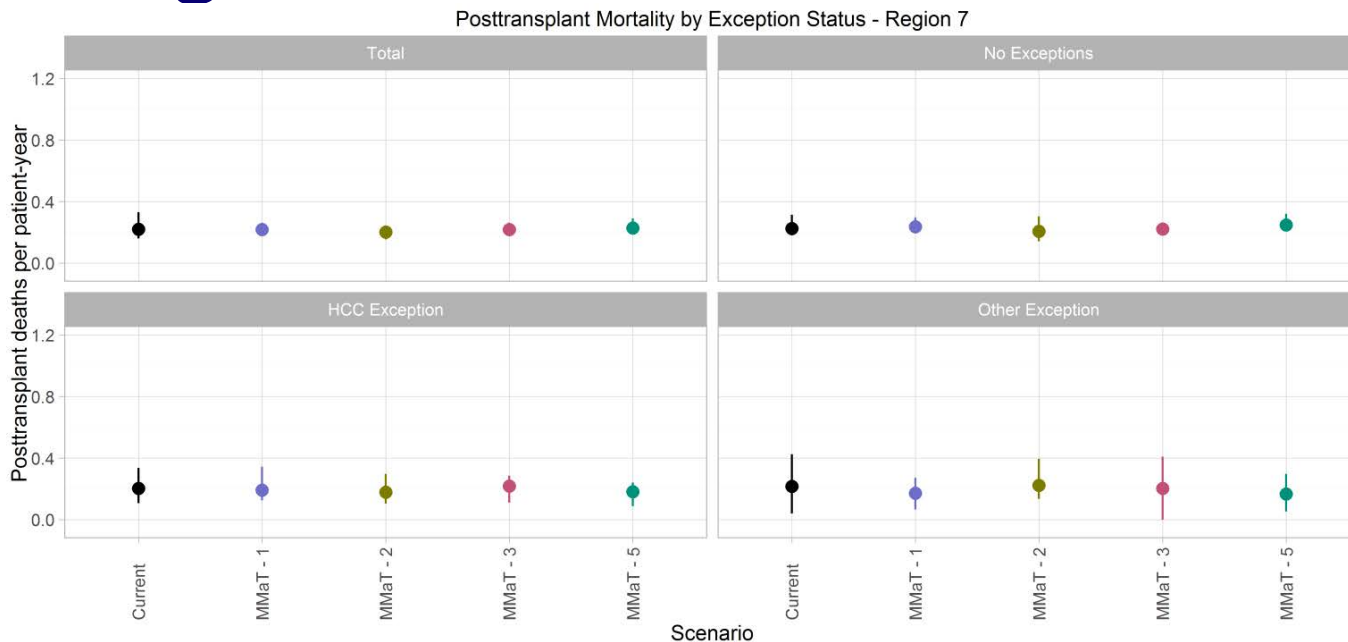




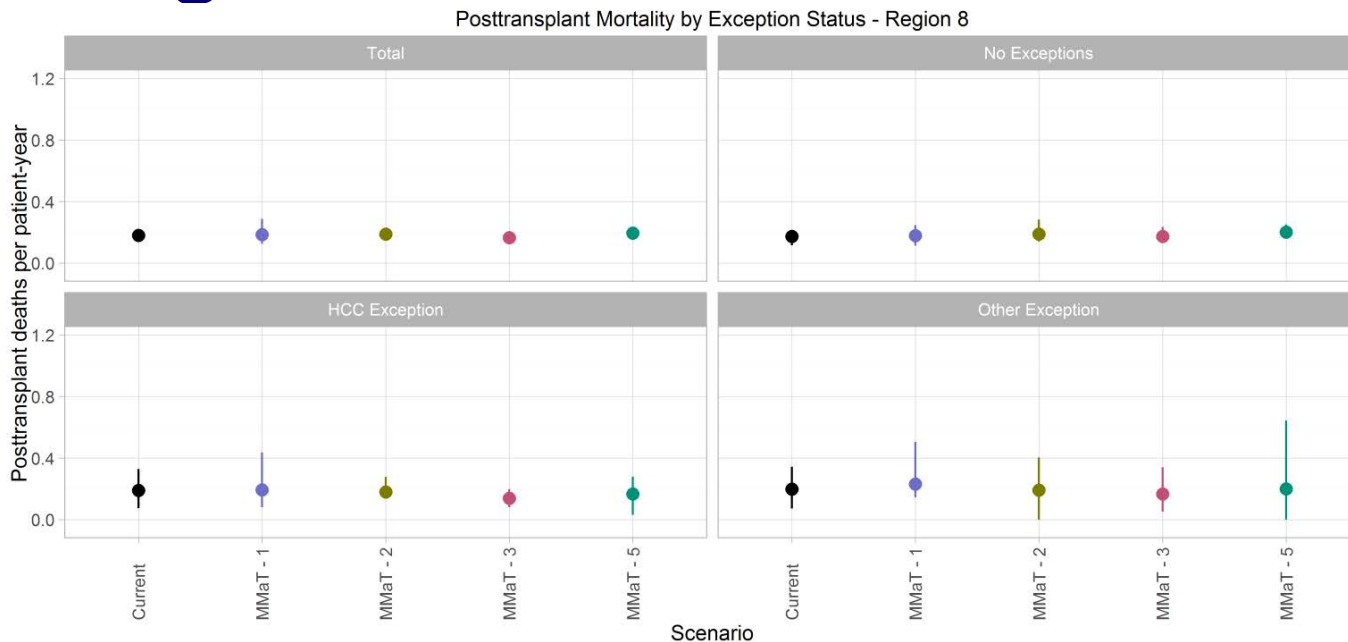
# Posttransplant mortality by exception status: region 6



# Posttransplant mortality by exception status: region 7



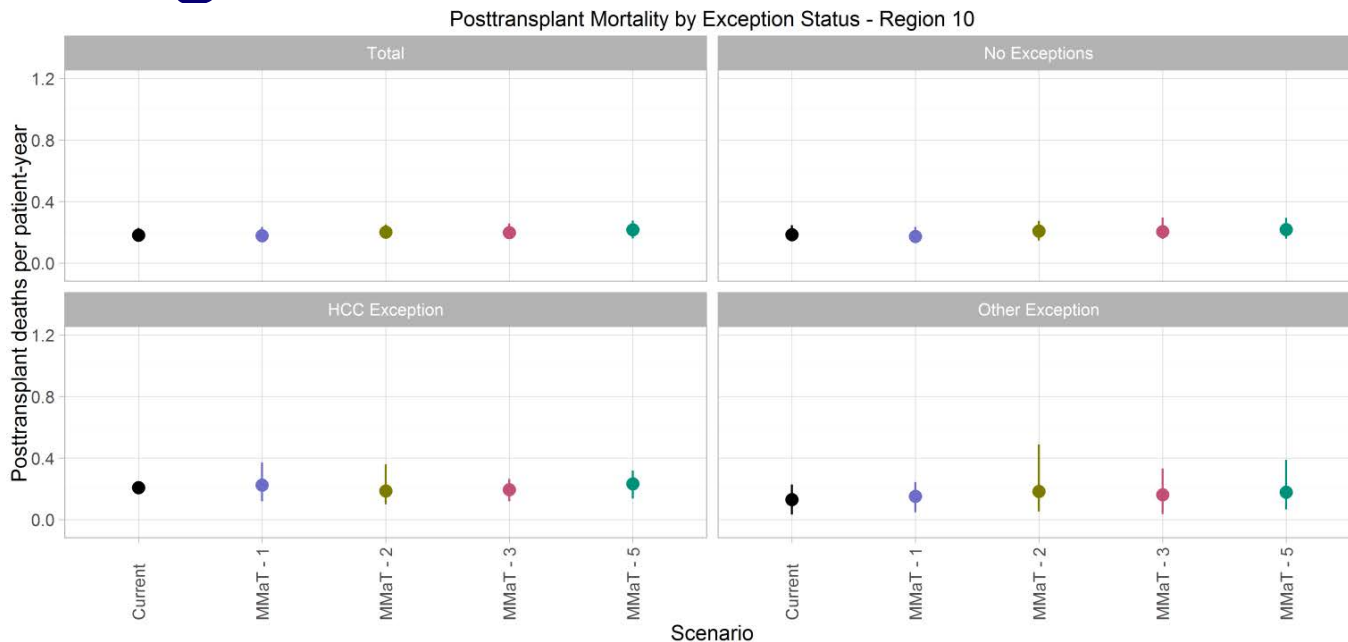
# Posttransplant mortality by exception status: region 8



# Posttransplant mortality by exception status: region 9



# Posttransplant mortality by exception status: region 10



# Posttransplant mortality by exception status: region 11

