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Disclosure of Information

I have no financial relationships to disclose.

-and-

I will not discuss off label use and/or investigational use in my presentation.

-and-

I do not intend to reference unlabeled/unapproved uses of drugs or products in my presentation.



What's New in Organ-Specific

Allocation?

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May 21, 2013



Outline

- Role of SRTR in allocation policy creation
- New proposed national allocation policy for kidney
- Potential change in waiting time for liver candidates with Hepatocellular Carcinoma (HCC)
- Access and outcomes of DCD liver transplants
- Future directions



SRTR's Complementary Role to the OPTN

OPTN	SRTR
Organ Allocation /	Research /
Policy Development	Policy Evaluation

When a committee is considering a change to allocation policy, the committee members may wish to simulate what changes may occur if the policy is implemented. SRTR uses Simulated Allocation Modeling Software to accomplish this goal.



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» Abstract 400: Israni et al., Oral, May 21, 4pm Rm 6B

» Abstract 478: Schnitzler et al., Oral, May 22, Rm 611-612



Limitations of Current System

- Variability in access to transplantation by candidate blood type
- High discard rates of kidneys
- Differences in access to transplantation for populations such as candidates with high CPRA
- Kidneys with long potential longevity allocated to candidates with significantly shorter longevity and vice versa
 - Results in unrealized graft years and high retransplant rates



KDPI: Correlated with Graft Survival

Estimated Graft Survival Rates by KDPI





Estimated Post-Transplant Survival (EPTS)

- Based on following recipient factors:
 - Candidate age
 - Length of time on dialysis
 - Prior transplant (any organ)
 - Diabetes status
 - (All negative factors, leading to higher EPTS score)
- Higher EPTS score = lower expected patient survival



New Proposed National Allocation Policy: CPRA Sliding Scale

- Currently, candidates with a CPRA of 80% or greater get 4 points; candidates with a CPRA below 80 get no additional points.
- To mediate the "spike" in points at 80, the kidney committee along with histocompatibility committee developed the CPRA sliding scale.

CPRA	Points
0-19	0
20 - 29	0.08
30 - 39	0.21
40 - 49	0.34
50 - 59	0.48
60 - 69	0.81
70 - 74	1.09
75 - 79	1.58
80 - 84	2.46
85 - 89	4.05
90 - 94	6.71
95	10.82
96	12.17
97	17.3
98	24.4
99	50.09
100	202.1



Proposed Point System to Rank-order Within Each Category

- 1 point per year (awarded as 1/365 point per day) for qualified time spent waiting
- 0-202 points based on degree of sensitization (CPRA)
- 4 points for prior living organ donors
- 1 point for pediatric candidates if donor is <35 yrs old
- 4 points for pediatric candidates (age 0-10 at time of match) when offered a zero antigen mismatch
- 3 points for pediatric candidates (age 11-17 at time of match) when offered a zero antigen mismatch



Overview of Allocation Components by Run

Concepts	Current	New
SCD allocation (defined as KDPI ≤ .85 for New Policy)	Х	Х
DCD allocation	Х	
ECD allocation (defined as KDPI > .85 for New Policy)	Х	Х
Payback system	Х	
Waiting time since listing	Х	
Back-dating dialysis time		Х
Waiting time points based on fractional years		Х
A2/A2B donor to B candidates priority(local, regional, and national)		Х
Highest scoring high CPRA classification	Х	
Pediatrics cannot receive non-0 mm ECD offers		Х

Overview, continued

Concepts	Current	New
Longevity Matching (top 20% survivors get first chance at top 20% kidneys)		Х
"Share 0.35" pediatric priority in New Policy (Donor < 35 yrs for Current)	Х	Х
CPRA sliding scale		Х
National priority sharing for CPRA 100%, regional priority sharing for CPRA 99%, local priority for CPRA 98% candidates		Х
Regional sharing for marginal kidneys (KDPI>.85)		Х
KP/PA System: current	Х	
KP/PA system: future		Х



Kidney Transplants by Recipient Age



To Table

Results of Simulations: Kidney Transplants by Recipient CPRA



Results of Simulations

Average for 10 iterations	Current	New
Number of candidates (on waitlist at start or joining during run)	122,669	122,669
Average number of primary transplant recipients (KI+KP)	11,531 (11,463-11,586)	11,365 (11,324-11,409)
Average median lifespan post-transplant (min, max of runs)	11.82 (11.75 - 11.85)	12.73 (12.65-12.79)
Average median graft years of life (min, max of runs)	8.82 (8.80-8.84)	9.10 (9.08-9.12)
Average median extra life-years for tx recipient versus waitlist candidate (min, max of runs)	5.01 (4.99-5.03)	5.27 (5.24-5.29)



Summary of Results for Kidney Allocation Policy

- Simulated current allocation policy closely matched distribution of 2010 kidneys
- The new policy simulation showed increases in:
 - average projected median lifespan posttransplant,
 - allograft years of life,
 - median lifespan increase adjusted for quality of life (LYFT) per transplant
- Distribution of kidneys did not change substantively by candidate race, HLA mismatches, or regional sharing
- Candidates with CPRA ≥20% were more likely to receive offers
- New allocation policy can potentially improve outcomes
 posttransplant



Summary of Results for Kidney Allocation Policy

- Proposed New Allocation Policy
 - Cost Saving
 - \$230,000,000 Year 1
 - \$47,000,000 Following Years
- Outcomes Primarily Accrue to Private Payer Patients
- Cost Savings Primarily Accrues to Medicare

Abstract 478: Schnitzler et al., Oral, May 22, Rm 611-612



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Abstract 191: Heimbach et al., Oral, May 20, 3:03pm, Rm 606-607



Background for HCC Analysis

- Request from Liver and Intestinal Organ Transplantation Committee to reduce priority for HCC candidates
- Model the impact of:
 - 3 month delay in MELD exception score, MELD 25
 - 6 month delay in MELD exception score, MELD 28
 - 9 month delay in MELD exception score, MELD 29
 - After the wait time, the candidate will be assigned the MELD score that would have been applied without the mandatory wait time
 - Every 3 months assigned additional MELD points equivalent to a 10% increase in mortality



Liver Simulation Allocation Models

- Simulate results between Jan 1, 2010 to Dec 31, 2010
- 28,053 candidates on waitlist on Jan 1, 2010 or joined during 2010
- 2773 (9.9%) candidates have automatic HCC exception points in or before 2010



Results for HCC Analysis

Average Number of Transplants by HCC Status



Transplant Rates by HCC Status



Waitlist and 90-Day Post Removal Death Rates by HCC Status



Summary of HCC Analysis

- Under current policy:
 - Transplant rates are much higher for HCC
 - Lab MELDs at transplant are much lower for HCC
 - Match MELDs at transplant are lower for HCC
- In the scenario with the 9 month delay:
 - Transplant rates decrease for HCC and increase for non-HCC so that they become similar
 - Death rates (HCC and non-HCC combined) do not increase
 - Lab MELDs at transplant increase for HCC and decrease for non-HCC
 - Match MELDs at transplant decrease for non-HCC



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Poster D1636: Kim et al., May 21, Sky Bridge 4D



Post Liver Transplant Patient Survival Probability for Recipients transplanted 2004-2011



Post Liver Transplant Graft Survival Probability for Recipients transplanted 2004-2011



Poster D1636: Kim et al., May 21, Sky Bridge 4D



Purpose

To determine whether DCD liver recipients are disadvantaged in terms of relisting and retransplant as compared to recipients of non-DCD livers requiring retransplantation.

Retransplant Analysis: Study Population

- Adult deceased-donor liver retransplant recipients, who have previously received their first liver transplant between January 1, 2004 and June 30, 2011 and the retransplant occurred more than 30 days after the primary transplant.
- Recipients of living donor liver transplants and multi-organ transplants are excluded for both first and second transplants.

Retransplant Analysis: Definitions

- Graft failure of retransplant patients: defined at the third transplant or death, whichever is first.
- Follow-up for retransplant graft failure: from the second transplant date to the earliest date of all-cause graft failure (including death), one year post retransplant, or November 1, 2011.
- Follow-up for retransplant patient survival: from the second transplant date through the earliest date of death, one year post retransplant, or November 1, 2011.
- DCD and DBD liver recipients: classified based on the donation type of the primary (first) transplant.

Retransplant Analysis: Number of Liver Recipients

► DBD

	N at Risk	Graft Failure	Patient Death
Retransplanted in 2004-2007	387	125	117
Retransplanted in 2008-2011	425	118	112

► DCD

	N at Risk	Graft Failure	Patient Death
Retransplanted in 2004-2007	58	19	17
Retransplanted in 2008-2011	80	19	17

Graft Survival after 2nd Liver Transplant (2004-2011)



Patient Survival after 2nd Liver Transplant (2004-2011)



Models for Graft Failure after 2nd Liver Transplant

Unadjusted

Variable	Hazard Ratio(95% CI)	p-Value
Primary transplant donor type: DCD (ref:DBD)	0.89(0.63-1.25)	0.5089

Adjusted

Variable	Hazard Ratio(95% CI)	p-Value
Primary transplant donor type: DCD (ref:DBD)	1.05(0.73-1.49)	0.8039

Summary of Outcomes for DCD vs DBD Second Liver Transplants

- No evidence that allograft or patient survival after a second transplant in prior DCD recipients is inferior to that of prior DBD recipients.
- DCD liver recipients who were re-registered to waitlist for second transplant, did not have worse waitlist survival than DBD recipients who were re-listed after day 14 posttransplant.
- DCD liver recipients were not disadvantaged in terms of relisting and re-transplant compared to recipients of DBD transplants.



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Future Directions

- Liver: MELD-Sodium policy out for public comment
- Liver: Broader sharing of MELD 35 plus approved
- Heart Allocation Policy Ongoing discussions with the Thoracic Committee
- Pancreas Allocation Policy Ongoing discussions about definition of pancreas allograft failure



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