Impact of extended 1A time for VADs on other heart transplantation candidates

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SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

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Disclosures

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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.

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Introduction

- Heart allocation policies remain under review in a quest to determine the most judicious algorithm.
- Since 2002, candidates with ventricular assist devices (VADs) have been afforded 30 days of elective medical urgency Status 1A time under OPTN policy 3.7.3 category 1A(a)(i).
- Only 22% of candidates with VADs undergo transplant during this period.

- **Goal**: to determine the impact of increased elective Status 1A time for candidates with VADs on outcomes for heart transplant candidates with and without VADs.

Methods

- Performed simulations using the thoracic simulated allocation modeling (TSAM) software and OPTN data
- Assessed the impact of extending the current policy awarding 30 days of Status 1A time for VADs to
  - 45 days
  - 60 days
  - 90 days
- Assessed transplant and mortality rates overall and for subgroups of interest, including
  - Candidates who used Status 1A time for other reasons: VAD complication, TAH, IABP, or ECMO
  - Status 1B candidates

TSAM process

Input real cohort of heart candidates waiting

July 1, 2009 – June 30, 2011

Extend the time VAD patients retain their elective Status 1A time by converting Status 1B time into Status 1A time using 3 scenarios: 45 days, 60 days, 90 days

For candidates transplanted in reality, “extend” waiting list time by appending data from similar candidates

Simulate match runs from July 1, 2009-June 30, 2011 based on new rules

Analyze outcomes

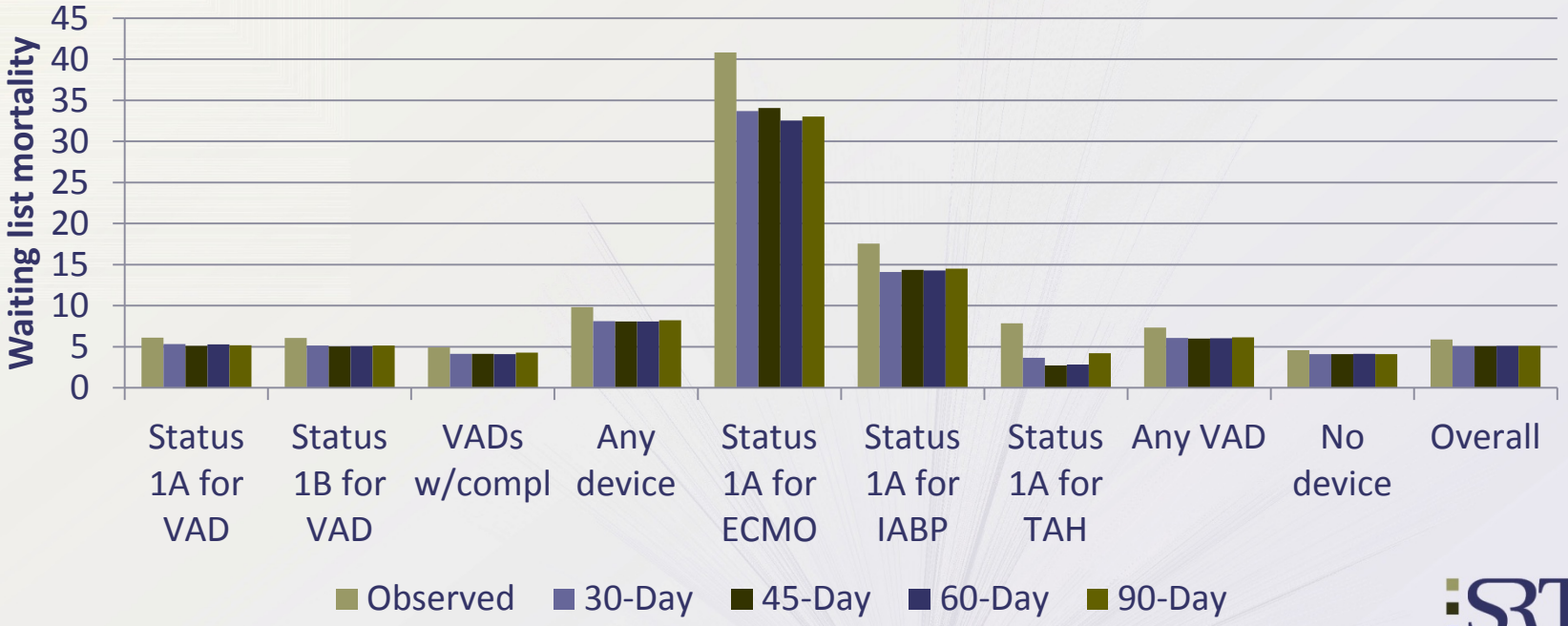
Limitation: TSAM cannot predict changes in listing and acceptance behavior

Study cohort

- Included 9,727 prevalent and new heart candidates on the waiting list between July 1, 2009, and June 30, 2011.
  - Mean age 45 years
  - 28% female
  - 18% had a VAD at listing
- During the cohort period
  - Nearly half were Status 1A
  - 15% used some Status 1A time for VAD
  - 6% used all of their Status 1A time for VAD
  - 7% died
  - 36% were transplanted

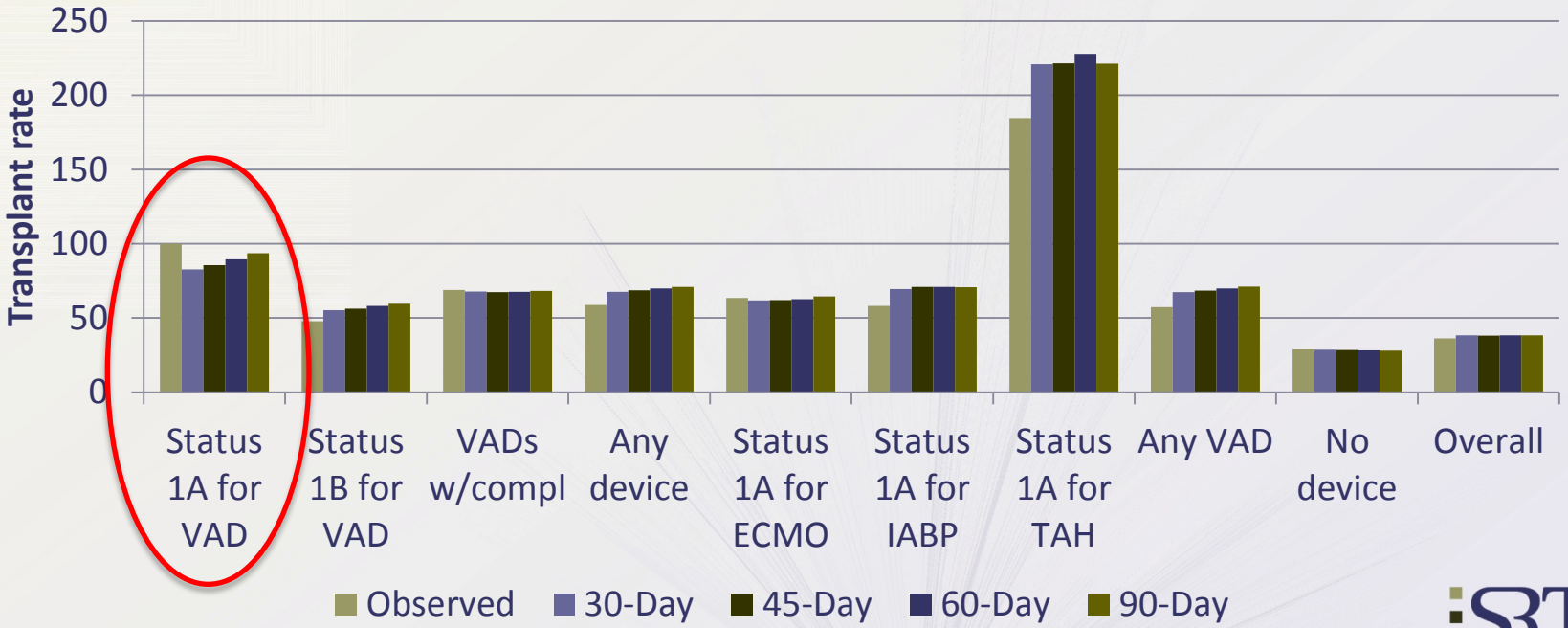
Results

- The simulations did not project a noticeable change in waiting list mortality



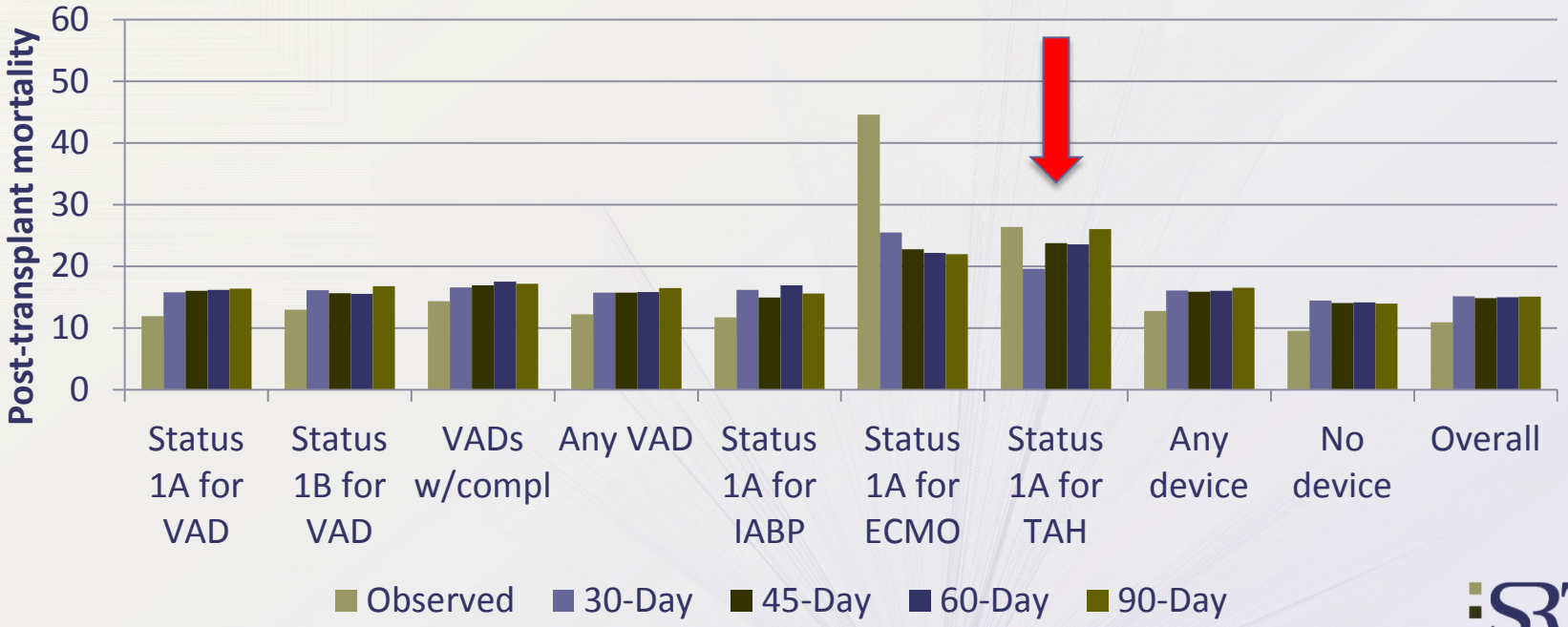
Results

- Transplant rates increased for candidates using Status 1A time for VAD
- No decrease in transplant rates for other groups



Results

- The simulations did not project a noticeable change in post-transplant mortality.

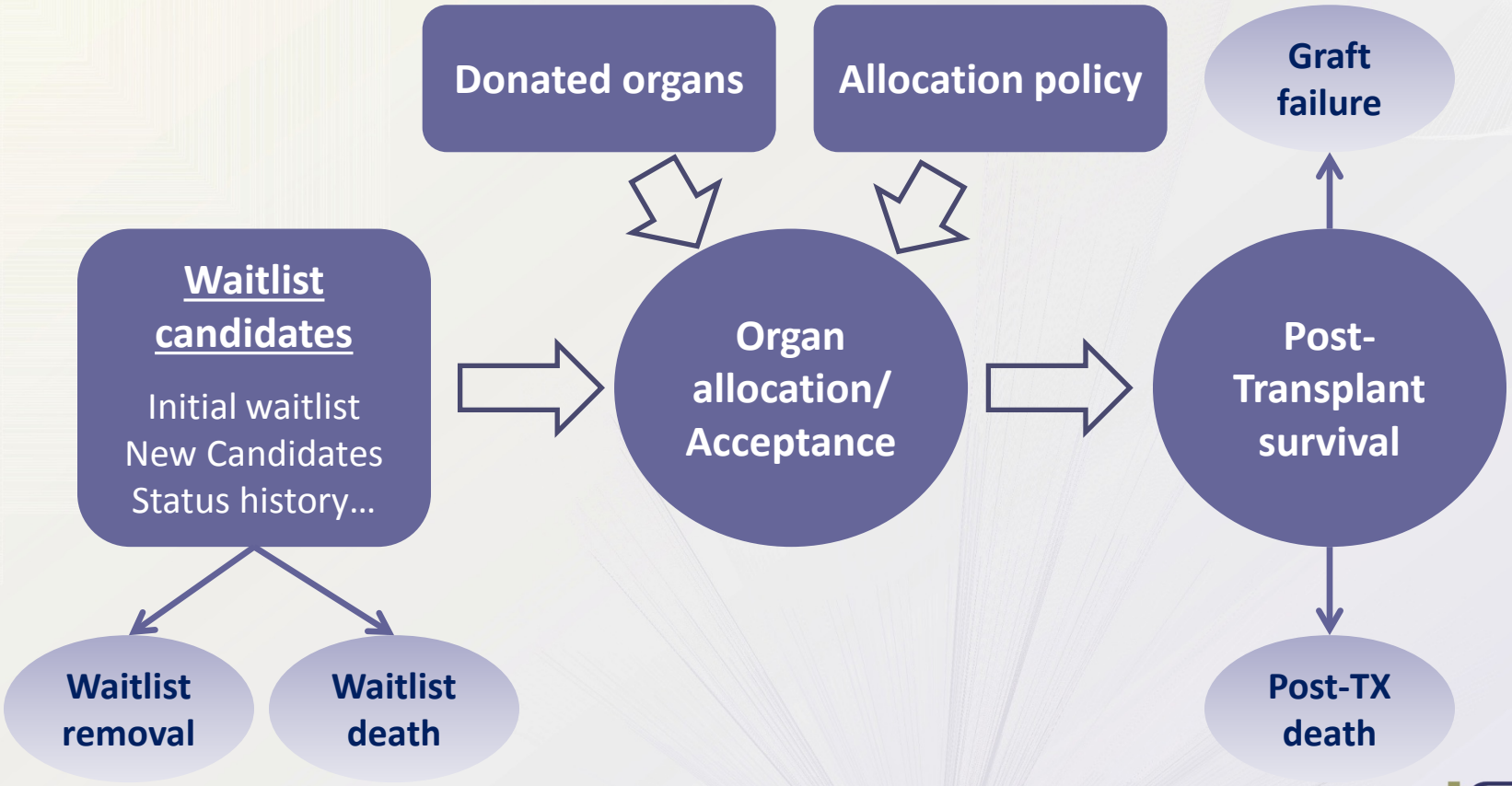


Conclusions

- TSAM simulations suggested that increasing the amount of elective Status 1A time to candidates with a VAD would improve access to transplant for those candidates.

- There was no evidence the policy change would negatively impact waiting list mortality, transplant rates, or post-transplant mortality for heart candidates and recipients as a whole or for candidates with:
  - Any VAD
  - VAD complications
  - TAH
  - IABP
  - ECMO
  - Status 1B

Allocation Modeling Flow Chart



Transplant Rates

	Observed	30-Day		45-Day		60-Day		90-Day	
Status	**Rate**	**Rate**	**Range**	**Rate**	**Range**	**Rate**	**Range**	**Rate**	**Range**
1A(a)(i): Stable VADs Status 1A	100.0	82.6	(80.9-83.4)	85.6	(83.7-87.9)	89.5	(86.8-91.3)	93.6	(91.1-96.2)
1B(a): Stable VADs Status 1B	47.8	55.2	(53.8-56.2)	56.2	(54.5-58.0)	58.1	(55.6-59.9)	59.5	(57.7-61.1)
1A(b): VADs w/complications	68.9	67.8	(63.8-70.7)	67.5	(64.7-69.7)	67.5	(63.4-70.4)	68.3	(65.0-71.4)
1A(a)(ii): TAH	184.6	221.0	(189.2-247.7)	221.5	(200.0-235.0)	228.0	(173.7-250.7)	221.3	(199.3-269.6)
1A(a)(iii): IABP	58.0	69.4	(67.7-73.1)	70.9	(67.2-73.7)	70.9	(68.1-73.4)	70.8	(68.8-72.9)
1A(a)(iv): ECMO	63.5	61.8	(56.0-69.0)	62.1	(55.8-68.8)	62.7	(57.2-67.8)	64.5	(59.2-70.9)
Any VAD	57.3	67.3	(66.3-68.2)	68.4	(67.0-69.6)	70.0	(67.4-71.2)	71.2	(69.9-72.2)
Any device	58.8	67.6	(66.7-68.2)	68.5	(67.1-69.4)	69.9	(67.9-71.0)	70.9	(69.7-71.6)
No device	28.8	28.7	(28.2-28.9)	28.3	(28.0-28.9)	28.1	(27.8-28.6)	27.9	(27.7-28.2)
Overall	36.3	38.3	(38.1-38.4)	38.2	(38.1-38.3)	38.3	(38.1-38.5)	38.3	(38.2-38.5)

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Posttransplant Death Rates

	Observed	30-Day		45-Day		60-Day		90-Day	
Status	**Rate**	**Rate**	**Range**	**Rate**	**Range**	**Rate**	**Range**	**Rate**	**Range**
1A(a)(i): Stable VADs Status 1A	11.9	15.8	(14.4-17.8)	16.0	(14.1-18.5)	16.2	(13.5-18.9)	16.4	(13.2-18.4)
1B(a): Stable VADs Status 1B	13.0	16.1	(15.0-18.4)	15.6	(13.5-17.8)	15.5	(13.9-17.7)	16.8	(15.5-19.0)
1A(b): VADs w/complications	14.4	16.6	(14.5-20.5)	16.9	(11.2-22.8)	17.5	(14.2-21.5)	17.2	(15.2-21.2)
1A(a)(ii): TAH	26.4	19.6	(7.6-31.3)	23.8	(9.8-37.4)	23.6	(9.8-36.1)	26.0	(13.0-39.1)
1A(a)(iii): IABP	11.7	16.2	(13.2-20.5)	14.9	(11.8-18.6)	16.9	(13.1-20.7)	15.6	(13.1-19.1)
1A(a)(iv): ECMO	44.6	25.5	(17.5-35.6)	22.8	(12.8-35.4)	22.2	(17.1-30.8)	22.0	(13.3-29.8)
Any VAD	12.2	15.7	(14.6-17.6)	15.7	(14.6-18.3)	15.8	(13.8-17.4)	16.5	(15.4-18.0)
Any device	12.8	16.1	(15.1-17.5)	15.9	(14.7-18.2)	16.0	(14.4-17.5)	16.5	(15.3-17.8)
No device	9.6	14.4	(13.4-15.7)	14.0	(12.2-16.3)	14.2	(12.8-15.7)	14.0	(12.7-15.7)
Overall	10.9	15.1	(14.2-16.1)	14.8	(13.7-16.2)	15.0	(13.6-16.2)	15.1	(14.1-16.0)

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