


## Implementation of MELDNa & Updates and Implications in Organ Allocation



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CLINICAL GASTROENTEROLOGY

## Liver Graft Allocation & Distribution Changes

**Recent**

- Share 35
- MELDNa
- HCC cap & delay

→

**Impending**

- Redistricting
- HCC downstaging
- National Review Board
- SLK safety net

→

**On Horizon**

- Net Benefit Allocation

### (I) Recent Policy Change : Share 35

**Share 35**

- Higher LT MELD
- More Regional Transport

→

**Adaptation**

- Multi-D care
- OR start times
- Wait for Regional offer

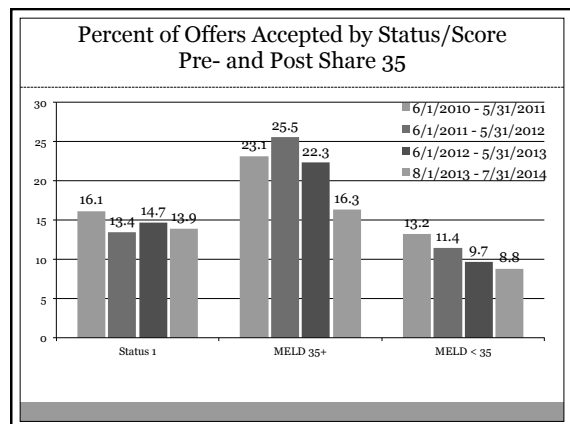
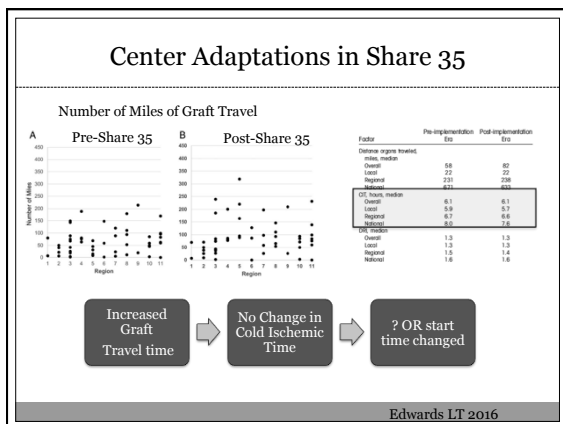
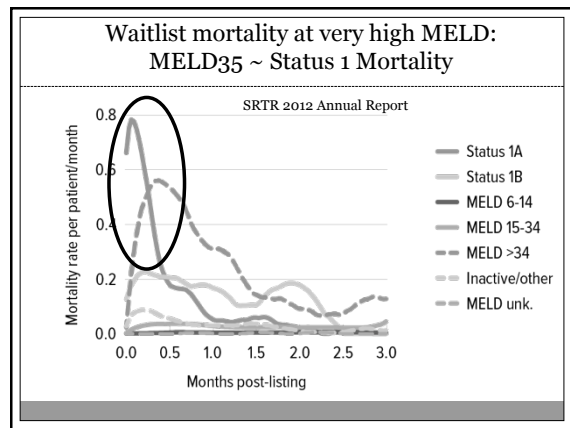
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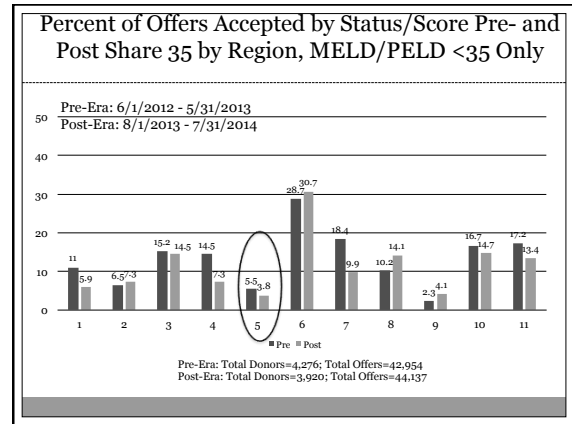
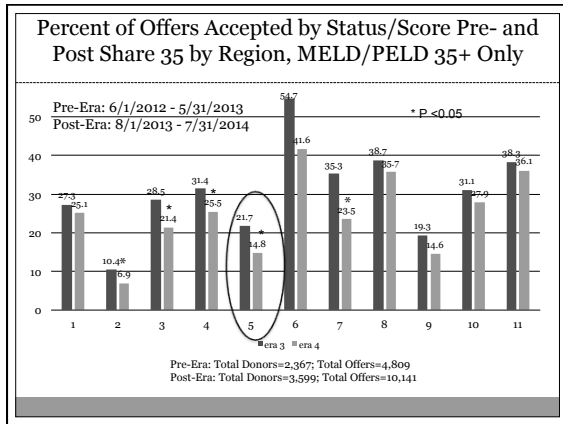
**Consequence**

- Logistics
- Cost
- Program Specific Reports

Share 35 Begins: June 2013

-WL Mortality  
 -Graft Survival  
 -Patient Survival  
 -Transplant Rate



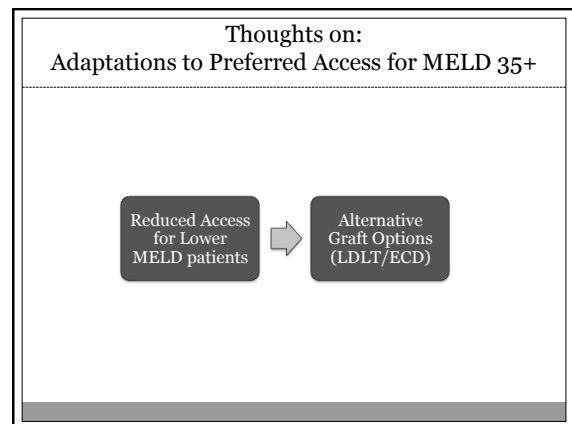
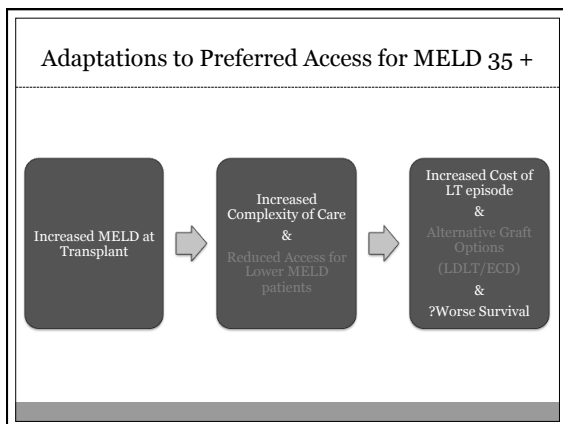
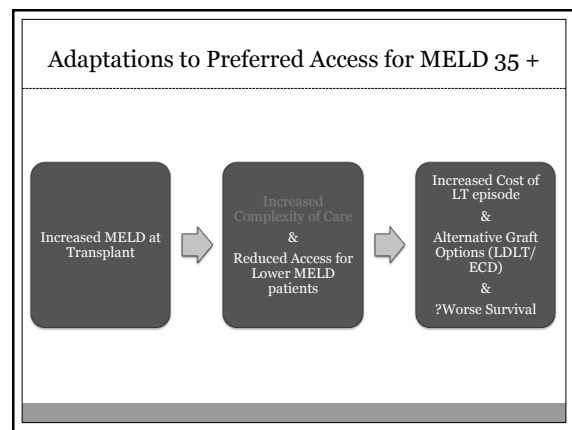


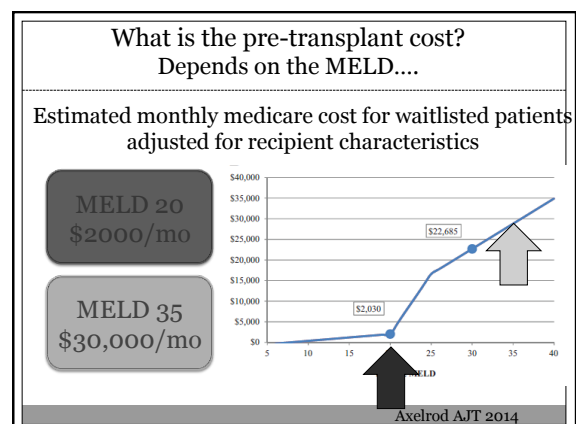
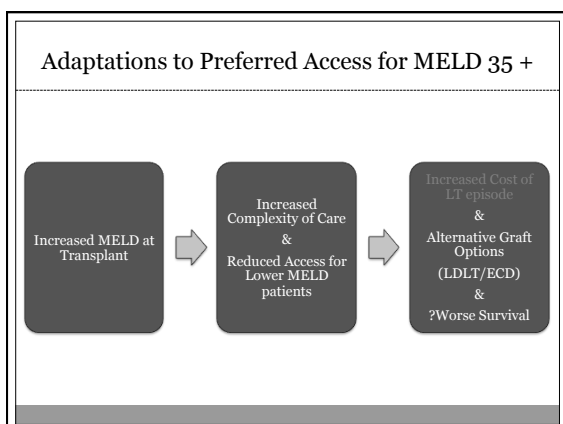
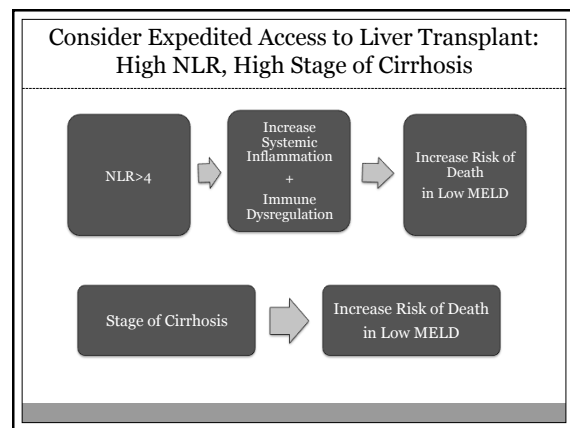
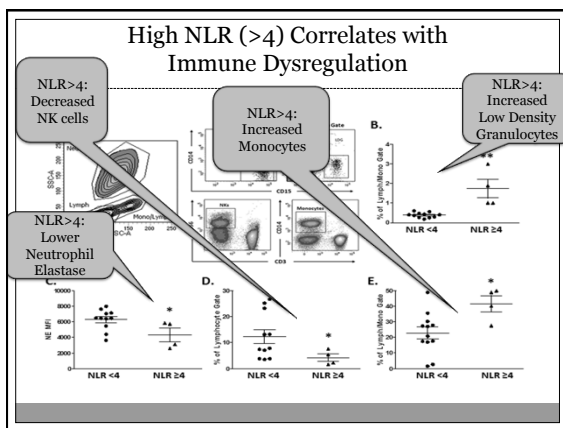
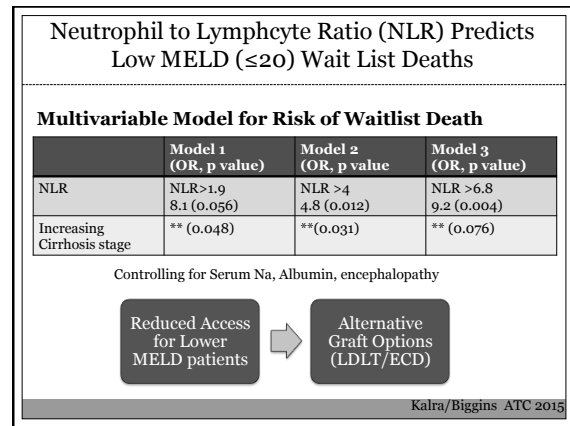
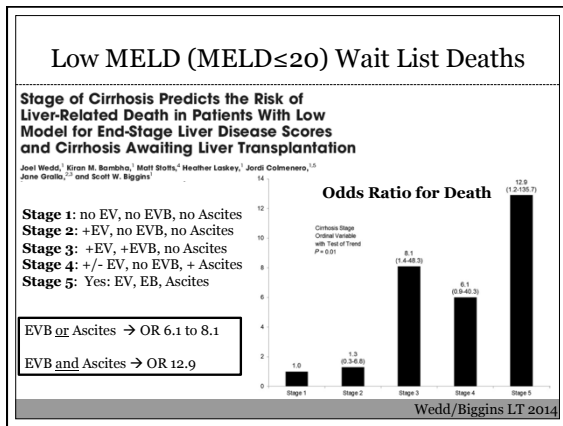
**Kidney Offer Acceptance: PSR Information**

- What information to include in the PSR?
  - Offer acceptance Information
    - Number of offers
    - Rate of acceptances versus rejections
    - Program-specific offer acceptance ratios
      - Include a 95% credible interval
    - Regional and National offer acceptance ratios

**Liver Graft Offer Acceptance Flags are coming**

**SRR**

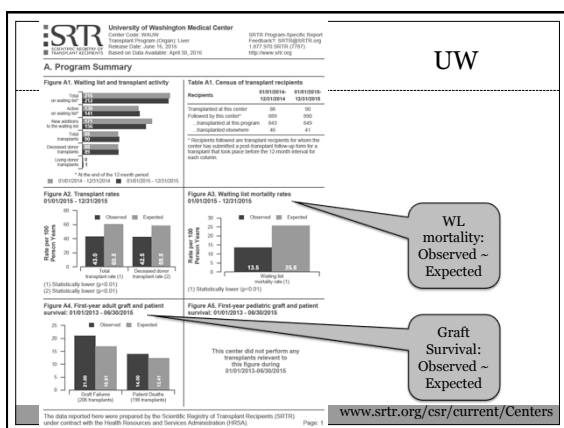
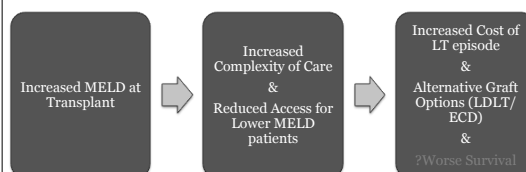




### Cost of transplanting high MELD patients: Charges (\$) at Center X – Central South USA

FISCAL YEAR	MELD GROUP	CASES	AVG CHARGES
2011	25-30	28	323,387
2011	35-40	16	473,318
2012	25-30	24	313,005
2012	35-40	6	525,002
2013	25-30	19	324,347
2013	35-40	16	534,087
2014	25-30	7	309,207
2014	35-40	23	645,044

### Adaptations to Preferred Access for MELD 35 +

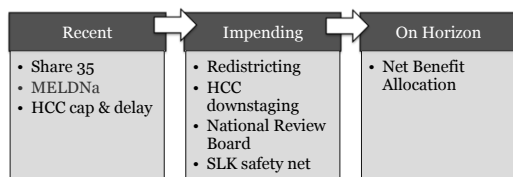


### PSRs:

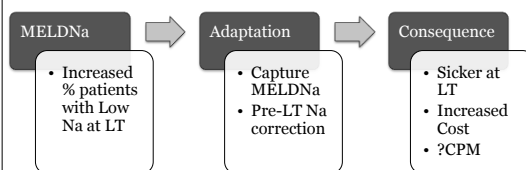
#### Different Audiences, Different Questions:

- Patients and families**
  - What will happen to me?
  - Percent survival at 1 year, 3 years
  - Chances of transplant or death while on the waiting list
  - CMS-required consent process
- Payers (including CMS) and MPSC**
  - Does a program perform up to standard or systematically fail to do so?
- Transplant programs**
  - What choices do our patients have?
  - What can we tell our patients about waiting time and survival?
  - How well are we doing? How can we improve?

### Liver Graft Allocation & Distribution Changes

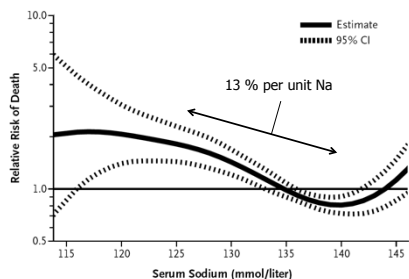


### (II) Recent Policy Change: MELDNa



MELDNa Begins: Jan 2016

### Serum Sodium Predicts 3 Month Wait List Mortality



Kim, Biggins NEJM 2008

### Reclassification: MELDNa vs MELD

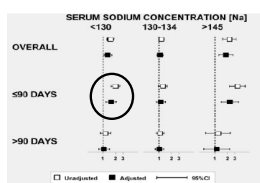
		MELDNa					Total
		<10	10-19	20-29	30-39	40	
LTx Probability		19%		58%		70%	
M E L D	<10	5	4	-	-	-	9
	10-19	-	54	67	-	-	121
	20-29	-	-	122	43	-	165
	30-39	-	-	-	116	-	116
	40	-	-	-	-	66	66
Total		5	58	189	159	66	477

32 Candidates with a significant change in probability LTx  
7% (32 of 477) waitlist deaths in 2006

Kim, Biggins NEJM 2008

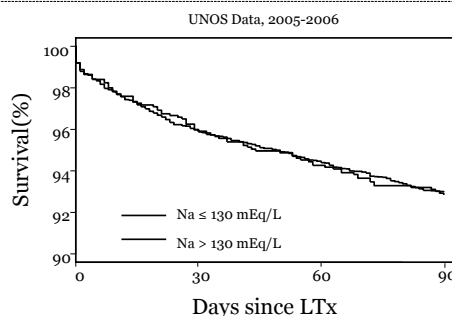
### Hyponatremia & Liver Transplantation Outcomes (UK)

- 5152 Liver Transplant Recipients, 1994-2005, UK and Ireland
  - Na < 130 at LT increased short term but not long term mortality
  - HR 1.55 or 55% increase with Na < 130
  - A small effect vs 13% pre-LTx mortality increase per unit Na



Dawwas LT 2007

### Hyponatremia & Liver Transplantation Outcomes (UNOS)



Kim AASLD 2008

### MELDNa Implemented January 2016

**MELDNa=**

$$\text{MELD } 1.32 * (137 - \text{Na}) - [0.033 * \text{MELD} * (137 - \text{Na})]$$

- Applied only to MELD > 11
- Lower limit Na 125mEq/L

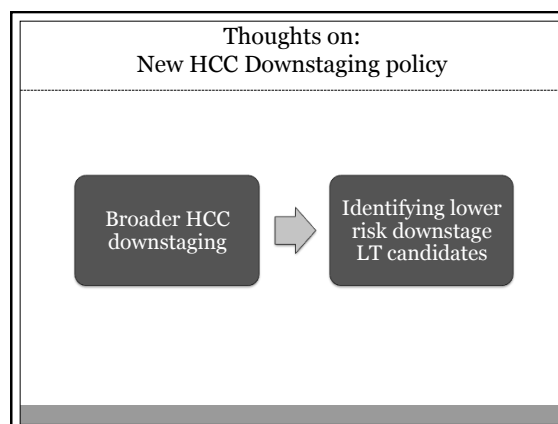
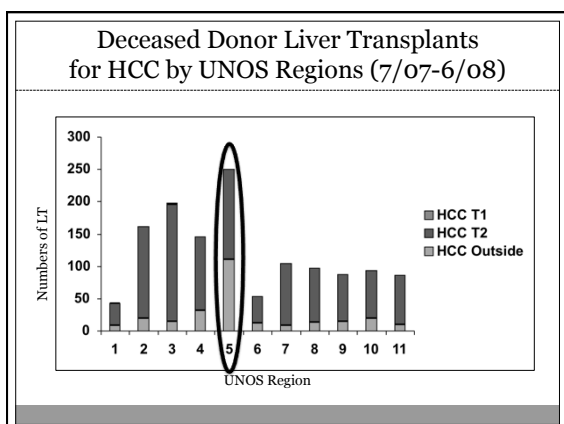
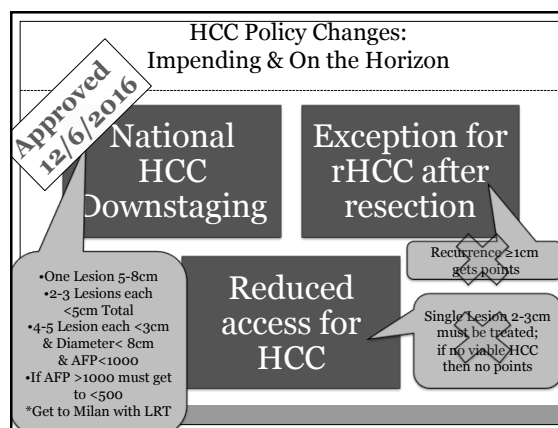
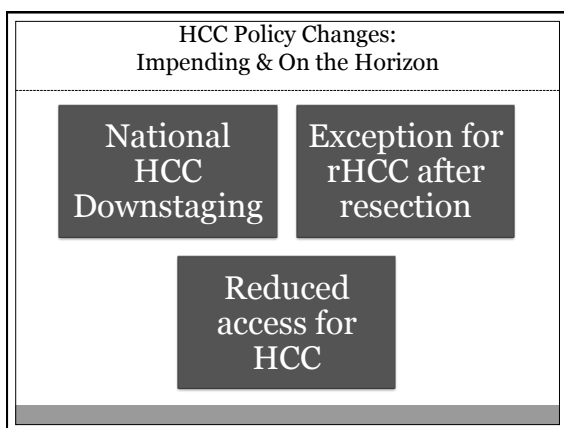
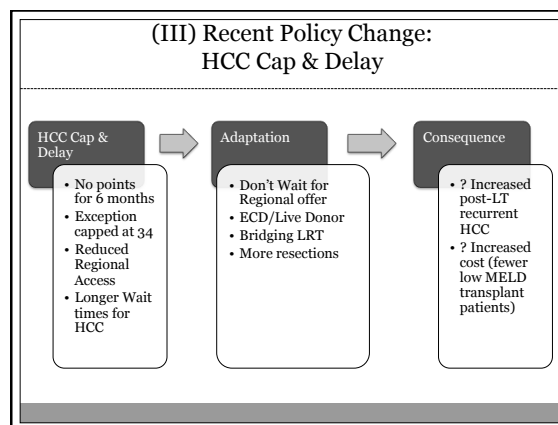
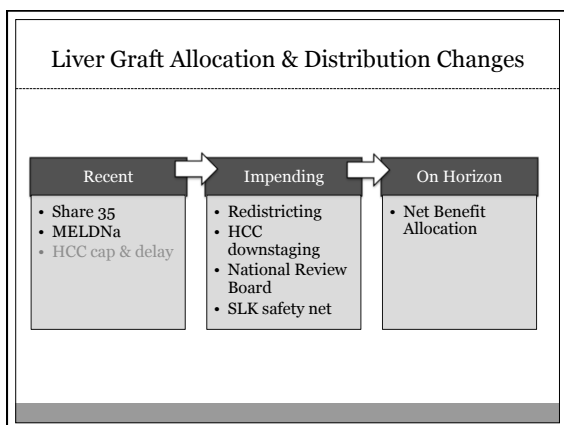
Biggins LT 2015

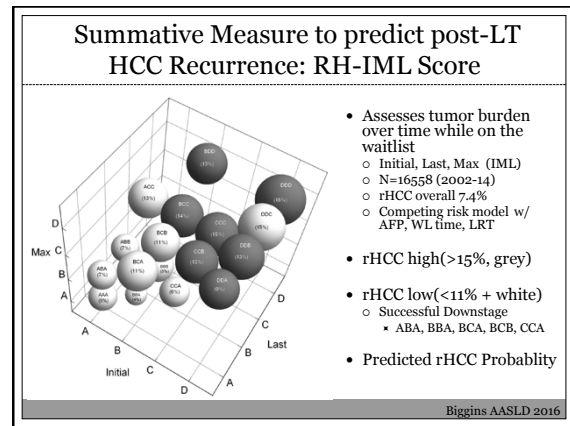
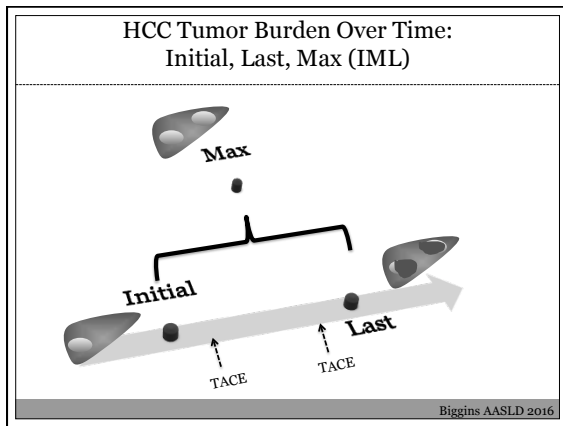
### Na & Liver Transplantation Outcomes

- 2454 Primary Liver Transplantations, 1990-2000
  - Mayo Clinic Rochester, UCSF, U Nebraska & Baylor
- Central Pontine Myelinolysis (CPM) : 13 (0.5%)

	Na<120	120<Na< 135	Na>135	p value
N	12	738	1704	--
Survival 1 mo	1	0.97	0.96	0.74
Survival 1 yr	0.83	0.88	0.88	0.66
Hospital days	26	15	14	<0.01
ICU days	4	3	3	<0.01
CPM	1 (8.3%)	9 (1.2%)	3 (0.2%)	<0.01

Yun, Kim, Benson, Biggins Hepatology 2009



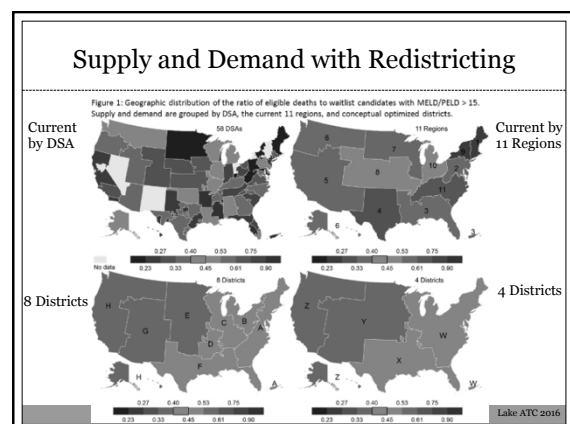
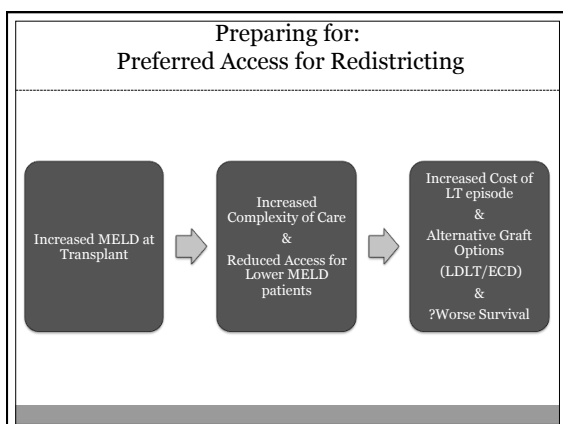
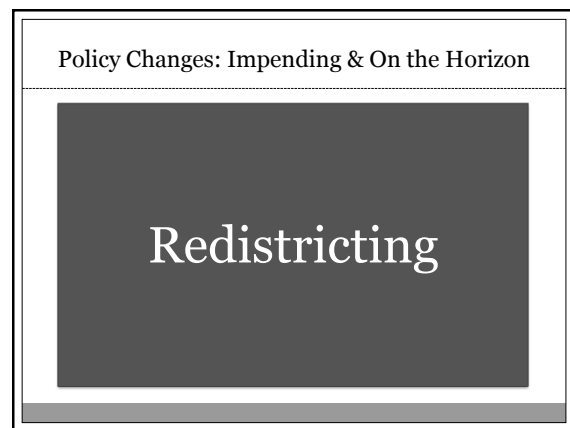


### RH-IML Calculator

Tumor Burden

	A	B	C	D
	<Milan	Milan	>Milan ≤UCSF	>UCSF
Initial	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Max	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Last	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wait time ≥ 6 mo?	<input type="radio"/>			
AFP ≥500 (ever)?	<input type="radio"/>			
Treatment (ever)?	<input type="radio"/>			

Recurrent HCC Risk:  
1 yr: 14% 2 yr: 23% 3yr: 28%



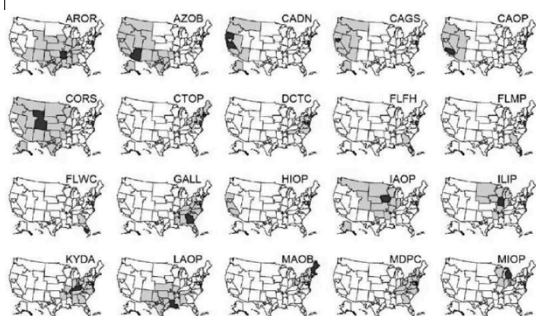
### Redistricting: Deaths and Disparity

	Total Deaths Prevented	Variance of Median Transplant MELD
Share 35	reference	7.55
Regional	-49	10.14
8 Districts	296	3.61
4 Districts	598	2.60
National	556	0.84

### Redistricting shifts transplants from MELD<25 to MELD>25

Number of patients with MELD at transplant	Share 35	8 Districts	4 Districts
6-15	7,004	7,761	7,498
16-25	11,754	8,595	7,387
25-30	2,800	3,798	4,631
30-35	3,868	4,480	4,859
35+	4,508	4,411	4,546

### Neighborhood Distribution



### UNOS Board on Redistricting (12/6/16)

- Agreement that a disparity exists with liver distribution which must be addressed
- Also further attention to:
  - Waitlist practices which vary according to region
  - Supply and demand metrics of liver distribution
  - A proposed maximum number of centers in a region
  - Effect on Veterans
  - HCC exception process

### Impending & On the Horizon

National Review Board & Guidelines

MELD Exception for Portal Hypertension Complications?  
No

MELD Exception Points:  
Replace MELD elevator with Median MELD  
(-3 or -5 points)

### Summary of Policy Changes: Impending & On the Horizon

National Review Board

HCC Downstaging

Redistricting

SLK criteria

Net Benefit

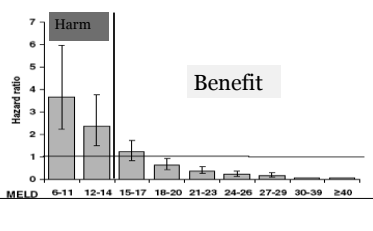
## SLK Criteria

Transplant nephrologist must confirm:	Transplant Center must document
<b>1. Chronic kidney disease</b> with a measured or calculated GFR less than or equal to 60 mL/min for greater than 90 days	<ul style="list-style-type: none"> <li>Dialysis for ESRD</li> <li><b>Most recent eGFR/CrCl is at or below 35 mL/min at the time of registration on kidney waiting list</b></li> </ul>
<b>2. Sustained acute kidney injury</b>	<ul style="list-style-type: none"> <li>Dialysis for six consecutive weeks</li> <li><b>eGFR/CrCl at or below 25 mL/min for at least six consecutive weeks (reported every 7 days)</b></li> <li>Any combination of #1 and #2 above for six consecutive weeks</li> </ul>
<b>3. Metabolic disease</b>	<b>Diagnosis of:</b> <ul style="list-style-type: none"> <li>Hyperoxaluria</li> <li>Atypical HUS from mutations in factor H and possibly factor I</li> <li>Familial non-neuropathic systemic amyloid</li> <li>Methylmalonic aciduria</li> </ul>

## SLK Safety Net

Sequence A KDPI ≤20%	Sequence B KDPI >20% but <35%	Sequence C KDPI ≥35% but ≤85%	Sequence D KDPI >85%
Highly Sensitized 0-ABDRmm Prior living donor Local pediatrics Local top 20% EPTS 0-ABDRmm (all) Local (all) Regional pediatrics Regional (top 20%) Regional (all) National pediatrics National (top 20%) National (all)	Highly Sensitized 0-ABDRmm Prior living donor Local pediatrics <b>Local SLK safety net</b> Local adults Regional pediatrics Regional adults National pediatrics National adults	Highly Sensitized 0-ABDRmm Prior living donor <b>Local SLK safety net</b> Local Regional National	Highly Sensitized 0-ABDRmm <b>Local SLK safety net</b> Local + Regional National

## The Benefit of Liver Transplant &amp; 'Share MELD 15' Policy



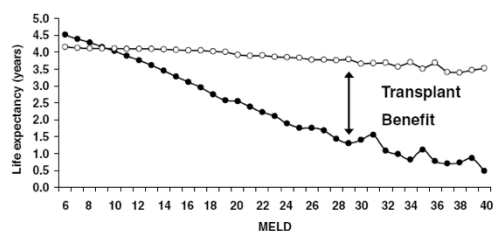
Merion Am J Transplantation 2005

Transplant Benefit:  
Covariates in the Models

- Predicted waitlist life (13 variables)
  - Cre, TB, INR, albumin, Age, Na, BMI, time on the waiting list, diagnosis, DM, dialysis, medical condition, HCC
  - C-statistic: 0.74
- Predicted post transplant life (16 variables)
  - Recipient:** Cre, albumin, age, diagnosis, DM, dialysis, prior LTx, life support, PVT, prior abd surgery, HCV
  - Donor:** age, race, cause of death, donation after cardiac death
  - Organ:** regional vs national sharing
  - C-statistic: 0.63

Schaubel, Guidinger, Biggins et al AJT 2009

## Transplant Benefit Allocation: Reconsidered



Schaubel, Guidinger, Biggins et al AJT 2009

## Summary of Recent Policy Changes:

Share 35

MELDNa

HCC cap  
& delay

