New UNOS Allocation System and Impact upon Cardiac Transplantation

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Advanced Heart Failure and Cardiac Transplant Program

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US Heart Allocation System

- 1989: 2-tiered local + 3 zone system
  - Status 1: ICU w/inotropes, mechanical circulatory support (MCS), or IABP
  - Status 2: all others
- 1999: 3-tiered urgency-based system
  - Status 1A: Early VAD mortality 5-10%/wk
  - Status 1B: Stable on home inotropes, stable LVAD
  - Status 2: Stable at home
- 2006: integrated pediatric transplants
  - Integration of geographical proximity
  - Utilizing ABO compatibility

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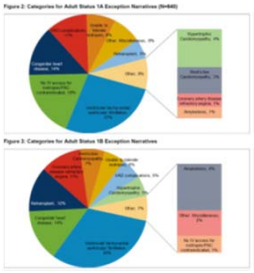
US Heart Allocation System

- Challenges
  - VAD morbidity/mortality evolving
    - No good predictive models for complications
    - VAD usage increased from 8.9% to 24.4%
  - Technology evolving, w/variable penetration
    - ECMO
    - Total Artificial Heart
  - Regional variability in wait times
    - Based on Donor Service Areas (DSA's), which were defined in the 1980's
    - March 2000 HHS Final Rule: "shall not be based on the candidate's place of residence or place of listing"
  - 67% of all transplants were being performed on status 1A's
  - Too many patients listed by exemption



OPTN/UNOS Proposal to Modify the Adult Heart Allocation System, p6

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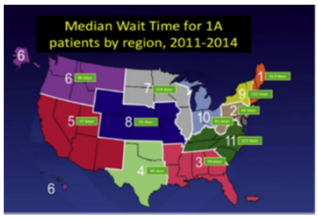
Wait times

- 162 percent increase in last decade
- Regional variability
  - Transplant center density
  - Population density
    - Donors and recipients
  - Cultural differences
  - Practice variability
    - Status based on treatment, not disease
- Sicker recipients
  - Older
  - Pre-sensitized
  - Retransplants



JACC HF 2017;5(12):862

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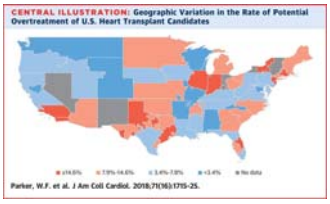
Overtreatment?



- Overtreatment defined as inotropic usage in pts absent hemodynamic criteria
- Odd of overtreatment 17.5x higher in top v. bottom quartile centers, and independent of patient factors
  - Exaggerated in competitive regions (New York, Chicago, LA)
  - Although trend, no better survival in higher quartile centers (p=0.08)

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Do Patients Supported With Continuous-flow Left Ventricular Assist Device Have a Sufficient Risk of Death to Justify a Priority Allocation? A Propensity Score Matched Analysis of Patients Listed in UNOS Status 2

Stefano Mastrobuoni, MD, MPH,[1] Angelo Maria Dell'Aquila, MD,[2] Olivier Van Caenegem, MD, PhD,[1] Alain Poncelet, MD, PhD,[1] Luc-Marie Jacquet, MD,[1] and José Garcia, MD[3]

Is it time for a cardiac allocation score? First results from the Eurotransplant pilot study on a survival benefit–based heart allocation

Jacqueline M. Smits, MD, PhD,[a] Erwin de Vries, MSc,[a] Michel De Pauw, MD, PhD,[b] Andreas Zuckermann, MD, PhD,[c] Axel Rahmel, MD,[d] Bruno Meiser, MD, PhD,[d] Guenther Laufer, MD, PhD,[c] Hermann Reichenspurner, MD, PhD,[d] and Martin Strueber, MD, PhD[e]

Towards a cardiac allocation score: a retrospective calculation for 73 patients from a German transplant center

Sebastian Claes[1], Michael Berchtold-Herz[2], Qian Zhou[1], Georg Trummer[2], Matthias Bock[3], Andreas Zirlik[1], Friedhelm Beyersdorf[2], Christoph Bode[1] and Sebastian Grundmann[1]*

Prediction of Waitlist Mortality in Adult Heart Transplant Candidates: The Candidate Risk Score

Carine Jasseron, MS, PhD,[1] Camille Legeai, MD,[1] Christian Jacquelinet, MD,[1] Pascal Leprince, MD,[2] Christelle Cantrelle, MS,[1] Benoît Audry, MS,[1] Raphael Porcher, PhD,[3] Olivier Bastien, MD,[1] and Richard Dorent, MD[2]

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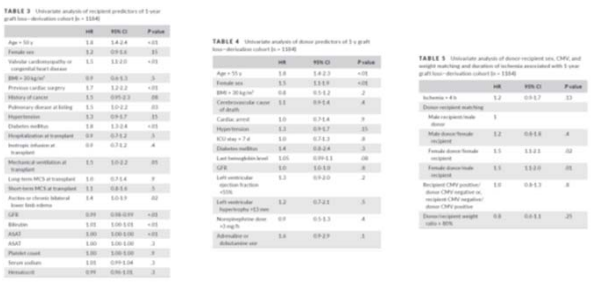

AJT. Dec 2019 (19):1509-10

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2018 Allocation system

- Subdivides status 1A and status 1B
  - Status 1A -> status 1,2,3
  - Status 1B -> status 4,5
  - Specific hemodynamic criteria defined
  - Only good for 14d
  - Renewal requires failure to wean
- Status 4
  - Hypertrophic and restrictive CMP
  - Retransplantation
  - Adult congenital heart disease
- Status 5
  - Combined organ transplant

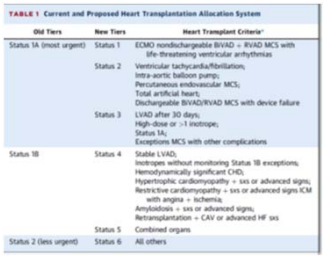

TABLE 1 Current and Proposed Heart Transplantation Allocation System

Old Tiers	New Tiers	Heart Transplant Criteria*
Status 1A (most urgent)	Status 1	ECMO nondischargeable BiVAD + RVAD MCS with life-threatening ventricular arrhythmias
	Status 2	Ventricular tachycardia/fibrillation; Intra-aortic balloon pump; Percutaneous endovascular MCS; Total artificial heart; Dischargeable BiVAD/RVAD MCS with device failure
	Status 3	LVAD after 30 days; High-dose or >1 inotrope; Status 1A; Exceptions MCS with other complications
Status 1B	Status 4	Stable LVAD; Inotropes without monitoring Status 1B exceptions; Hemodynamically significant CHD; Hypertrophic cardiomyopathy + sxs or advanced signs; Restrictive cardiomyopathy + sxs or advanced signs ICM with angina + ischemia; Amyloidosis + sxs or advanced signs; Retransplantation + CAV or advanced HF sxs
	Status 5	Combined organs
Status 2 (less urgent)	Status 6	All others

JACC HF 2017;5(12):906

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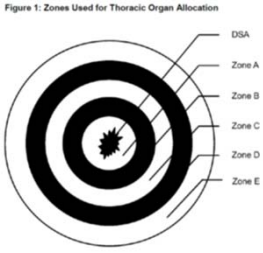
2018 Allocation system

- Mechanical circulatory support
  - VADs downgraded
  - ECMOs upgraded
- Broader organ sharing
  - Status 1 and 2 go out to Zone A (500 miles, now 250 miles)
  - Then, comes back to DSA for status 3 before going back out to Zone A



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2018 Allocation system

- <u>Pros</u>
  - Decreases geographic disparities
  - Recognizes changes in MCS outcomes
    - 80% VAD survival at 2 years
    - No improvement in ECMO outcomes
    - No improvement in percutaneous MCS
  - Recognizes disease previously requiring exemptions
    - Hypertrophic CMP
    - Restrictive CMP
    - Retransplant
    - Adult congenital heart disease
    - VT storm
    - Multiorgan transplant
- <u>Cons</u>
  - Short term support devices incentivized
    - More inpatient transplants?
    - Transplanting sicker patients?
  - Bias towards HFrEF
  - Highly-sensitized patients not addressed
  - Broader sharing = longer ischemic times

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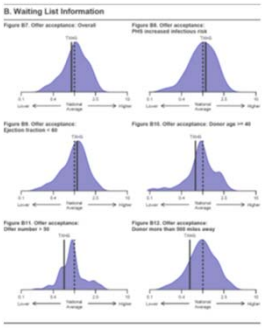
- Effects on recipients
  - 85% of transplants now on inpatients
  - Sicker recipients
- Effects on donor hearts
  - Ischemic times increased
  - More compromised donors
- Effects on transplant centers
  - Outcomes
  - "Robin Hood" effect
- Effect on communities?
  - Fewer transplant centers?
  - Fewer candidates due to distance?



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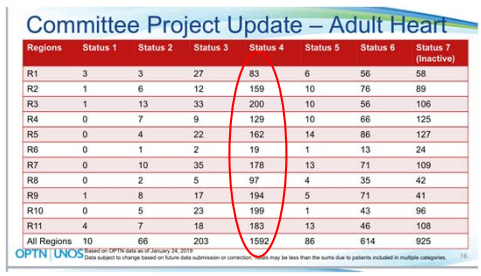
Challenges



Committee Project Update – Adult Heart

Regions	Status 1	Status 2	Status 3	Status 4	Status 5	Status 6	Status 7 (Inactive)
R1	3	3	27	83	6	56	58
R2	1	6	12	159	10	76	89
R3	1	13	33	200	10	56	106
R4	0	7	9	129	10	66	125
R5	0	4	22	162	14	86	127
R6	0	1	2	19	1	13	24
R7	0	10	35	178	13	71	109
R8	0	2	5	97	4	35	42
R9	1	8	17	194	5	71	41
R10	0	5	23	199	1	43	96
R11	4	7	18	183	13	46	108
All Regions	10	66	203	1592	86	614	925

OPTN | UNOS Based on OPTN data as of January 24, 2019. Data subject to change based on future data submission or corrections. Totals may be less than the sums due to patients included in multiple categories.

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Challenges

Committee Project Update – Adult Heart

Regions	Status 1	Status 2	Status 3	Status 4	Status 5	Status 6
R1	3	13	11	10	1	1
R2	2	24	11	10	0	2
R3	3	24	13	12	0	2
R4	4	27	15	9	0	0
R5	6	24	31	18	0	9
R6	0	6	6	6	0	4
R7	6	27	11	7	0	0
R8	2	18	4	6	0	1
R9	4	16	17	7	0	0
R10	5	20	9	8	0	0
R11	11	25	25	12	0	3
All Regions	46	224	153	105	1	22

OPTN | UNOS Data subject to change based on future data submission or correction. Totals may be less than the sums due to patients included in multiple categories. 17

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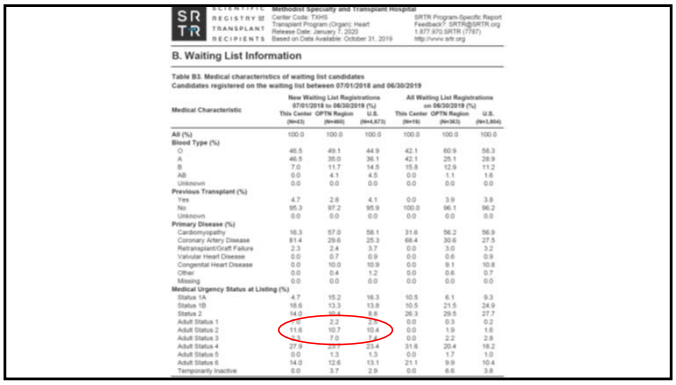

SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Methodist Specialty and Transplant Hospital
Center Code: TXHS
Transplant Program (Organ): Heart
Release Date: January 7, 2020
Based on Data Available: October 31, 2019

SRTR Program-Specific Report
Feedback? SRTR@SRTR.org
1.877.970.SRTR (7787)
http://www.srtr.org

B. Waiting List Information

Table B3. Medical characteristics of waiting list candidates
Candidates registered on the waiting list between 07/01/2018 and 06/30/2019

Medical Characteristic	New Waiting List Registrations 07/01/2018 to 06/30/2019 (%) This Center (N=43)	OPTN Region (N=455)	U.S. (N=4,873)	All Waiting List Registrations on 06/30/2019 (%) This Center (N=19)	OPTN Region (N=363)	U.S. (N=3,904)
All (%)	100.0	100.0	100.0	100.0	100.0	100.0
Blood Type (%)						
O	46.5	49.1	44.9	42.1	60.9	58.3
A	46.5	35.0	36.1	42.1	25.1	28.9
B	7.0	11.7	14.5	15.8	12.9	11.2
AB	0.0	4.1	4.5	0.0	1.1	1.6
Unknown	0.0	0.0	0.0	0.0	0.0	0.0
Previous Transplant (%)						
Yes	4.7	2.8	4.1	0.0	3.9	3.8
No	95.3	97.2	95.9	100.0	96.1	96.2
Unknown	0.0	0.0	0.0	0.0	0.0	0.0
Primary Disease (%)						
Cardiomyopathy	16.3	57.0	58.1	31.6	56.2	56.9
Coronary Artery Disease	81.4	29.6	25.3	68.4	30.6	27.5
Retransplant/Graft Failure	2.3	2.4	3.7	0.0	3.0	3.2
Valvular Heart Disease	0.0	0.7	0.9	0.0	0.6	0.9
Congenital Heart Disease	0.0	10.0	10.9	0.0	9.1	10.8
Other	0.0	0.4	1.2	0.0	0.6	0.7
Missing	0.0	0.0	0.0	0.0	0.0	0.0
Medical Urgency Status at Listing (%)						
Status 1A	4.7	15.2	16.3	10.5	6.1	9.3
Status 1B	16.6	13.3	13.8	10.5	21.5	24.9
Status 2	14.0	16.4	8.6	26.3	29.5	27.7
Adult Status 1	[illegible]	2.2	[illegible]	0.0	0.3	0.2
Adult Status 2	11.6	10.7	10.4	0.0	1.9	1.6
Adult Status 3	[illegible]	7.0	[illegible]	0.0	2.2	2.9
Adult Status 4	27.9	20.7	23.4	31.6	20.4	18.2
Adult Status 5	0.0	1.3	1.3	0.0	1.7	1.0
Adult Status 6	14.0	12.6	13.1	21.1	9.9	10.4
Temporarily Inactive	0.0	3.7	2.9	0.0	6.6	3.8

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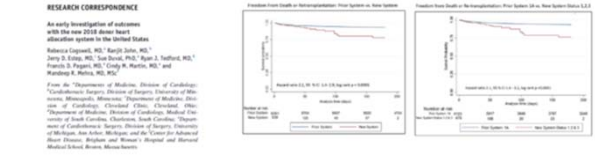
Challenges



RESEARCH CORRESPONDENCE

An early investigation of outcomes with the new 2018 donor heart allocation system in the United States

Looked at first 3 quarters since institution of new heart allocation system (Oct 2018 – Jun 2019)
90d survival rate 87.6% v. 94.5%, p<0.0001
180d survival rate 77.9% v. 93.4%, p < 0.0001
1yr hazard ratio for death or retransplantation 2.1, CI 1.5-3.0, p<0.0001

JHLT 2020;39(1):3

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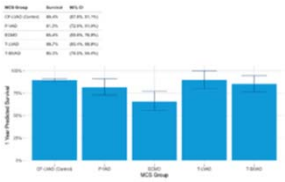
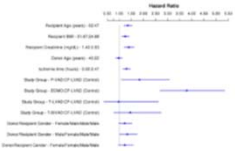
MK3

Challenges





1yr survival post-txp
ECMO 71.2%
p-VAD 79.9%
CF-LVAD 89.6%
No difference in acute rejection, CMV, AKI

Yin. JHLT Aug 2019;38(8):858-69

Bridging w/ECMO and P-VAD independent risk factors for 1yr mortality by multivariate analysis

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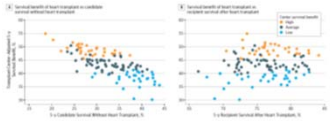
Challenges



Parker. JAMA Nov 2019;332(18):1789-98
29,199 candidate between 2006—15, 68% transplanted, 27% died or re-txp
High-survival centers performed transplant on those w/lower estimated survival w/o transplant (29%) than low-survival centers (39%)
High-survival centers used 1A therapies less (50%) than low-survival centers (63%), and less likely to perform txp in those w/o cardiogenic shock or use IABP or high-dose pressors (25% v. 31%), and less likely to use device-related complications exemption (20% v. 37%)
No significant difference in mean survival duration after transplant

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Challenges

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Slide 16

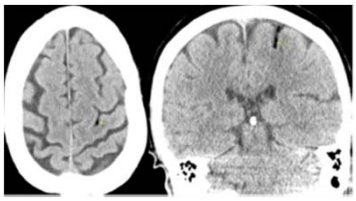
MK3 Michael Kwan, 2/16/2020

Challenges

Axillary intraaortic balloon pump rupture and cerebral embolism because of helium leak

Adam H. Obaidi, MD,[a] Chandra Kunavarapu, MD,[b] and Michael Kwan, MD[b]

From the [a]Department of Cardiovascular Disease, San Antonio Military Medical Center, Fort Sam Houston, Texas; and the [b]Advanced Heart Failure Program, Methodist Hospital, San Antonio, Texas.



JHLT Oct 2019: 38(10):1122-23

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Meeting the challenge

- Increase donation
  - Public service messages
  - Donor registries
  - Automated notification of OPOs
- Ongoing evolution of VAD therapy
  - Approaching equipoise w/transplant
- Reassessment
  - Allocation system to be reassessed
  - Intermediate step towards Cardiac Allocation Score?
- TransMedics Organ Care System®
  - PROCEED II Lancet Jun 2015;385(9987): 2577-84
    - Non-inferiority in 130 pts, 10 countries
- Donation after Circulatory Death
  - Traditionally, cardiac donation after brain death
  - Used in non-thoracic organs
  - *Ex vivo* perfusion may allow consideration
  - Regulatory (Germany, US) and logistical limitations
- ABO incompatible transplants
  - Precedence w/abdominal transplants
  - Bergenfeldt. JHLT Jul 2015;34:892-98
    - Higher 1 yr death rate, but censored survival beyond 1 yr comparable

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Hepatitis C donors

- Efficacy of direct-acting antiviral agents
- Younger donors
- Shorter waiting times (78d v. 329d)
- DONATE HCV-Trial: NEJM Apr 2019;380:1606-17
  - 36 lungs, 8 hearts
    - 42/44 w/immediate seroconversion
  - Early seroconversion, but excellent graft/patient survival after DAAV x 4 wks
    - 43% v. 33% ACR, OR 0.68 (CI 0.07-7.06)
    - 100% v. 83% survival, OR 0 (CI 0-9.25)
  - Only 1 post-txp death @ 8 mos from bacterial infection
  - No adverse safety issues identified
  - Shorter waiting times, shorter hospitalization v. non-HCV donors

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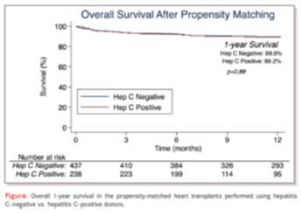
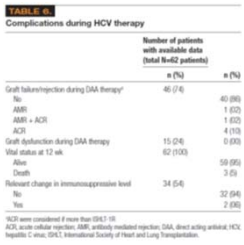
Hepatitis C donors



JAHA. Jan 2020;9(2):6



Transplantation. Sep 2019;5(9):e486

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Hepatitis C donors

- Dr Robert Montgomery
  - Director, NYU Langone Transplant Center
  - Pioneer in domino kidney transplant
- Familial CMP
  - ICD @ 29 y/o
  - Listed Sep 2018
  - VT storm Aug 2019
  - OHT 9/20/19
    - 4d waiting
  - Back to work after 2 mos

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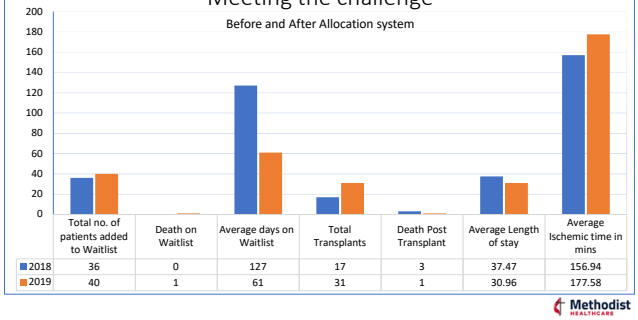
Meeting the challenge

Before and After Allocation system



	Total no. of patients added to Waitlist	Death on Waitlist	Average days on Waitlist	Total Transplants	Death Post Transplant	Average Length of stay	Average Ischemic time in mins
2018	36	0	127	17	3	37.47	156.94
2019	40	1	61	31	1	30.96	177.58

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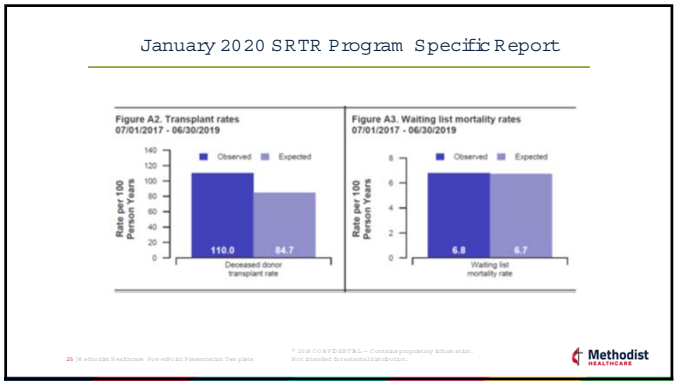

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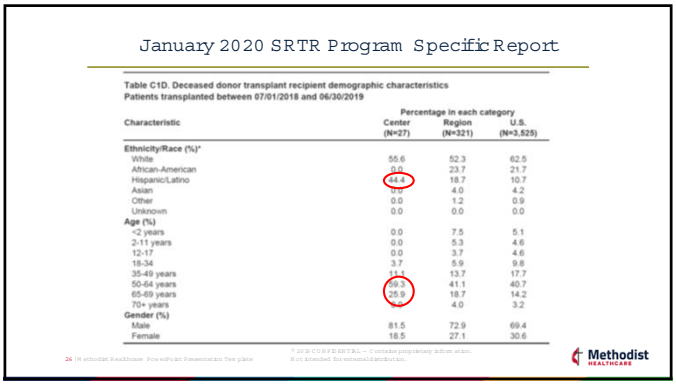

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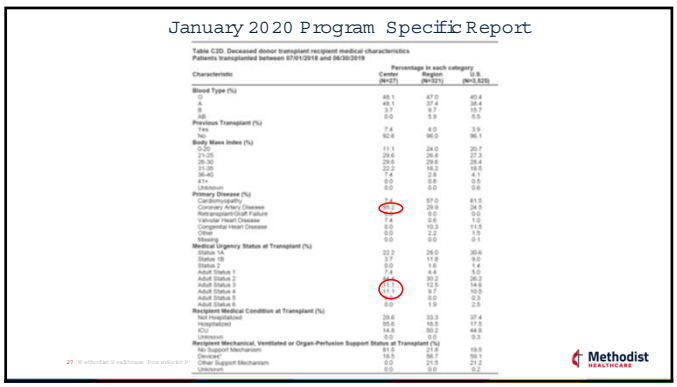

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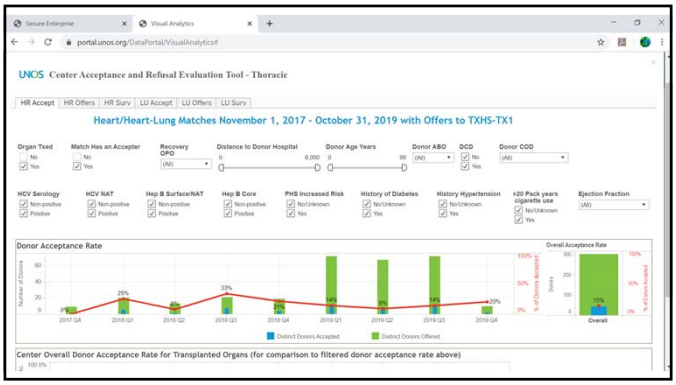

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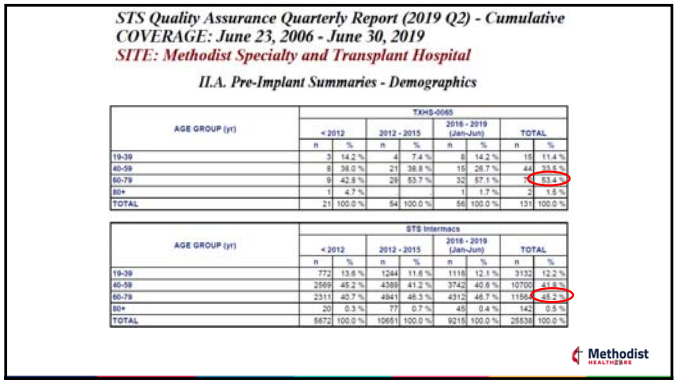

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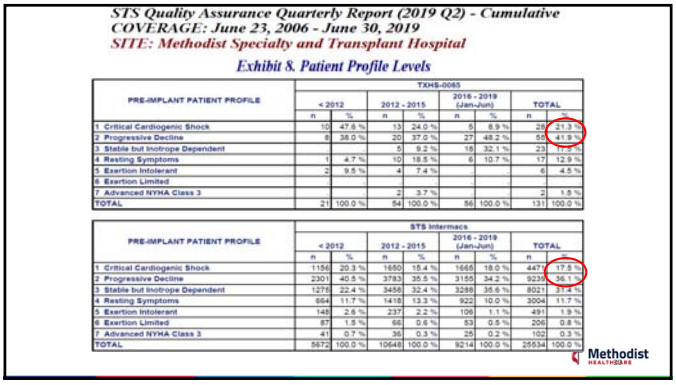

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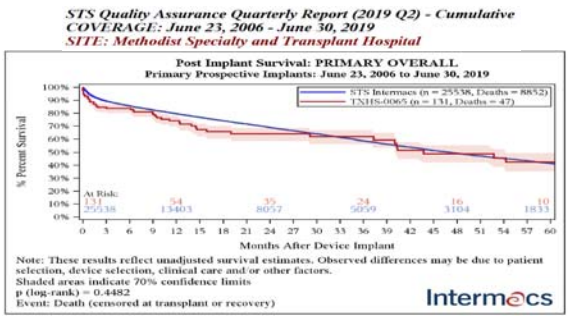
STS Quality Assurance Quarterly Report (2019 Q2) - Cumulative
COVERAGE: June 23, 2006 - June 30, 2019
SITE: Methodist Specialty and Transplant Hospital
Post Implant Survival: PRIMARY OVERALL
Primary Prospective Implants: June 23, 2006 to June 30, 2019
STS Intermacs (n = 25538, Deaths = 8852)
TXHS-0065 (n = 131, Deaths = 47)
% Percent Survival
At Risk:
131 54 35 24 16 10
25538 13403 8057 5059 3104 1833
Months After Device Implant
Note: These results reflect unadjusted survival estimates. Observed differences may be due to patient selection, device selection, clinical care and or other factors.
Shaded areas indicate 70% confidence limits
p (log-rank) = 0.4482
Event: Death (censored at transplant or recovery)
Intermacs
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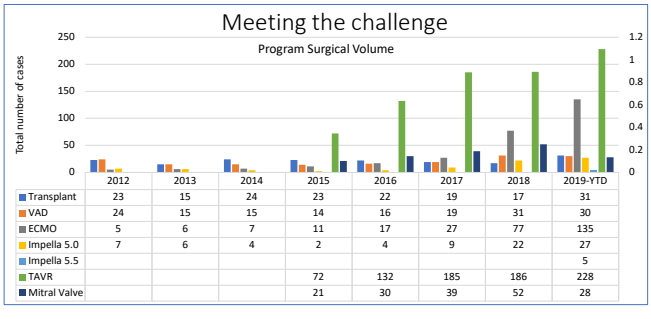
Meeting the challenge
Program Surgical Volume
Total number of cases
2012 2013 2014 2015 2016 2017 2018 2019-YTD
Transplant 23 15 24 23 22 19 17 31
VAD 24 15 15 14 16 19 31 30
ECMO 5 6 7 11 17 27 77 135
Impella 5.0 7 6 4 2 4 9 22 27
Impella 5.5 5
TAVR 72 132 185 186 228
Mitral Valve 21 30 39 52 28
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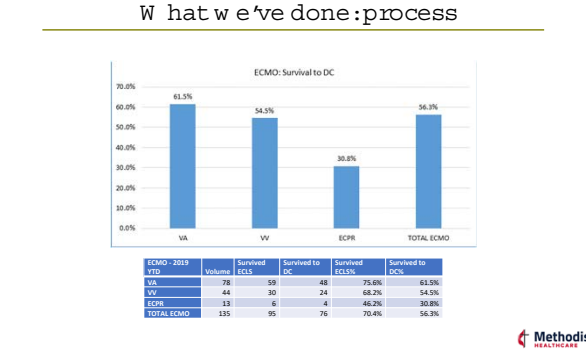
What we've done: process
ECMO: Survival to DC
61.5%
54.5%
30.8%
56.3%
VA
VV
ECPR
TOTAL ECMO
ECMO - 2019 YTD | Volume | Survived ECLS | Survived to DC | Survived ECLS% | Survived to DC%
VA 78 59 48 75.6% 61.5%
VV 44 30 24 68.2% 54.5%
ECPR 13 6 4 46.2% 30.8%
TOTAL ECMO 135 95 76 70.4% 56.3%
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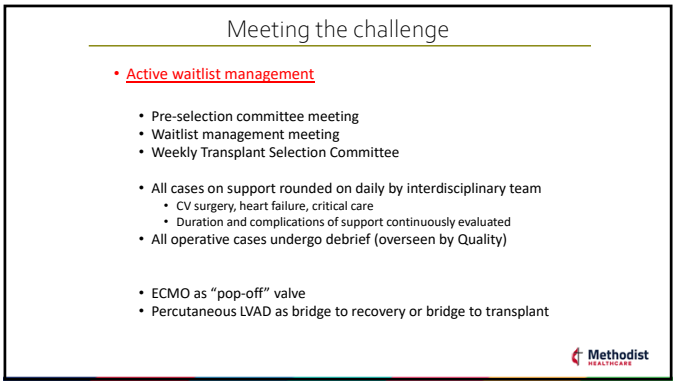
Meeting the challenge
Active waitlist management
Pre-selection committee meeting
Waitlist management meeting
Weekly Transplant Selection Committee
All cases on support rounded on daily by interdisciplinary team
CV surgery, heart failure, critical care
Duration and complications of support continuously evaluated
All operative cases undergo debrief (overseen by Quality)
ECMO as "pop-off" valve
Percutaneous LVAD as bridge to recovery or bridge to transplant
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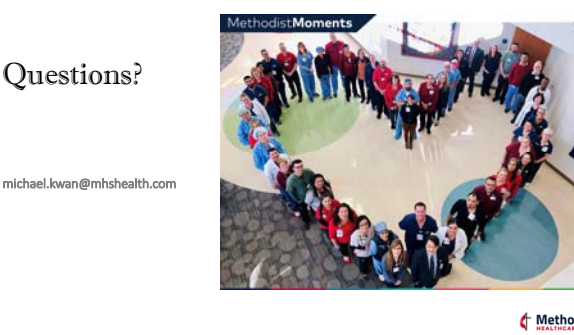
Questions?
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