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# Increasing Kidneys for Transplantation: Decreasing Discards

Matthew Cooper, MD Director, Kidney and Pancreas Transplantation Medstar Georgetown Transplant Institute Professor of Surgery Georgetown University School of Medicine Board of Directors, National Kidney Foundation

### I have no conflicts of interest



### I have no conflicts of interest



am, however, incredibly conflicted with the U.S. Organ Discard Rate.....

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### **Growing Incidence of ESRD**



Data Source: Reference Table D.1. Abbreviation: ESRD, end-stage renal disease.

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### Growing Incidence of ESRD



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### The Growing Waiting List



## **Kidney Transplant Totals**



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# Transplant is the preferred option

All cause mortality among Medicare beneficiaries



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## 5 year survival rates for ESRD by modality



### The Rising Deceased Donor Kidney Discard

### Rate in the U.S.



3159 kidneys were discarded in 2015

Stewart, D. Transplantation 2017; 101(3):575-587

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## NKF Consensus Conference to Decrease Kidney Discards

May 18-19, 2017

### **Conference Co-Chairs:**

Matthew Cooper, MD Stephen Pastan, MD



Special thanks to our sponsors:



# NKF Consensus Conference to Decrease Kidney Discards

Baltimore, MD

### **Over 65 participants representing:**

- Kidney patients and families
- Transplant surgeons and nephrologists
- Organ procurement organization (OPO) leadership
- Federal government
  - Centers for Medicare and Medicaid Services (CMS)
  - Health Resources and Services Administration (HRSA)
  - National Institutes of Health (NIAID/NIDDK)
- American Society of Transplantation (AST)
- American Society of Transplant Surgeons (ASTS)
- United Network for Organ Sharing (UNOS)
- Scientific Registry of Transplant Recipients (SRTR)Payers

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NKF Consensus Conference to Decrease Kidney Discards

## **Work Groups:**

- 1. <u>Donor Evaluation and Procurement</u> •Work Group Co-Chairs: Ryutaro Hirose, Kevin O'Connor
- 2. <u>Recipient Selection and Allocation</u> •Work Group Co-Chairs: Richard Formica, John Friedewald
- 3. Education and Research •Work Group Co-Chairs: Sumit Mohan, Jesse Schold



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# Work Group 1: Donor Evaluation and Procurement

Co-Chairs: Ryutaro Hirose, Kevin O'Connor

### **Participants:**

David Adam Axelrod Ginny Bumgardner Kevin Cmunt Renee F. Dupee Elling Eidbo Richard Hasz Nichole Jefferson Bertram Kasiske Kevin A. Myer Howard M. Nathan Richard V. Perez John D. Rosendale Lainie Friedman Ross Peter G. Stock Sean Van Slyck Dennis C Wagner



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## Objective – Work Group 1

 Help more patients by increasing the number of deceased donor kidneys transplanted

- # kidneys tx'd = (# donors x 2) (# kidneys not recovered)
- (# recovered kidneys discarded)
- Three strategic categories:
  - Increase donors
  - Increase kidney recovery from donors
  - Decrease kidney discards



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## Objective – Work Group 1

 Help more patients by increasing the number of deceased donor kidneys transplanted

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  - Decrease kidney discards



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## Wide Variation in Kidney Utilization

kidneys tx'd = (# donors x2) – (# kidneys not recovered) – (# recovered kidneys discarded)

**OPO A** (2015 & 2016: **340 donors** 680 - 89 - 195 = 396 (58% utilization) **209 donors** 418 - 17 - 34 = 367 (88% utilization)

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# Kidney Donor Profile Index (KDPI)

### **KDPI Variables**

- •Donor age
- Height
- •Weight
- Ethnicity
- •History of Hypertension
- History of Diabetes
- •Cause of Death
- •Serum Creatinine
- •HCV Status
- •DCD Status

The pathologic findings are NOT included in KDPI

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### Graft Survival & Discard Rates by KDPI



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# **Impact of KDPI Labeling on Kidney Discard**



# Graft outcomes with even the lowest quality kidneys exceed average dialysis patient survival



Donor reference population: All deceased kidney donors recovered for transplant in 2016. Based on OPTN data including primary, adult, deceased donor, kidney alone transplants, as of April 20, 2018.

### **The Donor Kidney Biopsy**





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### More History than Science??

Vol. 60, 334-339, No. 4, August 27, 1995 Printed in U.S.A.

0041-1337/95/6004-334803.00/0 TRANSPLANTATION Copyright © 1995 by Williams & Wilking

#### GLOMERULOSCLEROSIS AS A DETERMINANT OF POSTTRANSPLANT FUNCTION OF OLDER DONOR RENAL ALLOGRAFTS

LILLIAN W. GABER,<sup>1</sup> LINDA W. MOORE, RITA R. ALLOWAY, M. HOSEIN AMIRI, SANTIAGO R. VERA, AND A. ORAMA GABER

> Department of Pathology and Division of Transplantation, Department of Surgery, The University of Tennessee—Memphis, Memphis, Tennessee

Transplantation of kidneys from older donors is being advocated to expand the organ donor pool. How-ever, the prevalence of atherosclerosis and age-induced renal structural alterations account for the variable function of allografts procured from these older donors. Pretransplant biopsies are sometimes used to evaluate kidneys from older donors, but to date there are no defined criteria correlating the extent of structural alterations in these kidneys to subsequent function. We investigated the effect of glomerulosclerosis, a marker for nephrosclerosis, on graft outcome. Sixty-five baseline biopsies of kidney allografts were retrospectively analyzed to identify a referent point of glomerulosclerosis that correlated restrict point of giomeruloscierosis that correlated with inferior graft outcome. Age and death from non-traumatic cerebrovascular injuries were the main cor-relates for donor giomeruloscierosis (P<0.001). Al-lografis with poor function at 6 months defined as serum creatinize >2.5 mg/dl (n=13) or nephreetomy (n=4) had a mean of 20% glomerulosclerosis at the time of implantation compared with only 2% sclerosis in allografts with good function (P<0.05). Delayed graft function occurred in 22% and 33% of recipients with no glomerulosclerosis and those with less than 20% glomeruloscierosis respectively. In contrast, pa-tients receiving kidneys with >20% sclerosis had 87% incidence of delayed function (P < 0.05). Moreover, graft loss occurred in 7% of recipients of kidneys with less than 20% sclerosis and in 38% of recipients with >20% sclerosis (P<0.04). Measurements of serum creatinine in the donors did not distinguish the different attnine in the conors did not distinguish the different degrees of glomerulosclerosis found on blopsy. Our data indicate that donor glomerulosclerosis greater than 20% increases the risk of delayed graft function and poor outcome of transplanted kidneys. Therefore, we advocate the use of routine biopsies of kidneys from older (>50 yrs) donors and those donors with nontraumatic cerebrovascular accidents, despite seemingly normal preprocurement serum creatinine.

Increasing demand for cadaveric kidneys has motivated transplant conters to consider alternatives for maximizing the rate of acceptance of cadaver donor organs. Acceptance of older donors has the potential of increasing the organ donor pool by 20% (7). However, data regarding the long-term function and survival of such kidneys remains unsettled. Although several studies have demonstrated comparable survival rates for kidneys from young and old donors, (2–4)

<sup>1</sup> Address correspondence to Lillian W. Gaber, M.D., Department of Pathology, University of Tennessee—Memphis, 899 Madison Ave., Room 576—Main, Memphis, TN 38163.

others have expressed more caution in using old donor kidneys due to the increased risk of primary graft failure, delayed graft function (DGF),\* rejection, and overall reduction of graft survival (5, 6). This discrepancy can be largely explained by the shortcomings of the current criteria used for screening old donors. Clinical criteria used for donor evaluation based on detailed medical and social history and laboratory investigations have been largely adequate for identifying high-risk donors or marginal kidneys but have not been age-discriminatory (3). For example, age-related decline in renal function is often masked by a normal serum creatinine in elderly individuals-therefore, such marginal kidneys will be identified as acceptable. In addition, estimation of pephro sclerosis by gross examination of the kidney is, at best, crude and is capable of only distinguishing extreme renal scarring. Accurate determination of the structural and functional sta records determination of the alternation and functional sta-tus of the kidneys at the time of procurement is gatterfairly important for aging kidneys, since the impanetogic and he-modynamic changes induced by transplantation aggravate the preexisting festions of aging. Taking these factors into account, it is essential to establish specific selection criteria for all donors that guarantee acceptance of grafts with no or inimal preexisting pathology. Recently, structuralbased criteria for acceptance of extrarenal allografts have been identified (7). To date, however, and despite sporadic use of renal biopsies for donor kidney evaluation, there have been no published reports of histologic features that identify high-risk kidney allografts from old donors

Epidemiologic and biopsy studies of renal changes secondary to aging support the view that older donor kidneys are more likely to exhibit a greater degree of nephrosclerosis, reduction of renal plasma flow, and a decline in renal function (8-12). Furthermore, examination of donor kidney biopsies obtained at the time of transplantation has shown a greater prevalence of age-related pathology, with a striking 50% incidence of histologic manifestations of chronic nephron logic is kidneys procured from donors older than 50 years (13). The striking procured from donors older than 50 years (14), base has attributed in parts to the mendogs in the older donors can be attributed in parts to the mendogs in the older donors and be attributed in parts to the mendogs in the older donors with hypertension or vascular atheresclerosis, both highly associated with renal abnormalities (11, 22).

We therefore hypothesized that glomerulosclerosis, being a marker for nephron loss, will have a direct negative effect on

\* Abbreviations: CVA, cerebrovascular accident; DGF, delayed graft function; MAP, mean arterial blood pressure. 334 "Moreover graft loss occurred in 7% of recipients of kidneys with less than 20% and 38% with >20% sclerosis (P<0.04)."







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### Kidney Biopsy and Discard Rates by Year, KDPI>85



Biopsy — Discard

### Zero-Time Renal Transplant Biopsies: A Comprehensive Review

- Zero-time biopsies are valuable for ... research ... and as baseline for comparison with post-transplant histology.
- The predictive performance of individual lesions and of composite scores for post-transplant outcome is at best moderate.
- No histological lesion or composite score is sufficiently robust to be included in algorithms for discard.

M Naesens. Transplantation 2016; 100:1425



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### Zero-Time Renal Transplant Biopsies: A Comprehensive Review

- Association of 10 biopsy score formulas with post-transplant graft survival:
  - 5 judged to be poor
  - 3 judged to be unclear or not evaluated
  - 1 "moderate at best"
  - 1 moderate

M Naesens. Transplantation 2016; 100: 1425



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## **Practice Change**

•Biopsy practices (short term)

- •<u>Reduce</u>/eliminate clinically irrelevant biopsies
- •Jointly establish protocols to reach reasonable guidelines
- •Create local DSA based approval process (Biopsy criteria)
- •Example: No biopsy if:
  - •Age < 60 •Serum Cr < 2.0
    - •KDPI < 85%
    - •(exception: CMO approval upon request)
- •Disseminate background information/recommendations to community (not just transplant professionals)

•Proposed biopsy study: RCT of deceased donor kidney biopsies



## **Practice Change**

Pulsatile preservation of kidneys
Establish effective kidney perfusion protocols
Pump criteria
Example: DCD
KDPI >85%
Terminal Cr > 2.0
AKI
CMO exception





# Logistics of Pumping

•Logistical practices

- •Pump location
- •Transport kidneys on pump across DSA boundaries
- •Optimize OR timing for commercial flights
- •Pump kidneys when extended CIT is anticipated





Waters medical systems RM3

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### **Practice Change** Minimizing Mandatory Share Discards

•Always have a Plan 'B'

Backup all high-KDPI and high-CPRA kidneys locally

- •Grant local backup to national centers
  - •CIT increases significantly when no backup (17.9 vs 25.6 hrs)<sup>1</sup>
- •Machine perfusion to mitigate timing challenges <sup>1,2</sup>
- Send peripheral blood early for crossmatching in advance (3 programs) Added cost (~\$1000/donor)
- •Encourage infrastructure to allow for more virtual xmatch

1 Paramesh et al. OPO Strategies to Prevent Unintended Use of Kidneys Exported for High PRA (>98% cPRA) Recipients. Am J Transplant; doi: 10.1111/ajt.14220 2 Cannon et al. Machine perfusion: Not just for marginal kidney donors. Am Surg 2015; 81: 550–556

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## **Practice Change**

Strengthen OPO-Transplant Center relationships

- •Utilization feedback using UNOS OPO reports to review acceptance and discard behaviors
- •Use new tools developed by SRTR for joint review of clinical activity, acceptance practices, etc.

Review All Local Offers to assure no opportunity missed!





### WRTC DONOR ALLOCATION REVIEW SHEET

Date:	03/19/18	1	ORGAN			
UNOS ID:	AFCP283					
Hospital:	DCGW		R Kidney	DCCH		OUTCOME: Seq# TRANSPLANT CENTER
Age/Sex/Race:	33Y/F/W		_	DCGU		Transplanted - DCGU
COD:	CNS Tumor			DCGW		Allocated w/pancreas.
Donor Type:	SCD			DCWR		
ABO:	A			VAFH		
Ht/Wt/BMI	164cm/56.7kg/21.1					
Admit CR:	0.5					
Peak CR:	0.6					
Terminal CR:	0.5		L Kidney	DCCH	Declined	OUTCOME: Seg# TRANSPLANT CENTER
WIT if DCD	n/a		-	DCGU	Accepted	Transplanted 3 DCGU
Biopsy		1		DCGW	Accepted	
				DCWR	Declined	
Not done.				VAFH	Declined	
Authorization	3/16/2018 15:23	1				
Allocation Huddle	3/17/2018 16:58					
Start of Kidney Allocation	3/17/2018 17:13		Pancreas	DCGU	Accepted	OUTCOME: Seg# TRANSPLANT CENTER
Enter OR	3/19/2018 15:43			VAFH	Not offered	Transplanted 1 DCGU
Cross Clamp	3/19/2018 18:03					VAFH pts screened off for 16.
KDPI	22%	1				
Admit/History:		1				
Pt is a 33 yo C female with PMHx of r	newly diagnosed L parietal tumor s/p craniotomy and	1	Liver	DCGU	Accepted	OUTCOME: Seg# TRANSPLANT CENTER
resection on 3/12, exercise induced asthma, anxiety, and depression who presented initially						Transplanted 16 DCGU
on 3/10 with an episode of difficulty with speech production and difficulty understanding what						
she was reading. Pt was transferred to floor after left panetal craniotomy for resection of locion in the left parietal lefte until 2/14 where the way approxime and ecomplaining of						
headaches for which she underwent a	a CT at 12pm that was unremarkable. She then		Heart	DCCH	Not offered	OUTCOME: Seg# TRANSPLANT CENTER
overnight started to seize and had a repeat CTH at 2246 that showed significant increased				DCWH	Declined	Research 0 No recipient located
acute hemorrhage with extension into ventricles. The pt was brought to the ICU emergently,				VAFH	Declined	DCCH pts screened off for 2 16 or 73.
tachycardic in the 150s, hypertensive	in the 190s-200s/110s with two dilated and accome hypoxic. The pt was subsequently emergently				2000000	
unresponsive pupils and starting to become hypoxic. The pt was subsequency emergency intubated given 23%, hypertonic saline push and an EVD was placed at bedside. Heme/Onc						
was consulted for concern for coagule	opathy and the pt was given Vitamin K and transfused 2					
units FFP. Factor VIII, IX, XI activity I	evels were sent. Discussion was had with family and					
Neuro at bedside. Pt declared Brain L	Dead on 03/16/18 @ 1239 based on clinical and apnea					OUTCOME: Seg#TRANSPLANT CENTER
as either an anaplastic oligordendrooli	increased risk due to pris brain tumor being diagnosed		Riung	VAEH	Declined	Transplanted 234 FLUE
molecular analysis later this week. Pr	elim report attached to donornet**** *Exercise induced		Lung	VAEH	Declined	Transplanted 234 FLUE
asthma and light case of asthma whe	n she was a child, used inhaler prior to strenuous					
workouts. "Noted in chart: undiagno	sed factor XI deficiency **					
		1				
						OUTCOME: Seq# TRANSPLANT CENTER
		-	Intestine	DCGU	Not offered	Research 0 No recipient located
						DCGU pts screened off for 2, 16 or 19.

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### WRTC DONOR ALLOCATION REVIEW SHEET

Date:	04/21/18	ORGAN				
UNOS ID:	AFDS353					
Hospital:	DCGU	R Kidne				
Age/Sex/Race:	65/F/W					
COD:	CVA/Stroke					
Donor Type:	ECD					
ABO:	A					
Ht/Wt/BMI	5.3Ft-In/205lbs/36.3					
Admit CR:	1.11					
Peak CR:	1.18					
Terminal CR:	0.64	L Kidne				
WIT if DCD	n/a					
Biopsy						
RT: Glomeruli sclerosis 28% Kidney	interstitial fibrosis/inflamation: absent Ki	Iney arterial				
sclerosis: Yes 26-50%. LT: Glomeru	li sclerosis 26% Kidney interstitial fibroris	/inflamation:				
absent Kidney arteriai scierosis: yes	26-30%					
Authorization	4/20	/2018 11:37				
Allocation Huddle	4/20	/2018 14:19				
Start of Kidney Allocation	4/20	/2018 14:42 Pancrea				
Enter OR	21/2018 0:29					
Cross Clamp	4/2	1/2018 3:10				
KDPI	86%					
Admit/History:		Liver				
65yo/F/W with a PMHx HTN. Last k	now normal ~2130 eveing of (4/17). Was	noted to be				
absent from work morning 4/18. She	was found down by EMS and given nar	an for				
where she was intubated and stat C	TH showed diffuse SAH concentrating in	the I				
ambient/interpeduncular/suprasellar	cistern with + intraventricular blood and	dilation of the Heart				
temporal horns and 4th ventricle. She was transferred to DCGU for further management.						
ICP14 after EVD was inserted in ICU (previously ICP was 30). At time of referral, patient is						
GCS3, no sedation. PERL sluggish 4mm. +cough, no gag. Family are aware of prognosis.						
Pt pronounced BD at 1214 on 4/19/2018 via clinical exam and apnea test where CO2 rose						
1011411070.						
		P Lung				
		Llung				
		L Lung				
		In the set of the				

Kidney	DCCH DCGU DCGW DCWR VAFH	Not offered Declined Declined Declined Declined	OUTCOME: Transplanted DCCH pts screen	Seq# 994 ned off	TRANSPLANT CENTER NJHK for 16 or 101.
Kidney	DCCH DCGU DCGW DCWR VAFH	Not offered Declined Declined Declined Declined	OUTCOME: Transplanted	Seq# 4424	TRANSPLANT CENTER NYUC
ancreas	DCGU VAFH	Not offered Not offered	OUTCOME: Not recovered	Seq# 0	TRANSPLANT CENTER Poor Organ Function
iver	DCGU	Accepted	OUTCOME: Transplanted	Seq# 4	TRANSPLANT CENTER DCGU
eart	DCCH DCWH VAFH	Not offered Not offered Not offered	OUTCOME: Research Research only at	Seq# 0	TRANSPLANT CENTER Age/Function
Lung Lung	VAFH VAFH	Not offered Not offered	OUTCOME: Not recovered Not recovered	Seq# 0 0	TRANSPLANT CENTER Poor Organ Function Poor Organ Function
testine	DCGU	Not offered	OUTCOME: Not recovered	Seq# 0	TRANSPLANT CENTER Poor Organ Function

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### My Data Files

### Recovery and Usage Maps (RUM) Report

### My Visual Analytics

The Recovery and Usage Maps (RUM) Report is an interactive Tableau dashboard that provides detailed information regarding the recovery and transplantation of deceased donor organs (Phase 1 – Kidney). The Recovery map displays DSA level recovery/transplant information based on user selected donor characteristics. The Usage map displays which transplant centers are transplanting the organs from the types of donors the user selected.

- Organ Offers Report TXC
- Organ Offers Report OPO
- Kidney Waitlist Management Tool
- Recovery and Usage Maps (RUM) Report
- Living Kidney Donor Follow-up Report

### Documentation

#### Have feedback or questions? dataportalfeedback@unos.org

Authenticated as external\13704 - welcome DCGU-TX1 member!



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# Practice Change PHS Increased Risk kidneys

PHS increased-risk donors (IRDs) are almost 20% of the donor pool

Discard rates higher for IRDs than non-IRD counterparts

- •Wasteful to discard these: there should be *someone* on the list who would benefit
- Apply evidence-based decision support to accept
- Patients need clear information about risk/benefit of IRD kidney compared to dialysis

Transplantation is NOT risk-free →limitations of Behavioral Health, Assessment from next of kin, etc.




### Center acceptance behaviors

- Identify centers seeking growth
- •Can't assume all centers seeking growth
- Capitalize on forthcoming acceptance behavior reports coming
  from SRTR and make changes to allocation
- •May change reliance on the "OPO Expedited Placement List"
- •OPO Subcommittee  $\rightarrow$  Expedited Placement Workgroup





#### Long Term Change: Economic Factors

Reduce economic disincentives
Adjustment of SAC costs by kidney quality
Should there be some 'reward' for accepting kidneys likely to be discarded

•Revision of payment for renal transplant

- •Develop DRG with and without complications (or high risk for discard) for renal transplant
- •Carve out biologic agents from DRG/Global Payments

Disseminate best practices for efficient use of high risk organs
 Dual Kidney Transplantation / Peds En-bloc Transplantation
 Early discharge to outpatient dialysis
 Centers of Excellence for High Risk for Discard Organs



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#### Finances of ECD and Non-ECD kidney transplants



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# **Current Kidney Allocation Considerations**

- Demographic characteristics
  - Aging of the population
  - Greater burden of comorbidities
  - Extended time on the waiting list
- Allocation reform
  - Kidney allocation which prioritizes patients with increased allosensitization and long dialysis time
- Geographic variation
  - Unique to transplant reflecting donor supply and patient demand misalignment

June 21, 2019

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# **Economic Considerations - Recipient**

	Decease	d Donor	Living	Donor
Parameter	Estimate	P-Value	Estimate	P-Value
Recipient Characteristics				
EPTS Score Rank				
0-20	Reference			
21-50	\$1,096	0.005	-\$461	0.25
51-85	\$2,292	<.0001	\$278	0.61
85-100	\$5,257	<.0001	\$1,312	0.23
Female	-\$1,589	<.0001	-\$469	0.18
Race				
Caucasian	Reference			
Black	-\$434	0.23	\$2,011	0.03
Other	\$6,588	<.0001	-\$997	0.17
BMI				
<18.5	\$1,819	0.075	-\$95	0.93
18.5-24.9	Reference			
25-29.9	\$1,062	0.003	\$587	0.16
30-35	\$2,292	<.0001	\$1,814	0.0001
>35	\$2,037	0.0001	\$2,139	0.001
Unknown	\$4,420	0.006	\$10,263	<.0001

June 21, 2019

Axelrod et al. AJT 2016

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# **Economic Considerations - Recipient**

	Decease	d Donor	Living	Donor
Parameter	Estimate	P-Value	Estimate	P-Value
Cause of Disease				
Diabetes	Reference			
Hypertension	\$1,280	0.004	\$2,582	<.0001
Glomerulonephritis	-\$451	0.36	-\$1,980	0.0006
Polycystic Kidney Disease	-\$1,776	0.005	-\$2,105	0.002
Other	-\$277	0.56	-\$690	0.21
Peripheral Vascular disease	-\$436	0.56	\$2,231	0.02
Working at Transplant				
Νο	Reference			
Yes	-\$1,923	<.0001	-\$2,690	<.0001
Unknown	-\$4,819	<.0001	-\$7,594	<.0001
PRA/cPRA				
0-20	Reference			
21-50	\$3,638	<.0001	\$4,700	<.0001
51-80	\$5,558	<.0001	\$8,080	<.0001
81-90	\$5,002	<.0001	\$10,355	<.0001
91-97	\$8,785	<.0001	\$13,230	<.0001
98_100	\$9,097	<.0001	\$17,784	<.0001

June 21, 2019

Axelrod et al. AJT 2016

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# **Economic Considerations - Donor**

Donor Characteristics	Decease	d Donor	Living	Donor
Parameter	Estimate	P-Value	Estimate	P-Value
Age (per year)	\$62	<.0001	\$3	0.84
Female	-\$717	0.02	-\$818	0.02
Race				
Caucasian	Reference			
Black	-\$1,511	0.001	\$789	0.42
Other	\$2,595	<.0001	\$1,426	0.05
Diabetes	\$3,370	<.0001	-\$9,713	0.19
Hypertension	\$665	0.04	\$1,610	0.17
Donation after Cardiac Death	\$6,182	<.0001		
Cause of death				
Anoxic Injury	Reference			
Cerebrovascular Accident	-\$3,040	<.0001		
Head Trauma	-\$2,322	<.0001		
CNS Tumor	-\$980	0.71		
Other	-\$1,618	0.12		
HLA o Mismatch	-\$4,332	<.0001	-\$3,799	<.0001
HLA o-DR Mismatch	-\$2,968	<.0001	\$426	0.34

June 21, 2019

Axelrod et al. AJT 2016



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#### Adult Dual Unilateral Kidney Transplant (DUKT) – High KDPI Donors



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### Adult Dual Unilateral Kidney Transplant (DUKT) – High KDPI Donors



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#### Pediatric En-bloc Kidneys



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### Pediatric En-bloc Kidneys



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Journal of Transplantation Volume 2016 (2016), Article ID 2586761, 6 pages http://dx.doi.org/10.1155/2016/2586761

**Research Article** 

#### Intermediate-Term Outcomes of Dual Adult versus Single-Kidney Transplantation: Evolution of a Surgical Technique

Ana K. Islam,<sup>1</sup> Richard J. Knight,<sup>1</sup> Wesley A. Mayer,<sup>2</sup> Adam B. Hollander,<sup>2</sup> Samir Patel,<sup>3</sup> Larry D. Teeter,<sup>4</sup> Edward A. Graviss,<sup>4</sup> Ashish Saharia,<sup>1</sup> Hemangshu Podder,<sup>1</sup> Emad H. Asham,<sup>1</sup> and A. Osama Gaber<sup>1</sup>

**RESULTS:** Of 516 deceased donor kidney transplants, 29 were DKT and 487 were SKT. Mean follow-up was 43 ± 67 months. DKT recipients were older and more likely than SKT recipients to receive an extended criteria graft (p < 0.001). For DKT versus SKT, the rates of delayed graft function (10.3 versus 9.2%) and acute rejection (20.7 versus 22.4%) were equivalent (p = ns). A higher than expected urologic complication rate in the DKT cohort (14 versus 2%, p < 0.01) was reduced through modification of the ureteral anastomosis. Graft survival was equivalent between DKT and SKT groups (p = ns) with actuarial 3-year DKT patient and graft survivals of 100% and 93%. At 3 years, the groups had similar renal function (p = ns).



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### Long Term Change: Technology & Innovation

- •Warm perfusion
- Device development
- •Centralized organ recovery suites → Less travel
- •Centralized infectious disease testing labs



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# Work Group 2: Recipient Selection and Allocation

Co-Chairs: Richard Formica, John Friedewald

 Mark Aeder •Adam Bingaman •Gabriel M. Danovitch •Jon Friedman •Howard M. Gebel •Sharon Klarman •David Klassen •Daniela Ladner •Allan Massie •Jennifer E. Milton

 Charles Modlin •Cathi Murphey •Emilio D. Poggio •Fiona Portington •Luke Preczewski •Timothy L. Pruett •Axel Rahmel •Lloyd E. Ratner Peter Reese •Darren E. Stewart



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# Objective

• Right kidney to the right patient at the right time

# **Mission Statement**

• Optimize access to kidney transplantation by improving utilization of kidneys across the entire KDPI spectrum



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#### Good Kidney

#### Intermediate Kidney

#### HR Discard Kidney

Broad Acceptance

#### Aggressive Center, Risk Taking Surgeon

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## Odds of discard of kidneys is highest in UNOS regions with the lowest transplant rates



## **Expectations**

# •Align expectations across the continuum (patient, center, payers, regulators

- •What are we solving to?
  - •Maximize 1 year graft/patient survival?
- •What should we solve to?
  - •Optimize ESRD patient survival?
  - •Optimize organ utilization?
  - •Getting patients off dialysis or avoiding dialysis?
  - •Maximizing value to all parties?
  - •Maximize quality of life?
  - •Needs to be measured and defined



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### Outcomes

Continuing to define "time zero" for outcomes as the day of transplant will continue our cycle of misaligned quality metrics
Some time prior to transplant as time zero may be more relevant to patients – getting off dialysis
Still need better quantification of patient preferences

# Expectations

• Without utility, there is no equity

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# Oversight, Oversight, Oversight!

NAME <u>DISTANCE</u> <u>TRANSPLANT VOLUME</u> <u>TRANSPLANT RATE</u> <u>OUTCOME ASSESSMENT</u>

#### OUTCOME ASSESSMENT

The outcome assessment is a risk-adjusted assessment evaluating how often patients are alive with a functioning transplanted organ 1 year after transplant. The assessment is assigned after case-mix adjustment for the types of recipients who undergo transplant at the program and the donors used by the program. Programs are placed in the better or worse than expected category if we have 97.5% or greater probability that their outcomes are better or worse than expected based on national norms, respectively; otherwise they are placed in the "As Expected" category. Search results are sorted by adult outcome assessments then by Transplant Volume by default, so programs with the best assessments appear at the top of the list. You can choose to view assessments for pediatric recipients from the recipient drop-down list above; however, SRTR may not evaluate outcomes for pediatric recipients if too few transplants are performed. Click here for more information. You may also evaluate this data using the <u>5-tier system</u>.

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ADULTS

Georgetown University	N/A
Medical Center	
Washington, DC	
View Summary Data	
View Complete Report (PDF)	
Also transplants Intestine, Kidney-	
Pancreas, Liver, Pancreas	

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22.4 PER 100 PEOPLE PER YEAR



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#### Consequences, Consequences, Consequences!



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### Patients, Patients, Patients!



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# Do we really know our comparator?



Schold J CJASN 2014, 9 (10) 1773-1780

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# Do we really know our comparator?



Schold J CJASN 2014, 9 (10) 1773-1780

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Possible New Benchmarks/ Balanced Scorecard

- •Number of referrals from dialysis centers
- •Number of pre-emptive referrals
- •Time to evaluation
- •Time to listing
- •Listing rates (need to be risk adjusted)
- •Time to transplant
- •Transplant rate
- Active vs. Inactive candidates



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# **Recipient Selection**

•Listing criteria are not uniform among centers

- •Candidates unaware of differences from center to center
- •Is education and universal access more important?
- •A menu of transplant center practices (what is offered, who is accepted at that center data driven)
- •Guidelines are not mandatory, but centers must have criteria and follow their own criteria
- •Centers of Excellence?





#### Donor History & Management

What is the maximum donor age your center will consider?	80
Will your center consider kidneys from a donor with an unknown cause of death?	Yes
Will your center consider kidneys from a donor with a history of cancer (other than a primary brain tumor):	
less than one year ago?	Yes
1 to 5 years ago?	Yes
6 to 10 years ago?	Yes
more than ten years ago?	Yes
Will your center consider kidneys from a donor with a primary brain tumor that is:	
malignant (i.e. Glioblastoma, Astrocytoma, Medulloblastoma)?	No
non-malignant (i.e. Meningioma, Ependymoma, Neuroblastoma)?	Yes
Will your center consider kidneys from a donor with meningitis as the cause of death?	Yes
Will your center consider kidneys from a donor:	
with evidence of current injection of non-prescription drugs?	Yes
with history of past injection of non-prescription drugs?	Yes
that is male who has had sex with another man in the last 5 years?	Yes
<ul> <li>who has engaged in sex in exchange for money/drugs in the last 5 years?</li> </ul>	Yes
who has been an inmate of a correctional system?	Yes
• with other high risk factors (such as being exposed in the preceding 12 months to known or suspected HIV infected blood through percutaneous inoculation or contact with an open wound, nonintact skin, or mucous membrane; or defined as "high risk" based on OPO criteria)?	Yes
with an unknown history (no historian available)?	Yes
Will your center consider kidneys from a donor with a positive result from any of the following infectious disease tests:	
Hepatitis B Surface Antigen?	Yes
Hepatitis B Core Antibody with no IGG/IGM testing?	Yes
Hepatitis B Core Antibody with IGM testing?	Yes
HBV NAT?	
Anti-HCV?	Yes
HCV NAT?	
HTLV I or II?	No
Syphilis?	Yes
MedslarGeorgelowi	1

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#### Age Specific(Donor Age)

Questions within the section should be answered for each of the 4 donor age groups.

Identify the duration for which your center will consider donor kidneys for the specified circumstance.

For donors aged:	<45 years	45-54 years	55-64 years	>64 years
With a history of hypertension and compliant with medication?	11 - 20 years			
With a history of hypertension and period(s) of non-compliance within the last 5 years?	11 - 20 years	11 - 20 years	11 - 20 years	6 - 10 years
Who is an insulin dependent diabetic?	11 - 20 years	11 - 20 years	6 - 10 years	6 - 10 years
With diabetes and requires oral medication?	>20 years	>20 years	>20 years	>20 years

#### Identify the maximum acceptable amount of cardiac arrest (downtime) for which your center will consider donor kidneys.

For donors aged:	<45 years	45-54 years	55-64 years	>64 years
With CPR?	>30 min	>30 min	>30 min	>30 min
Without CPR?	>30 min	>30 min	>30 min	>30 min

Enter the appropriate criteria your center will consider for each of the following questions.

For donors aged:	<45 years	45-54 years	55-64 years	>64 years
What is the maximum acceptable peak serum creatinine level?	8 mg/dl	8 mg/dl	3 mg/dl	3 mg/dl
What is the maximum cold ischemic time (based on arrival time) on cold storage?	36 hrs	30 hrs	30 hrs	24 hrs
What is the maximum acceptable percentage of glomerular sclerosis for a biopsled kidney?	30 %	30 %	30 %	30 %



### Know Your Data!!!

	SCIENTIFIC	Georgetown University Medical Center	
SR	REGISTRY 으트	Center Code: DCGU	SRTR Program-Specific Report
ТR	TRANSPLANT	Transplant Program (Organ): Kidney Release Date: January 5, 2018	Feedback?: SRTR@SRTR.org 1.877.970.SRTR (7787)
	RECIPIENTS	Based on Data Available: October 31, 2017	http://www.srtr.org

#### **B. Waiting List Information**

#### Table B10. Offer Acceptance Practices: 07/01/2016 - 06/30/2017

Offers Acceptance Characteristics	This Center	OPO/DSA	Region	U.S.
Overall				
Number of Offers	19,528	32,015	261,260	1,547,378
Number of Acceptances	132	254	1,594	12,795
Expected Acceptances	54.9	148.2	1,847.1	12,785.8
Offer Acceptance Ratio*	2.35	1.70	0.86	1.00
95% Credible Interval**	[1.97, 2.77]			

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## Know Your Data!!!

Medium-KDRI Donors (1.05 < KDRI < 1.75)				
Number of Offers	9,167	16,564	146,025	1,021,475
Number of Acceptances	73	129	803	6,593
Expected Acceptances	25.9	66.7	924.5	6,581.3
Offer Acceptance Ratio*	2.69	1.91	0.87	1.00
95% Credible Interval**	[2.11, 3.33]			
High-KDRI Donors (KDRI > 1.75)	1. Sec. 1. Sec			
Number of Offers	8,032	11,571	72,514	309,605
Number of Acceptances	34	37	155	1,119
Expected Acceptances	11.5	22.0	166.5	1,118.3
Offer Acceptance Ratio*	2.67	1.63	0.93	1.00
95% Credible Interval**	[1.87, 3.61]			

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### **Report of Organ Offers**

#### My Data Files

#### Organ Offers Report TXC

My Visual Analytics

The visual display of the transplant center Report of Organ Offers (ROO) allows you to interact with all organ offers to your center during the recent 120 days. The file is updated weekly and includes both summarized and individual offer data.

- Organ Offers Report TXC
   Organ Offers Report OPO
- Kidney Waitlist Management Tool
- Recovery and Usage Maps (RUM) Report
- Living Kidney Donor Follow-up Report

#### Documentation

Have feedback or questions? dataportalfeedback@unos.org

#### Authenticated as external\13704 - welcome DCGU-TX1 member!



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# Kidney Offer Acceptance Metrics: High Acceptance

Offer Acceptance Ratios Across Donor Characteristics

Donor Characteristics	Number of Offers	Number of Acceptances	Expected Acceptances	Offer Acceptance Ratio
Overall	2781	93	21.2	4.09
KDRI: < 1.05	77	3	2.64	1.08
KDRI: 1.05-1.75	1681	54	14.45	3.4
KDRI: > 1.75	1023	36	4.12	6.21
DCD Donor	262	10	1.14	3.82
PHS Increased Infectious Risk	839	26	4.38	4.39
HCV+	4	4	0.14	2.81
Weekend	824	30	6.26	3.87



# Kidneys are harder to place on the weekend



Day of the week



King et al. CJASN 2018 Accepted

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#### Kidneys procured over the weekend are more likely to be discarded even after adjusting for quality



Higher quality kidneys discarded on the weekend Discard data calculated using data from 2000 through 2013 Day of Procurement

# Recipient Selection – New Allocation Categories

- Selection for expedited placement
  - · New "EPTS" vs. pre-transplant survival for brevity matching
    - · Candidates would "roll out" of the group with added waiting time
    - · Greatest benefit from high KDPI kidneys is with rapid access
    - Once several years accrued or passed on multiple offers, roll out of the intentionally small pool of candidates



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# Survival Benefit from Rapid Transplant (SBRT)

#### Proposed model


### Excellent quality kidneys from deceased donors are being discarded



### Work Group 3: Research and Education

#### Co-Chairs: Sumit Mohan, Jesse Schold

#### **Participants:**

- Kevin C. Abbott
- Charles Alexander
- Anthony F. Bonagura
- Mariana C. Chiles
- Kevin Fowler
- Melissa Greenwald
- Leal C. <u>Herlitz</u>
- Ian R. Jamieson
- Liise K. Kayler
- Alan B. Leichtman
- Jonah Odim

- Chirag R. Parikh
- Marcus R. Pereira
- Andreas Price
- <u>Kunam</u> Reddy
- Alan I. Reed
- James R. Rodrigue
- Daniel Schwartz
- Jon Snyder
- Sarah E. Taranto
- Bob Walsh



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### Accurate Assessment of organ quality

•Biopsy – as currently performed its contribution to assessing quality is unclear – and very far from being a "gold standard"

•Advocate for a trial to evaluate biopsy utility

- •Biopsy technique/preparation/interpretation/reporting should be standardized
- •Central read by a renal pathologist using digital pathology

•Gross organ photo for donor net

There is some variability in the utilization of gross photos of kidneys on donor net
Develop guidelines/standards for presenting gross photos: Adequately removing fatty tissue, highlighting vasculature



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### Accurate Assessment of organ quality

•Biopsy – as curre far from being a " •Advocate fo •Biopsy techi •Central read

Gross organ phot
There is son donor net
Develop gui fatty tissue, l
Make postir

unclear – and very standardized dneys on the ately removing andatory

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# Recognition that Discard $\rightarrow$ Complex Issue

- Solving the regulatory environment alone is only 1 piece of the puzzle.
  - Regulatory
  - Education (patient and provider)
  - Financial
  - Medical
- People need to get beyond the notion that 'true' risk adjustment models are the problem.
  - The field of transplantation is advanced in its data, monitoring, and quality improvement capabilities.
  - Improved and targeted data collection to capture risk, particularly recipient risk, should be a priority.



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### **Education/Research Needs**

•Develop and evaluate interventions designed to increase acceptance of kidneys that are at disproportionate risk of discard (IRD, high KDPI, etc.)

•Recognize patients are not the principal barrier to reducing organ turndown rates

 Identify factors contributing to variability in organ acceptance practices within/between providers and programs

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# Patients prioritize waitlist over posttransplant outcomes for selecting a transplant center



Only published national survey identifying patient centered criteria on selecting a transplant center Over 500 respondents for survey conducted in 2017

Husain SA et al. Am J Transplant. 2018 Nov;18(11):2781-2790

## **Education/Research Needs**

•Develop and evaluate interventions designed to modify provider behavior (i.e., increased acceptance of IRD kidneys)

- •Education alone will not reduce turndown rates
  - •Knowledge is a necessary but insufficient agent of behavioral change
- Impact of incentive structure
- •Evaluate benefit of new monitoring and feedback systems

Identify and disseminate provider and center best practices re:
 organ acceptance



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# SR TR

SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

# Offer Acceptance Decision Tool

The Idea: Enter donor, recipient, and offer characteristics and get projected likelihood of graft function and survival if accepting the offer or declining the offer.



# Offer Acceptance Decision Tool





# Offer Acceptance Decision Tool





## Growth in the need... and the waitlist





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# **Conference Recommendations**

•OPO Initiatives/Directives

Communication

•Improve 'real-time' communication with Tx Center at time of organ offer (Go back to the phone)

•Collaborate with Tx Center to review all discards in the DSA

•Expand OPO and Tx Center relationships beyond the DSA  $\rightarrow$  Region



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#### •OPO Initiatives/Directives

- •Allocation
  - •Expand the use of virtual crossmatching, esp. with high cPRA recipients

•Routinely send prospective crossmatch material to several programs with recipients on matchrun

•Grant 'local backup' to centers for exported organs to minimize CIT

•Always identify 'local backup' for organs within DSA for high CPRA recipients or high KDPI organs

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•OPO Initiatives/Directives •Financial

•Develop risk-stratified (high risk of discard) Organ Acquisition Costs for organs that substantially increase the costs for Tx Centers



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#### •Transplant Programs

•Management

•Waitlist management practices should work to educate patients on the acceptance of higher risk organs to prevent delays (HCV+, PHS IR, high KDPI)

•Develop and implement decision-support tools to help physicians evaluate benefits of accepting higher risk organs for particular recipient

•Disseminate best practices from Tx Centers that routinely accept high risk organs (COIIN)



### •UNOS

•Create expedited placement pathways to directly offer kidneys with high KDPI, or at risk of discard, to small subset of centers that opt-in. Centers must maintain high rates of acceptance to remain.

•Identify organs that <u>become</u> a high risk for discard during standard allocation, and shunt them to patients at 'rescue centers' that utilize high risk organs.

•Standardize provision of gross photos of procured kidneys and post on DonorNet.

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### •SRTR

•Develop Quality of Life (QOL) metrics to support use of higher risk organs expected to have higher rates of graft loss.

•Re-evaluate all transplant center metrics that 'punish' transplant centers that utilize high risk organs.

•Monitor and report organ acceptance as an index of transplant center performance.



•NIH/Research

•Standardize technical aspects of obtaining and interpreting renal biopsies, and focus on their use of ruling in, rather than ruling out.

•Complete a randomized trial of renal biopsy use in organ procurement and acceptance.

•Fund research into organ procurement methodology.





•Payors

•Develop a risk-adjusted payment system to compensate Tx Centers for the increased costs of higher risk kidneys.



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### Thank-you!



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