

OPTN/UNOS Living Donor Committee

Report to the Board of Directors

Christie Thomas, MB, FRCP, FASN, FAHA - Chair

Sandra Taler, MD - Vice Chair

St. Louis, MO

November 12, 2012

Living Donor Committee

- Develops policy and guidance related to the donation and transplantation of organs from living donors to recipients.
- Improve the informed choice of prospective living donors, and the safety, protection and follow-up of all living donors.

Change in Living Donation Oversight

June 16, 2006

HHS directive to develop policies regarding living organ donors and organ donor recipients.

- The notice stated:
 - the consequence of centers non-compliance with living donor policy matches that of centers non-compliance with deceased donation policy; and
 - policies should “promote the safety and efficacy of living donor transplantation for the donor and recipient.”

Living Donation Oversight

June 2007

- Policy 7.1.5

The follow-up period for living donors will be a minimum of two years

- Policy 7.3.2

Living Donor Registration Forms (LDR) must be **submitted** to the OPTN within 60 days of the form generation date. ...

The recipient transplant center must **submit** LDF forms for each living donor at six months, one year and two years from the date of donation.

Living Donation Oversight

June 2007

- New Bylaws approved requiring centers to develop and follow their own protocols for living donor:
 - evaluation,
 - preoperative, operative, and post-operative care
 - submission of required follow-up forms
- Centers required to disclose their requirement to:
 - develop a plan to collect the required follow-up information for each donor and submit LDF forms addressing the health information of each living donor at six months, one year, and two years after donation
 - have written protocols with a plan to collect follow-up information about each donor.

Improving LD Follow-up - MPSC

September 2008 –MPSC Living Donor Workgroup on Data Submission Issues. Final recommendations included:

- Enforce a minimum standard for submission of complete LDF forms. The workgroup suggested a minimum initial standard of 75%, to increase over time.
- Require as prescribed in existing policies, that LDF forms must be submitted at 6 months, one-year and two years post donation, and that the forms may not be submitted earlier than 60 days before any of these post-donation intervals

Improving Living Donor Follow-up

June 2009 – Living Donor Data Task Force reported to the Board:

- As currently collected, the OPTN data are incomplete beyond the point when the discharge form is submitted (up to six weeks post donation, but much earlier for most donors) and therefore useless making conclusions about living donor safety or related research
- Require center reporting and completion of data through a limited time interval (discharge through 6-12 months), with the duration dependent on whether funding is made available to the centers; this would strengthen the requirement for centers to report a limited set of data elements.
- The Board took no action on these recommendations

Living Donation Policy Development

November 2009 - the OPTN/UNOS Board resolved that the Committee should develop:

- A policy proposal to **establish a threshold** for acceptable submission of living donor follow-up
- A resource outlining best practices for the submission of living donor follow-up based on its review of high performing programs

Living Donation Policy Development

The Committee identified and surveyed living kidney donor and living liver donor programs with successful follow-up to produce a best practices resource

March 2011 - “Guidance for Developing and Implementing Procedures to Collect Post-Donation Follow-up Data from Living Donor” was offered to living donors programs and is available through the OPTN website.

- The resource has been highlighted in the UNOS Update, and promoted on the Transplant Administrators and Transplant Coordinators List Serves

Living Donation Policy Development

- *Guidance for Developing and Implementing Procedures to Collect Post-Donation Follow-up Data from Living Donor* contains more than 70 best practices which centers could consider for improving living donor follow-up
- The Committee has begun work on a updated best practices for follow-up resource and is again planning to interview the centers with the most successful living donor follow-up through out the country.

Living Donation Oversight

November 2009 - HRSA notified the OPTN that although helpful, the resources developed to date were not sufficient and that policies were still required.

Living Donation Policy Development

April 2010 - Representatives of the ASTS, the AST, NATCO, OPTN/UNOS, and HRSA met to discuss and develop a new process for incorporating clinical input into developing OPTN/UNOS policies with the potential to direct or prescribe medical care.

Living Donation Policy Development

The goal of the new process:

- earlier involvement from the professional societies in any policy that might impact clinical practice;
- quicker policy development; and
- greater acceptance by the transplant community at large.

Living Donation Policy Development

A Joint Societies Policy Steering Committee (comprised of members from the AST, ASTS, NATCO, OPTN/UNOS, and HRSA) would be given an opportunity to make recommendations on any OPTN policy under development that has the potential to prescribe medical care.

The Steering Committee established a Joint Societies Workgroup (JSWG) to make recommendations for living donor consent, medical evaluation, and follow-up policies.

Living Donation Policy Development

- **June 2010** - *Proposal to Improve Reporting of Living Donor Status* released for public comment. Under the proposal centers would be required to report a valid status (alive or dead) for at least 90% of living donors at required post-operative intervals.
- The proposal received favorable public comment.
- The ASTS opposed the proposal and asked that the proposed policy be delayed so it could be based on JSWG recommendations

Living Donation Policy Development

June 2011 - The JSWG completed work on three resources representing the consensus of its members:

- Guidance Document for the Informed Consent of Living Kidney Donors
- Position Paper on the Medical and Psychosocial Evaluation of Living Kidney Donors; and
- Recommendations for Donor Follow-up and Data Submission

Living Donation Policy Development

In response this Committee worked to quickly develop policy proposals for the consent, medical evaluation, and follow-up of living kidney donors for next public comment cycle (September – December 2011)

Living Donation Policy Development

April 2012 – The Committee approved final language for three proposals (consent, medical evaluation and follow-up) and approved the proposals for Board consideration (June 25-26)

June 18, 2012 – The professionals societies objected to:

- “substantive changes” in the proposals
- failure to follow required procedures

The OPTN President agreed to delay Board consideration of the proposals pending further discussion between JSWG and the LD committee.

June 2012 –

OPTN/UNOS Board Approves New Strategic Plan

- Goal 1: Increase the number of transplants
- Goal 2: Increase access to transplants
- Goal 3: Improve survival for patients with end stage organ failure
- Goal 4: Promote transplant patient safety
- Goal 5: Promote living donor safety
- Goal 6: Promote the efficient management of the OPTN

Goal 5: Promote living donor safety

- Adopt new policy for consent of potential living kidney donors
 - Provide training/educational materials on new policies
- Develop policy for consent of potential living liver donors
- Collaborate with other organizations to create and promote information for potential living kidney and liver donors
- Adopt new policy for medical and psychosocial evaluation of potential living kidney donors
 - Provide training/educational materials on new policies
- Develop policy for medical and psychosocial evaluation of potential living liver donors
- Develop program outcome measures (PSRs) for living donor organ recovery

Goal 5: Promote living donor safety

- Consider treating live donor portion of kidney or liver transplant programs as a separate program
- Adopt new policy for medical and psychosocial evaluation of potential living kidney donors
 - Provide training/educational materials on new policies
- Adopt new policy for living kidney donors follow-up
- Develop policy for follow-up of living liver donors.
- Identify and communicate effective member practices regarding living donor follow up
- Determine appropriate methodology for studying long-term outcomes research
 - Determine feasibility of collaborating with other organizations to facilitate long-term outcomes research

Living Donation Policy Development

- **September 2011** – Proposals distributed for public comment
- **June 25, 2012** – ASTS concerns provided to the LD Committee
- **July 6** – AST concerns provided to the LD Committee
- **July 6** – Conference call with the JSWG and LD Committee leadership
- **August 14**- Joint LD Committee and JSWG LiveMeeting
- **September 10** - LD Committee Meeting – JSWG Chair attended and presented

Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up

OPTN policy applicable to all forms

- **7.8 DATA SUBMISSION STANDARD**

- **7.8.1** Each OPO, Transplant Center and Histocompatibility Laboratory must meet the following standard for submission of data collected on all forms to the Transplant Registries: 95% of expected forms **complete** within three months of the due date and 100% of expected forms **complete** within six months of the due date.

Living Donation Policy Development

April 2012 – UNOS Living Donor Kidney Site Survey Update

Most common violations for the fifteen centers surveyed :

- 7 centers did not address the center's requirement to provide donor follow-up.
- 10 centers were unable to provide documentation that they addressed the benefit and need for follow-up with potential
- 2 centers did not address two or more of the required elements (i.e. benefit and need for follow-up, advocating on behalf of the donor)
- One center lacked documentation of an IDA consult for 9 of 10 donor charts examined

JSWG Recommendations for Donor Follow-up and Data Submission

...While 2-year follow-up of living donors should not be expected to yield definitive data regarding the long-term safety of organ donation, the provision of limited data at defined time points provides value. For example, finding abnormal kidney function at one of these time points would be relatively rare but of great importance to both the donor and the transplant community

JSWG Recommendations for Donor Follow-up and Data Submission

An individual's presentation to a transplant center with an interest in living donation should be recognized as the initial stages of a contract between two parties. The patient enters with the promise of an altruistic, selfless, and potentially life-saving gift of an organ for transplantation. The center promotes the safety of living donation and a genuine interest in the health of that individual beyond the date of donation

JSWG Recommendations for Donor Follow-up and Data Submission

Mandatory follow-up at 6 months, 1 year and 2 years following surgery is the transplant community's responsibility to maintaining the public's trust and demonstrating a sincere interest in that contract we share with current and future living donors.

Living Donation Policy Development

Based on OPTN Data

- A relatively small percentage of Living Kidney Donors currently opt out of follow-up, as reported by transplant centers. For living kidney donors who donated between 7/1/09 and 6/30/10, 4.5% of donors who had a 6-month LDF had a patient status of 'Living: Donor contacted, declined follow-up with transplant center', and 7.7% of donors who had a 1-yr LDF declined follow-up.

Original proposal language distributed for public comment

- **12.8.3.1** - Transplant centers that recover living donor organs must report accurate and timely follow-up data on the LDF form for at least 90% of their living kidney donors at the required reporting intervals, which at a minimum must include:

Donor Status

- Patient status
- Cause of death, if applicable and known
- Working for income, and if not working, reason for not working

Original proposal language (2)

- **Kidney Clinical Information**
 - Serum creatinine
 - Urine protein
 - Maintenance dialysis
 - Donor developed hypertension requiring medication
 - Diabetes

Original proposal language (3)

- **Complications**

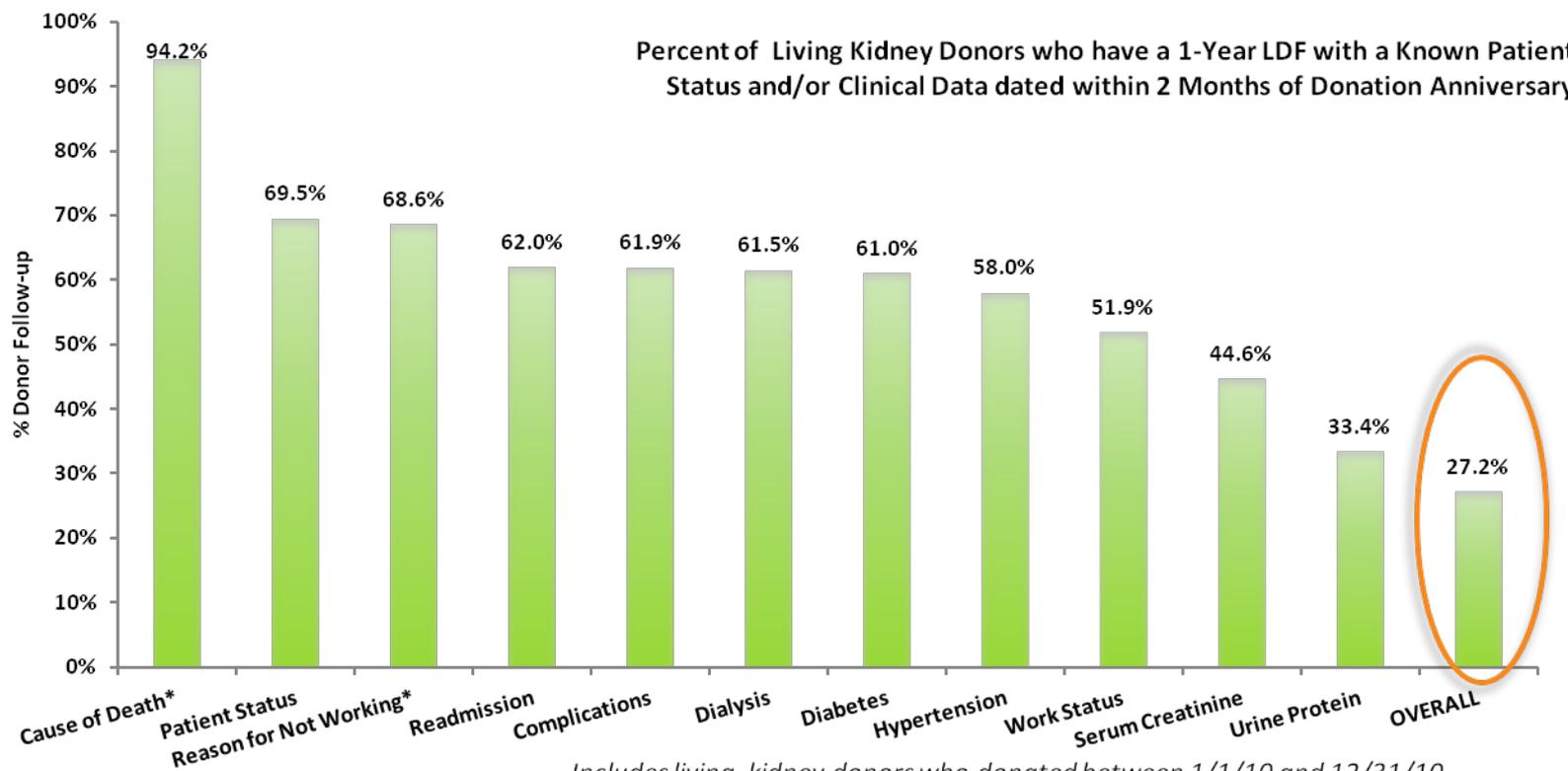
- Has the donor been readmitted since last LDF form was submitted?
- Kidney complications

Living donor follow-up data within 60 days of the six-month, one-year, and two-year anniversary of donation is considered timely.

Follow-up Proposal – Public Comment Results (90% Threshold)

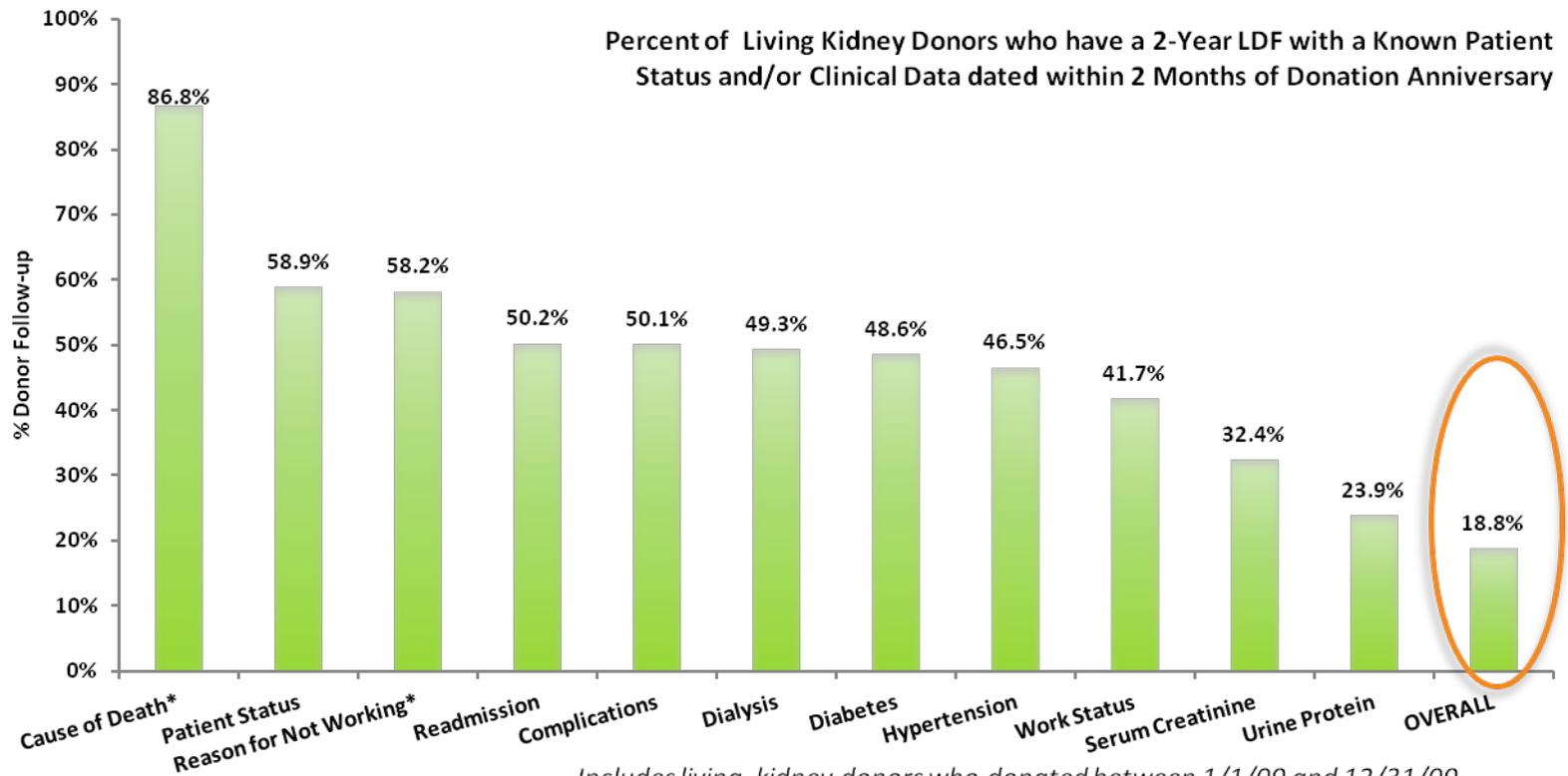
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	102	83 (81.2%)	0 (%)	15 (14.7%)	4 (3.9%)
Regional	11	5 (45.5%)	4 (36.4%)	2 (18.2%)	0
Committee	19	5 (83.3%)	0 (%)	1 (16.6%)	4

Percent of Living **Kidney** Donors who have a Validated **1-Year** LDF Form with a Known Patient Status and/or Clinical Data dated within 2 Months of the Donation Anniversary



Includes living kidney donors who donated between 1/1/10 and 12/31/10.
*If applicable

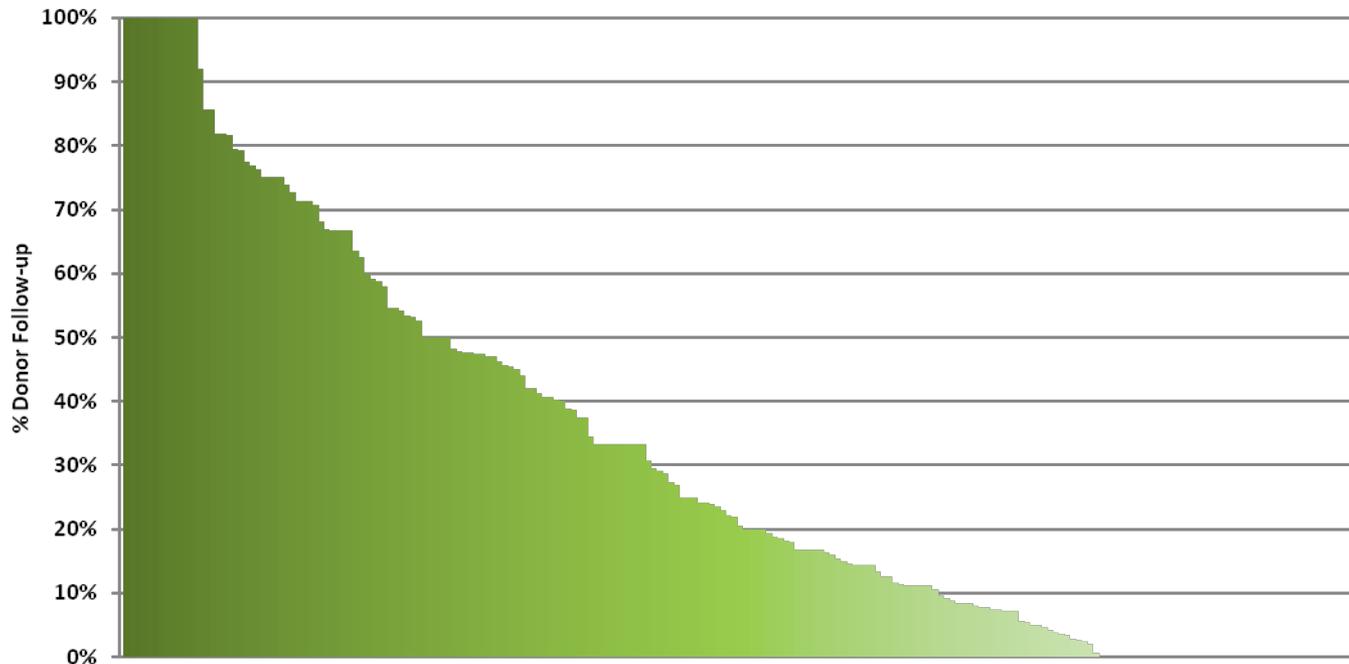
Percent of Living **Kidney** Donors who have a Validated **2-Year** LDF Form with a Known Patient Status and/or Clinical Data dated within 2 Months of the Donation Anniversary



Includes living kidney donors who donated between 1/1/09 and 12/31/09.

*If applicable

Percent of Living **Kidney** Donors who have a Validated **1 Year** LDF Form with a Known Patient Status (Alive or Dead, Not Lost-to-Follow-up) and Clinical Data dated within 2 Months of the Donation Anniversary, by Program



Note: Each bar represents 1 program (N=215). Includes living kidney donors who donated between 1/1/10 and 12/31/10. 45 programs (blank area on right side of graph) reported status and clinical data for 0% of their donors.

April 2012 -LDC Approved Policy Proposal Language for the (June 2012) Board Meeting

- **12.8.3.1**
- Transplant centers that recover living donor organs must report accurate, complete and timely follow-up data on the LDF form for at least: 90% of their living kidney donors at required reporting intervals.
- 70% of their living kidney donors who donate between September 1, 2012 and August 31, 2013;
- 80% of their living kidney donors who donate between September 1, 2013 and August 31, 2014;
- 90% of their living kidney donors who donate beginning September 1, 2014.
- Living donor follow-up data within 60 days of the six-month, one-year, and two-year anniversary of donation is considered timely. The completed data on the LDF at a minimum must include:

April 2012 -LDC Approved Policy Proposal Language for the (June 2012) Board Meeting

- **12.8.3.1** (continued)

- **Donor Status**
 - Patient status
 - Cause of death, if applicable and known
 - Working for income, and if not working, reason for not working
 - Loss of medical (health, life) insurance due to donation

- **Kidney Clinical Information**
 - Serum creatinine
 - Urine protein
 - Maintenance dialysis
 - Donor developed hypertension requiring medication
 - Diabetes

- **Complications**
 - Has the donor been readmitted since last LDF form was submitted?
 - Kidney complications

Living Donation Policy Development

- **September 2011** – Proposals distributed for public comment
- **June 25, 2012** – ASTS concerns provided to the LD Committee
- **July 6, 2012** – AST concerns provided to the LD Committee
- **July 6, 2012** – Conference call with the JSWG and LD Committee leadership
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- **Sept 10, 2012** - LD Committee Meeting – JSWG Chair attended and presented

LDC Approved Policy Proposal Language For Board Consideration (September 2012 Meeting)

▪ 7.2 General Submission of Forms

The Transplant Candidate Registration, Deceased Donor Registration, ~~Living Donor Follow-up~~, Recipient Histocompatibility, Donor Histocompatibility, and Recipient Malignancy Forms must be submitted to the OPTN within 30 days of the form generation date. The Living Donor Follow-up Form must be submitted to the OPTN with 60 days of the form generation date.

LDC Approved Policy Proposal Language For Board Consideration (September 2012 Meeting)

- **12.8.3 Reporting Requirements**

Transplant centers that recover living donor organs must complete the LDR form when the donor is discharged from the hospital or within six weeks following the transplant date, whichever is first. Living Donor Registration Forms (LDR) must be submitted to the OPTN within 60 days of the form generation date. ~~Transplant centers that recover living donor organs must complete the LDR form when the donor is discharged from the hospital or within six weeks following the transplant date, whichever is first.~~ Transplant centers that recover living donor organs must submit LDF forms for each living donor at six months, one year and two years from the date of donation

LDC Approved Policy Proposal Language For Board Consideration (September 2012 Meeting)

▪ 12.8.3.1

Transplant centers that recover living donor organs must submit Living Donor Follow-up (LDF) forms for each living donor at six months, one year, and two years from the date of donation.

The transplant center must report accurate, complete, and timely follow-up data for Donor Status and Clinical Information using the LDF form for at least:

- 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 70% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 80% of their living kidney donors who donate after December 31, 2014.

LDC Approved Policy Proposal Language For Board Consideration (September 2012 Meeting)

- **12.8.3.1 (continued)**
- The transplant center must report accurate, complete, and timely follow-up Kidney Laboratory Data using the LDF form for at least:
 - 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
 - 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
 - 70% of their living kidney donors who donate after December 31, 2014.

LDC Approved Policy Proposal Language For Board Consideration (September 2012 Meeting)

- **12.8.3.1** (continued)
- Donor Status and Clinical Information
 - Patient status
 - Cause of death, if applicable and known
 - Working for income, and if not working, reason for not working
 - Loss of medical (health, life) insurance due to donation
 - Has the donor been readmitted since last LDF form was submitted?
 - Kidney complications
 - Maintenance dialysis
 - Donor developed hypertension requiring medication
 - Diabetes
- Kidney Laboratory Data
 - Serum creatinine
 - Urine protein

LDC Approved Policy Proposal Language For Board Consideration (September 2012 Meeting)

- **12.8.3.1** (continued)
- Living donor follow-up data collected within 60 days of the six-month, one-year, and two-year anniversary of donation is considered timely.
- Follow-up rates will be calculated separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.

Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up

Questions

Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up

- **RESOLVED**, that modifications to Policy 12.8.3.1 (Living Kidney Donor Reporting Requirements), Policies 7.2 (General Submission of Forms), 12.8.3 (Reporting Requirements), and 12.10 (Required Protocols for Kidney Recovery Hospitals) are hereby approved as set forth in Resolution 10, effective February 1, 2013.

Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors

Informed Consent Proposal – Public Comment Results

Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	97	81 (83.51%)	0 (%)	12 (12.37%)	4 (4.12%)
Regional	11	9 (81.8%)	2 (18.2%)	0	0
Committee	6	6 (100%)	0	0	13

Living Donation Policy Development

During public comment, the UNOS Policy Department and Department of Evaluation and Quality identified and provided recommendations to address “technical issues” in the proposals.

- In general, the recommendations were necessary to make the proposed policies monitorable or measurable.
- The Committee made other modifications to the proposals to address common themes identified during public comment

Living Donation Policy Development

- **September 2011** – Proposals distributed for public comment
- **June 25** – ASTS concerns provided to the LD Committee
- **July 6** – AST concerns provided to the LD Committee
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- **September 10** - LD Committee Meeting – JSWG Chair attended and presented

Consent Proposal Modifications

If the recovery hospital and the recipient hospital...	Then...	Including <i>all</i> the following information....
Are the same	The recovery hospital must provide the potential donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent SRTR center-specific reports.	<ol style="list-style-type: none"> 1. National 1-year patient graft survival 2. The hospital's 1-year patient and graft survival 3. Notification about all CMS outcome requirements not being met by the transplant hospital
Will not be the same and the recipient hospital is known	The recovery hospital must provide the potential donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR center-specific reports.	<ol style="list-style-type: none"> 1. National 1-year patient and graft survival 2. The recipient hospital's 1-year patient and graft survival 3. Notification about all CMS outcome requirements not being met by the recipient hospital
Will not be the same, and the recipient hospital is not known	The recovery hospital must provide the potential donor with national program-specific transplant recipient outcomes from the most recent SRTR center-specific reports.	

Consent Proposal Modifications

LDC Approved Policy Language (4/12)

g. Education about expected post-donation kidney function and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the donor in the future to include:

1. Donors will have some permanent loss of kidney function at donation.

Proposed Modification

g. Education about expected post-donation kidney function and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the donor in the future to include:

1. Donors will have a 25-35% permanent loss of kidney function after donation.

Consent Proposal Modifications

JSWG Original Recommendation	LDC Approved Policy Language (4/12)	No Proposed Modification
<p>...The potential donor will need to consent to evaluation, which includes, but is not limited to the following:</p> <ul style="list-style-type: none"> • Disclosure that transplant centers are required to report living donor follow-up information for two years. The agreement of the potential donor to commit to post-operative follow-up testing coordinated by the designated-transplant center a minimum of two years. 	<p>The recovery hospital must obtain informed consent from any potential living kidney donor which must include, but is not limited to, documentation in the donor chart of the following:</p> <p>k. Disclosure that recovery hospitals are required to report living donor follow-up information at the time intervals specified in Policy 12.8.3, and have the potential donor commit to post-operative follow-up testing coordinated by the living donor recovery hospital.</p>	<p>The recovery hospital must obtain informed consent from any potential living kidney donor which must include, but is not limited to, documentation in the donor chart of the following:</p> <p>k. Disclosure that recovery hospitals are required to report living donor follow-up information at the time intervals specified in Policy 12.8.3, and have the potential donor commit to post-operative follow-up testing coordinated by the living donor recovery hospital</p>

New Consent Proposal Modifications

Current Policy Language

12.7.10.1 Vessel recovery and transplant

- The consent forms used by the donor recovery transplant center must include language that indicates that vessels may be used for transplant.
- The vessels from a living donor can only be used for the implantation or modification of a solid organ transplant for the original intended recipient

Proposed Policy Change

12.7.10.1 Vessel recovery and transplant

- A recovery hospital may only recover extra vessels for transplant if the living donor consents to the removal of extra vessels for transplant. ~~The consent forms used by the donor recovery transplant center must include language that indicates that vessels may be used for transplant.~~
- The vessels from a living donor can only be used for the implantation or modification of a solid organ transplant for the original intended recipient.

Amendment to Resolution 11

Resolution 11- Amendment 1

- Line 191, after The living

insert

kidney

- Line 195, after 12.4.1 The IDA must assess the potential

insert

living kidney

Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors

Questions?

Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors

- **RESOLVED**, that modifications to Policies 12.2 (Informed Consent of Living Kidney Donors), 12.4 (Independent Donor Advocates), 12.7.10.1 (Vessel Recovery and Transplant), and 12.10 (Required Protocols for Kidney Recovery Hospitals) are hereby approved as set forth in Resolution 11, effective February 1, 2013.

Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors

Medical Evaluation Proposal – Public Comment Results

Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	96	74 (77.08%)	0 (%)	18 (18.75)	4 (4.17%)
Regional	11	9 (81.8%)	0	2 (18.2%)	0
Committee	7	5(71.4%)	1 (14.2%)	1 (14.2%)	4

Med Eval Proposal Modifications

LDC Approved Policy Language (4/12)	Proposed Modification
<p>J) Screening for transmissible diseases:</p> <p>Infectious disease testing must include:</p> <p>CMV (Cytomegalovirus) Antibody EBV (Epstein Barr Virus) Antibody HIV 1,2 (Human Immunodeficiency Virus) antibody testing HepBsAg (Hepatitis B surface antigen) HepBcAB (Hepatitis B core antibody) HepBsAB (Hepatitis B surface antibody) HCV (Hepatitis C Virus) antibody testing RPR (Rapid Plasma Reagin Test for Syphilis) Screening for Tuberculosis (intradermal PPD or Interferon Gamma Release Assay (IGRA) testing)</p>	<p>Infectious disease testing must include:</p> <p>CMV (Cytomegalovirus) Antibody EBV (Epstein Barr Virus) Antibody HIV 1,2 (Human Immunodeficiency Virus) antibody testing HepBsAg (Hepatitis B surface antigen) HepBcAB (Hepatitis B core antibody) HepBsAB (Hepatitis B surface antibody) HCV (Hepatitis C Virus) antibody testing RPR (Rapid Plasma Reagin Test for Syphilis) Screening for Tuberculosis (intradermal PPD or Interferon Gamma Release Assay (IGRA) testing) <u>For tuberculosis (TB), living donor recovery centers must determine if the potential donor is at increased risk for this infection, and if so testing must include:</u> <u>Screening for latent TB using either intradermal PPD or Interferon Gamma Release Assay (IGRA)</u></p>

Med Eval Proposal Modifications

LDC Approved Policy Language (4/12)	Proposed Modification
<p>K) Cancer screening:</p> <p>Centers must develop protocols consistent with the U.S. Preventive Services Task Force (USPSTF), and once developed follow their own protocols for screening:</p> <ul style="list-style-type: none">Cervical CancerBreast CancerProstate CancerColon CancerSkin CancerLung cancer	<p>K) Cancer screening:</p> <p>Centers must develop protocols consistent with the American Cancer Society (ACS), and once developed follow their own protocols for screening:</p> <ul style="list-style-type: none">Cervical CancerBreast CancerProstate CancerColon CancerSkin CancerLung cancer

Med Eval Proposal Modifications

LDC Approved Policy Language (4/12)

L) EXCLUSION CRITERIA

Transplant programs that perform living kidney donor recoveries may exclude a donor with any condition that, in the Transplant Program's medical judgment, causes the donor to be unsuitable for organ donation.

Transplant programs that perform living kidney donor recoveries must exclude all donors who meet any of the following exclusion criteria:

- Age less than 18 years and mentally incapable of making an informed decision

Proposed Modification

L) EXCLUSION CRITERIA

Transplant programs that perform living kidney donor recoveries may exclude a donor with any condition that, in the Transplant Program's medical judgment, causes the donor to be unsuitable for organ donation.

Transplant programs that perform living kidney donor recoveries must exclude all donors who meet any of the following exclusion criteria:

- **Both** age less than 18 years and mentally incapable of making an informed decision

Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors

Questions?

Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors

- **RESOLVED**, that modifications to Policies 12.3.3 (Psychosocial Evaluation of the Living Kidney Donor) and 12.3.4 (Medical Evaluation of the Kidney Living Donor), and Policy 12.10 (Required Protocols for Kidney Recovery Hospitals) are hereby approved as set forth in Resolution 12, effective February 1, 2013.

Amendment to Resolution 12

Resolution 12- Amendment 1

- Line 227, after *of the living donation process.*

strike

Specific protocols shall include the

- Line 229, after *and two-years post donation*

strike

▪

Proposal to Require Reporting of Unexpected Potential or Proven Disease Transmission Involving Living Organ Donors

Why Change Policy

- Help improve the reporting of disease transmissions involving living donors.
- Would require members to report any unexpected potential or proven living donor-derived disease transmission, including infections or malignancies to the OPTN contractor .

Board-Approved Revisions (Nov. 2010)

Affected policies

- 2.0 -- Minimum Procurement Standards for an Organ Procurement Organization
- 4.0 -- Identification of Transmissible Diseases in Organ Recipients

Included rules for communication and reporting of all unexpected suspected potential or proven transmissions, including infections or malignancies.

Board-Approved Revisions (Nov. 2010)

Confusion over whether the 2010 policy revisions also apply to living donors.

Need for updated policies to clearly require the reporting of unexpected potential or proven transmissions involving living organ donors.

Living Donor-Derived Disease Transmission

Unexpected transmission – a condition that was not known or detected prior to recovery and transplant of a living donor organ

Expected transmission – a condition known prior to transplant

Example: A CMV positive donor donating to a CMV negative recipient who is given prophylaxis to prevent development of the illness.

Living Donor Consent Policy

Needs to be modified because:

- In the proposed policy the timeframe to report potential transmissions is limited to the donor evaluation through organ recovery.
- Under this proposal, the timeframe to report potential transmissions would be expanded from donor evaluation through the first two years post donation.

Reporting Living Donor-Derived Disease Transmission

Potential donors would need to consent that malignancies or infections (relevant to recipient care and identified post transplant) could be reported to:

- local, state or federal public health authorities;
- the OPTN Contractor ; and/or
- disclosed to their organ recipient's transplant center up to two years post donation.

Reporting Living Donor-Derived Disease Transmission

- **RESOLVED**, that modifications to Policies 4.5 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancies) and 12.2 (Informed Consent of Living Donors) are hereby approved as set forth in Resolution 13, effective February 1, 2013.

Living Donor Committee Contacts

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