SR TR

S C I E N T I F I C R E G I S T R Y 으 T R A N S P L A N T R E C I P I E N T S

Understanding Pharmaceutical Care Needs of Living Kidney Donors through Linked Transplant Registry and Pharmacy Claims Data

The SRTR Living Donor Collective

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DISCLOSURES

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I have no financial relationships to disclose within the past 12 months relevant to my presentation. The ACCME defines 'relevant' financial relationships as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

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Consensus Conference on Best Practices in Live Kidney Donation: Recommendations to Optimize Education, Access, and Care

Meeting Report [AST COP, Am J Transplant 2015; 10:1656]

"Live donor kidney transplantation is the **best treatment option** for most patients with late-stage chronic kidney disease"



BALANCING ACT

Living donation raises complex considerations

DONOR RISKS Short-term Long-term

- Medical
- Psychosocial/ financial



BENEFITS

- Improved recipient health
- Psychosocial benefits of altruism



LDKT HAS DECLINED DESPITE GROWING NEED



Reasons for decline likely multi-factorial, but may include **uncertainty about donor risks**.



LKD FOLLOW-UP IN US OPTN REGISTRY

• Limited in scope, duration, completeness

- Recipients: Tracked in OPTN registry for life of graft
- **1987 Baseline** living donor registration (LDR)
- 1999 6-mo and 1-yr LDF forms implemented
 - Blood pressure, BMI, serum creatinine, dialysis, death
- June 2004
 - Additional predonation data (insurance, employment , functional status, HTN, DM, proteinuria)
 - Postdonation medically treated HTN, DM; proteinuria
- March 2008: follow-up period for living donors extended to 2 years after donation
- February 2013: mandated thresholds for data collection and completeness
- No psychosocial outcomes

TRENDS IN FOLLOW-UP DATA SUBMISSION



*January 1 – June 30, 2015



IMPORTANCE OF CONTROLS

[Lentine & Segev, JASN 2017; 28:12]

Risk Perspective

Descriptive

Comparative, within-donor

Comparative, LKD vs. general non-donor

Attributable, LKD vs. highly selected non-donor



ESRD IN LKD VS HEALTHY NON-DONORS

15-year cumulative incidence: LKD vs. controls

SR SCIENTIFIC REGISTRY 약 TRANSPLANT DECIPIENTS

The NEW ENGLAND JOURNAL of MEDICINE

January 2015

ORIGINAL ARTICLE

Gestational Hypertension and Preeclampsia in Living Kidney Donors

Amit X. Garg, M.D., Ph.D., Immaculate F. Nevis, Ph.D., Eric McArthur, M.Sc., Jessica M. Sontrop, Ph.D., John J. Koval, Ph.D., Ngan N. Lam, M.D., Ainslie M. Hildebrand, M.D., Peter P. Reese, M.D., Leroy Storsley, M.D., John S. Gill, M.D., Dorry L. Segev, M.D., Ph.D., Steven Habbous, M.Sc., Ann Bugeja, M.D., Greg A. Knoll, M.D., Christine Dipchand, M.D., Mauricio Monroy-Cuadros, M.D., and Krista L. Lentine, M.D., Ph.D.,

for the DONOR Network*

WHAT DO WE WANT TO KNOW & WHY?

• Outcomes that are important to:

- Patients & families
- Transplant programs
- Primary care providers
- Knowledge that is used in:
 - Decision making for future donors
 - Minimizing risk for current donors
 - Maximizing opportunity for donation

SCIENTIFIC REGISTRY 아 TRANSPLANT RECIPIENTS

SCIENTIFIC REGISTRY 약 TRANSPLANT RECIPIENTS

SRTR PROJECT PLAN

Program role

- register all potential living donor candidates evaluated, including those who:
 - become donors
 - are suitable but do not donate
 - are found not to be suitable to donate
- record reasons for not donating

SRTR will

- obtain follow-up information
- report to transplant programs
- report to the general public

LIVING DONOR COLLECTIVE TIMELINE

September 2016

-Feasibility study completed -HRSA awards LDC pilot project to

SRTR/MMRF

October 2016

-First Steering Committee call

- Submitted HRSA-OMB request to collect new data December 2016 -Additional staff -First Living Donor Collective pilot project sites teleconference

LIVING DONOR COLLECTIVE TIMELINE

ary- May 2017

- 60 day public comment

-Pilot sites inperson meeting

-Complete contracting, web

, etc.

<u> May - Nov 2017</u>

-Train sites, est. data collection process

- Patient brochure

-OMB approval

December 2017

Begin entering donor candidates

LIVING DONOR COLLECTIVE TIMELINE

<u>2018 – 2019</u>

- Enrollment
- Follow-up surveys
- Data linkages

<u>2020</u>

- Expand sites

- Develop allinclusive LDC

Pilot Sites

Kidney and liver programs:	6
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Rochester Methodist Hosp, Mayo Clinic

Johns Hopkins Hospital

University of Pittsburgh Med Center

Univ. of Minnesota Medical Center

Baylor University Medical Center

Mount Sinai Medical Center

Kidney-only programs: 4

Emory University Hospital

UCLA Medical Center

Hennepin County Med Center

Saint Louis University Hospital

Total participating programs: 10

OPTN & SRTR-LDC DATA COLLECTION

DATA LINKAGES: NOVEL OUTCOME ASCERTAINMENT

Lentine et al., *Am J Transplant* 2016;Sep 2 [ePub] Lentine et al., *Am J Transplant* 2016;16:1848 Axelrod et al., *Am J Transplant* 2016;Aug 27 [ePub] Alhamad et al., Transplantation. 2016;100:1086 Lentine et al., *Transplantation* 2015;99:1723 Lentine et al., *Trials* 2015; 6:412 Lentine et al., *Clin Transplant.* 2015;29:927 Lentine et al., *Transplantation* 2015;99:187 Lentine et al., *Am J Nephrol* 2015;41:165 Lentine et al., *Am J Nephrol* 2014;40:174

PILOT ASSESSMENT OF PHARMACEUTICAL USE

Research Strategy

• Linkage of the **national transplant registry** with other data sources, combine value of:

Confirmed patient status (e.g., LKD, recipient)

Baseline patient and procedure characteristics

Additional outcome and exposure information

Pharmacy fill records

- Non-obtrusive measure of **medication exposure**
- Surrogate measure of comorbidity

Predonation Prescription Opioid Use: A Novel Risk Factor for Readmission After Living Kidney Donation [Lentine et al, AJT 2017; 27:744]

- Predonation narcotic use level bore graded associations with 1-year readmission
 - LKD with the highest predonation narcotic use were twice as likely to be readmitted as non-users (6.6% vs 3.2%, aOR 1.94)

Obesity predicts New-Onset Diabetes after Living Kidney Donation [ATC 2017. 'Renal & Urology News' Highlight]

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INCIDENCE OF TREATMENTS for PDDM ACCORDING TO BMI AT

PILOT ASSESSMENT OF PHARMACEUTICAL USE

Sample – Linkage:

- 1) SRTR data for LKD (1987-2012)
- 2) pharmacy fill records from a nationwide pharmacy claims (2005–2014) clearinghouse

Measures

- Utilization patterns of diabetes treatments, antihypertensive medications, and antidepressants
 - Measures of conditions before and after donation

PILOT ASSESSMENT OF PHARMACEUTICAL USE

Prescription fills among living kidney donors, before and after donation.

	Percentage of Donors with Prescription Fills in Given Years Before and After Donation									
	Yea	r Before Dona	tion	Year After Donation						
Type of Prescription	Voor 2	Voor 2	Voor 1	Voor 1	Voor 2	 Vaar 2 Vaar 4 Vaar 6 Vaar 9 Vaar 10				
	(N=22 740)	(N=27.720)	(N=32.065)	(N=26.507)	(N=22 726)	(N=20.064)	(N=26 765)	(N=22.354)	(N=46.934)	
	(11-23,749)	(N-27,750)	(N-32,003)	(14-30,397)	(14-32,720)	(14-29,901)	(11-20,703)	(11-22,334)	(14-10,034)	
Diabetes Treatment										
Diabetic supplies	0.28%	0.26%	0.24%	0.26%	0.36%	0.58%	0.89%	1.25%	1.51%	
Insulin	0.10%	0.08%	0.06%	0.07%	0.09%	0.12%	0.19%	0.31%	0.37%	
Oral hypoglycemic agents	0.30%	0.37%	0.35%	0.23%	0.35%	0.66%	1.12%	1.82%	2.29%	
Antihypertensive										
Medications										
Diuretics	2.47%	2.56%	2.62%	2.26%	2.82%	3.93%	5.45%	6.84%	8.64%	
Calcium channel blockers	0.62%	0.65%	0.74%	1.16%	1.37%	1.90%	2.66%	3.31%	3.57%	
Beta-blockers	1.58%	1.72%	1.87%	2.05%	2.52%	3.38%	4.35%	5.56%	6.69%	
ACE inhibitor	1.72%	1.71%	1.91%	2.38%	3.22%	5.08%	6.86%	9.18%	11.33%	
Other antihypertensives	0.23%	0.29%	0.28%	0.29%	0.31%	0.48%	0.67%	0.82%	0.97%	
Antidepressant										
Medications										
Tricyclic antidepressants	1.58%	1.72%	1.46%	1.63%	1.89%	1.92%	2.12%	2.17%	2.26%	
SSRIs	9.66%	9.86%	9.29%	8.68%	9.70%	9.38%	9.65%	9.37%	8.96%	
SNRIs	2.21%	2.30%	2.18%	2.02%	2.38%	2.44%	2.66%	2.80%	2.92%	
MAOs	0.00%	0.01%	0.01%	0.00%	0.00%	0.01%	0.01%	0.03%	0.01%	
New generation	3 41%	3 54%	3 66%	3 21%	3 74%	3 82%	3 93%)	4 15%	4 22%	
antidepressants	5.4170	5.5470	5.0070	3.21/0	5.7 470	5.6270	5.5570	7.1370	7.2270	

Denominators = Number of donors having any medication prescription filled in that given year.

Abbreviations: ACE, angiotensin converting enzyme inhibitor; SSRI, selective serotonin reuptake inhibitor; SNRI, serotonin-norepinephrine reuptake inhibitor; MAO, monoamine oxidase inhibitor.

DATA LINKAGES: SRTR-LDC

DATA TO MAKE A DIFFERENCE

Sitemap Contact Us Center Portal Login

About LDC V For Transplant Programs V For Potential Donors V

Making Strides Towards a Difference One dataset at a time

What happens after organ donation?

Whether an organ is given to help save the life of a family

SCIENTIFIC REGISTRY 안 TRANSPLANT RECIPIENTS

CONCLUSIONS

- Use of antihypertensive and diabetes medications increase over time after living kidney donation, while antidepressant use appears stable.
- Linked registry and pharmacy claims data have rich potential to help describe incidence and prevalence of medically treated conditions before and after donation.
- Future work in the Collective will compare pharmaceutical care needs of living donors to needs of controls with similar baseline good health.

