

# Joint Societies Workgroup Response

## Kidney Living Donor Proposals

### *Living Donor Follow-up*

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Chair, JSWG



# Current state of OPTN Living Donor Follow-up

- There is a great need to improve LD follow-up, and a high bar should be set for donor follow-up in order to improve outcomes and minimize complications
- The JSWG commends the LD committee for their efforts and commitment to improving the follow-up of living donors in order to maximize health and safety and minimize complications
- Unfortunately, performance metrics have been difficult to develop because the data submitted on current Living Donor Follow-up (LDF) forms are too incomplete for analysis, and it is difficult to determine what is feasible as “best practice”



# Current OPTN Living Donor Data Collection Forms

Form submission required, but clinical data not mandated

- Living Donor Registration (LDR) form
  - Due at earlier of discharge or 6 weeks post-donation
- Living Donor Follow-up (LDF) form
  - 6 months
  - 1 year
  - 2 years\*

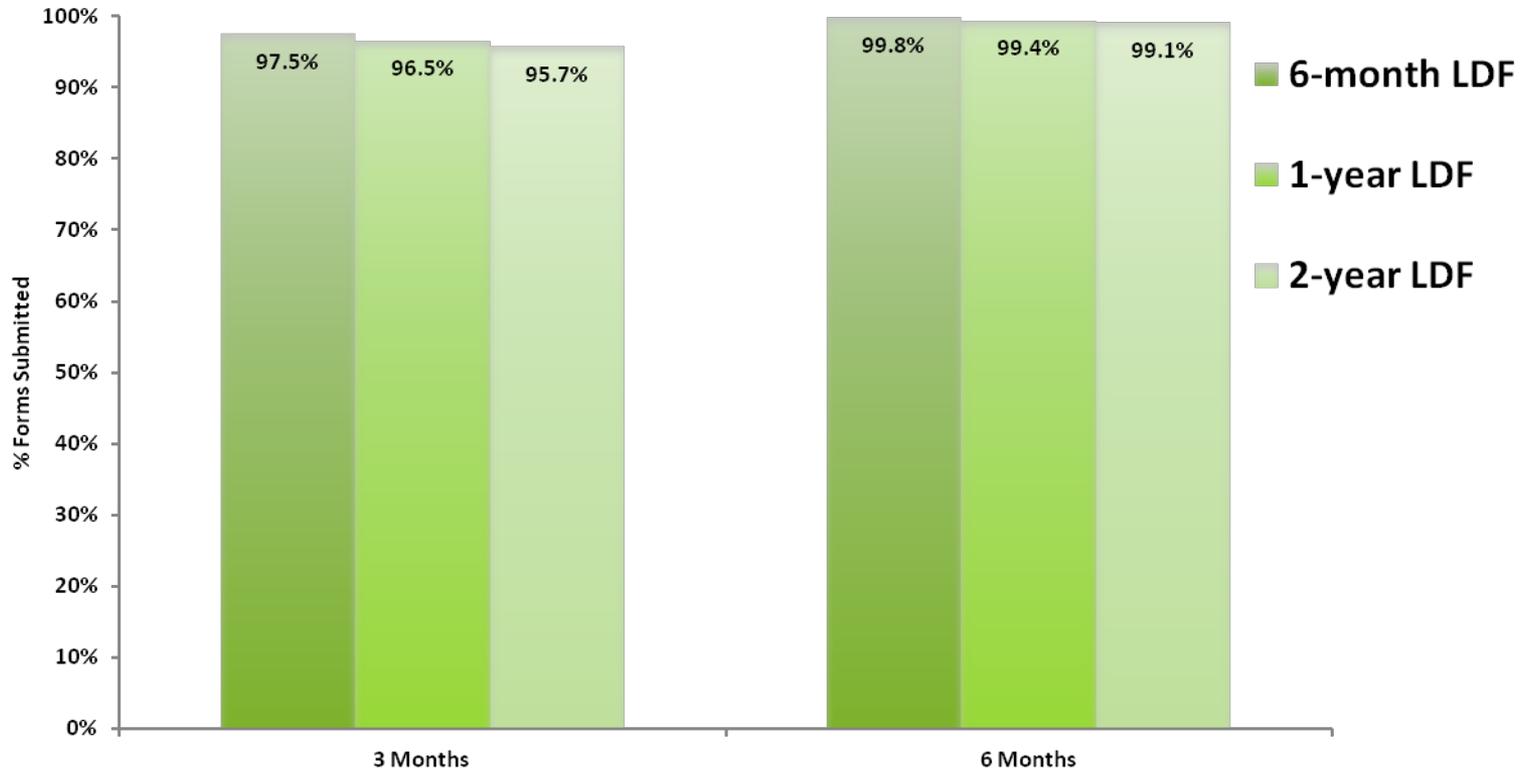
\*required for all living donors after March 2008, first 2 year LDF forms were due March 2010



# Compliance with current OPTN Policy 7.8.1

Centers are very good at submitting FORMS

Percent of living kidney donor forms submitted within 3 and 6 months of due date, as required by OPTN Policy 7.8.1



Cohort for 6-month LDF:

July 1, 2010 – June 30, 2011 (N=5741)

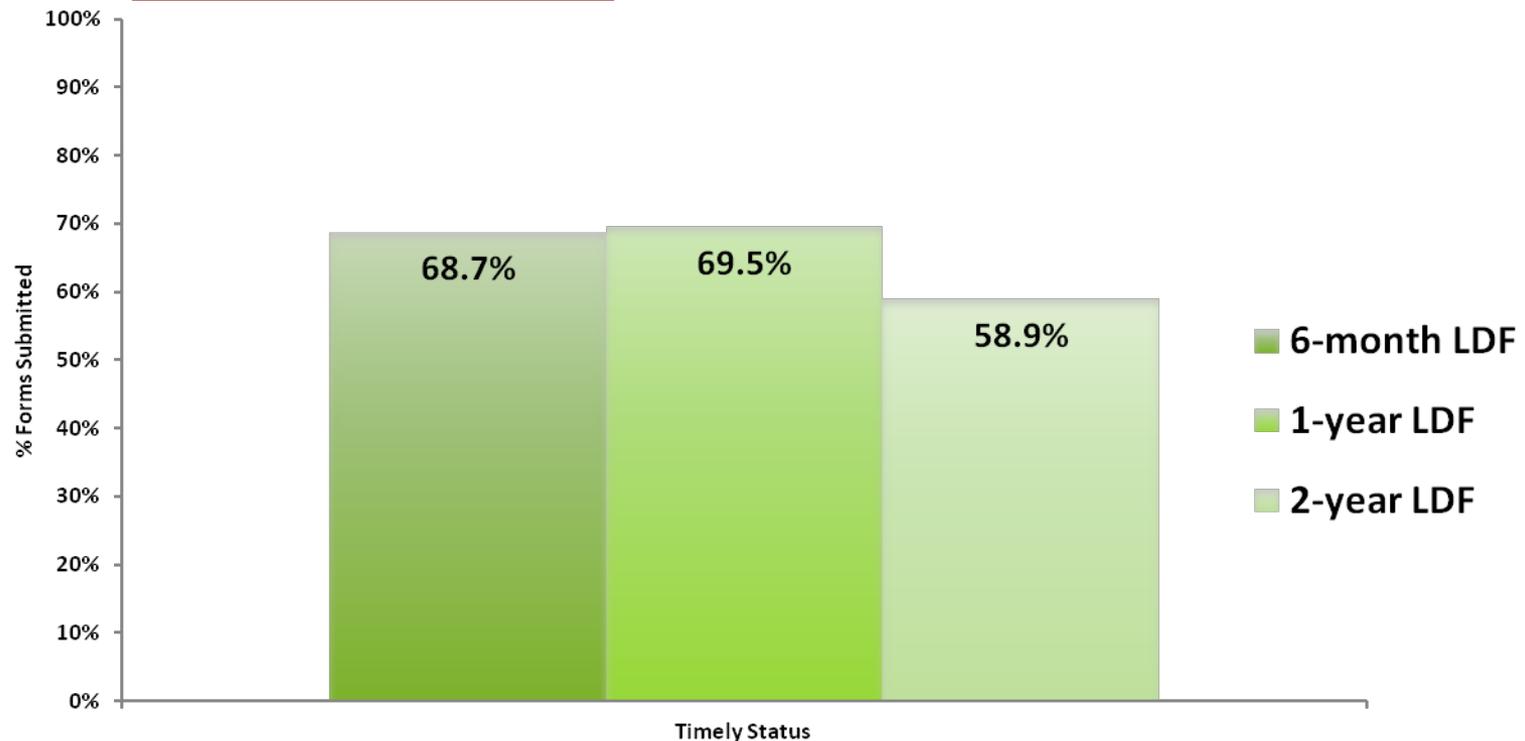
Cohort for 1-year LDF:

January 1, 2010, - December 31, 2010 (N=6007)

# Compliance with OPTN Policy 7.8.1

**KNOWN PATIENT STATUS and Clinical data are not as complete**

Percent of Living Kidney Donors who have LDF with a Known Patient Status and/or Clinical Data dated within 2 Month window



Cohort for 6-month LDF:

July 1, 2010 – June 30, 2011 (N=5741)

Cohort for 1-year LDF:

January 1, 2010, - December 31, 2010 (N=6007)

Cohort for 2-year LDF:

January 1, 2009 – December 31, 2009 (N=6182)

# Living Kidney Donor Proposed Clinical Status Metrics

## Donor Status

- Patient status
- Cause of death, if applicable and known
- Working for income, and if not working, reason for not working
- Loss of Insurance (health, disability, life) related to donation

## Kidney Clinical Information

- **Serum creatinine (lab)**
- **Urine protein (lab)**
- Maintenance dialysis
- Donor developed hypertension requiring medication
- Diabetes

## Complications

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

# Living Kidney Donor Proposed Ramp Up Times for LDF

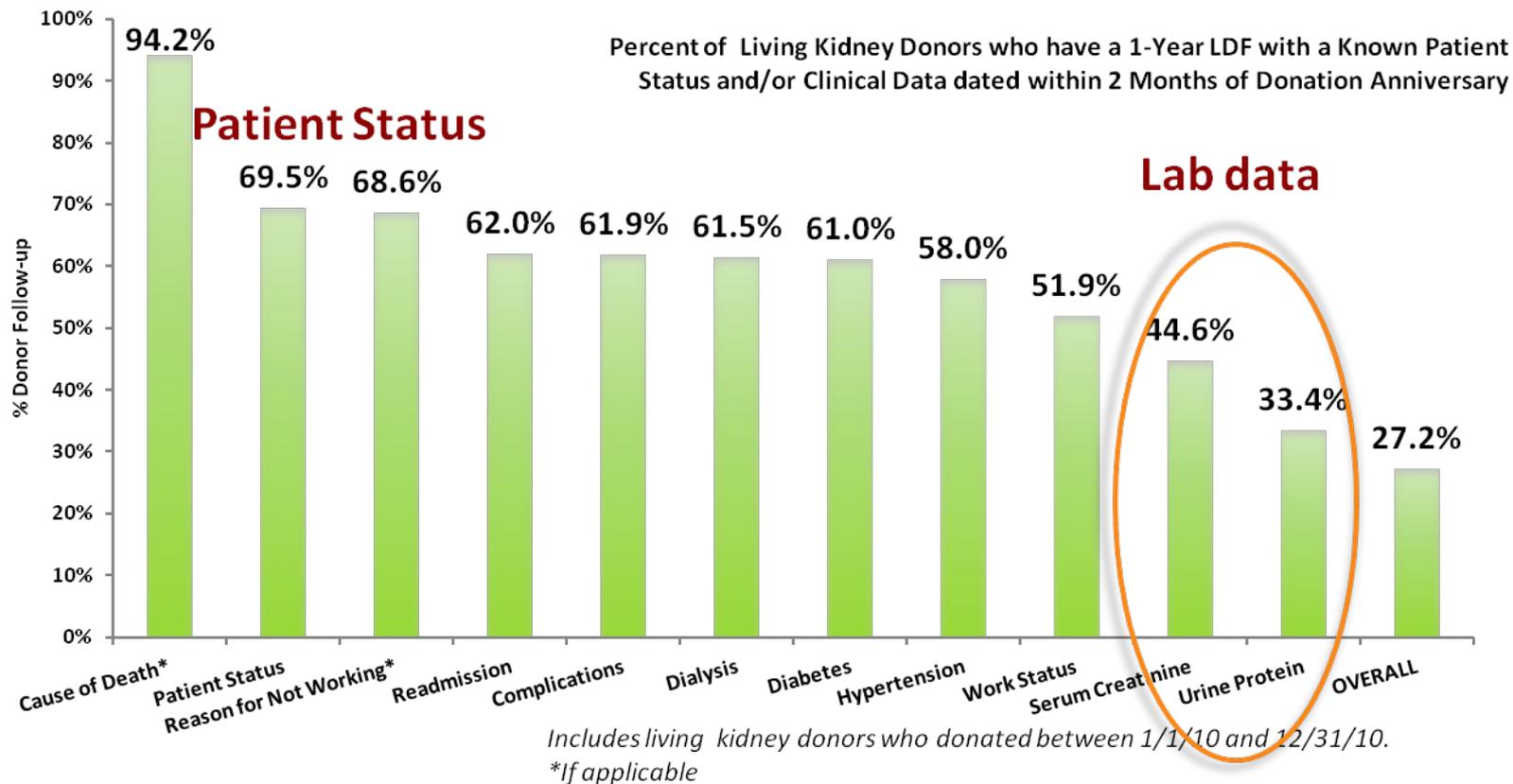
The transplant center must report accurate, complete, and timely follow-up data for Donor Status and Clinical Information using the LDF form for at least:

- **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

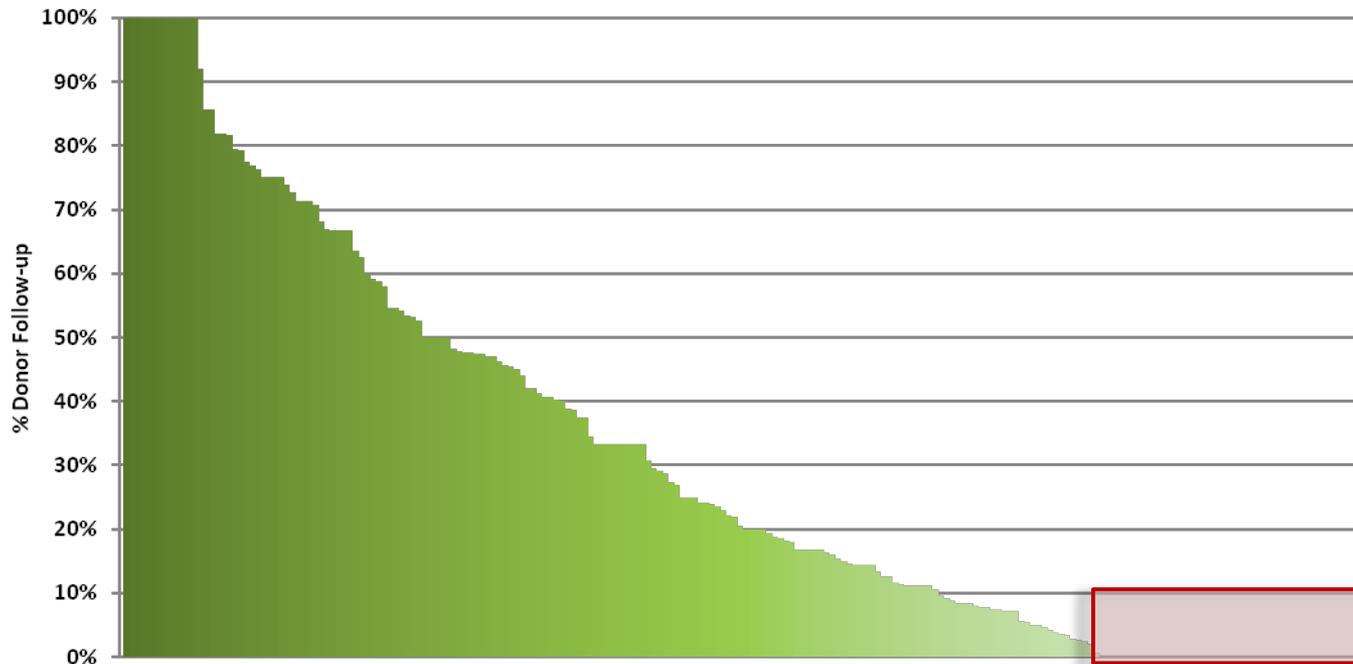
The transplant center must report accurate, complete, and timely follow-up Kidney Laboratory Data using the LDF form for at least:

- **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.

# 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

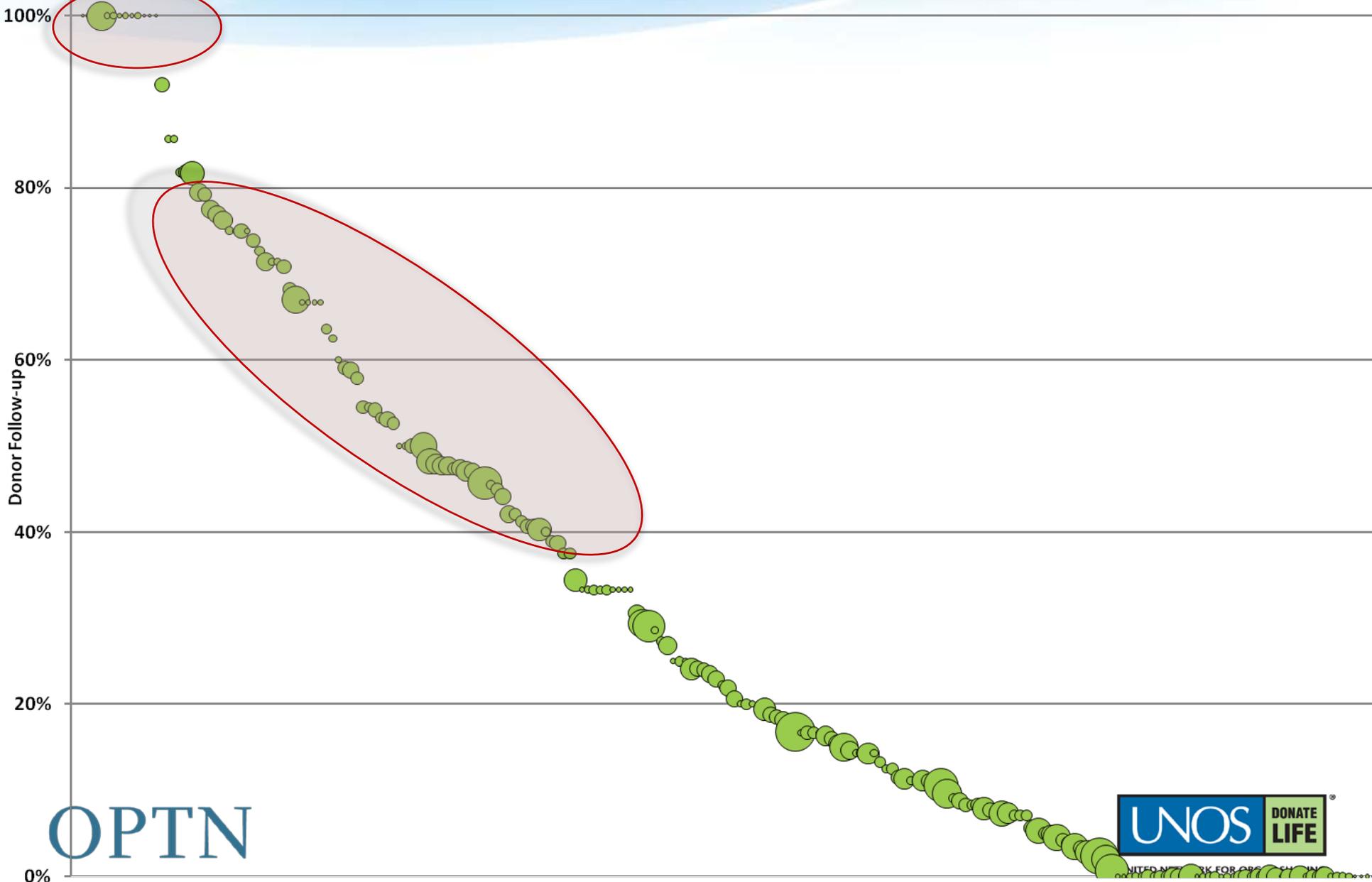


## Percent of Living **Kidney** Donors who have a Validated **1 Year** LDF Form with a Known Patient Status (Alive or Dead, Not Lost-to-Follow-up) and Clinical Data dated within 2 Months of the Donation Anniversary, by Program



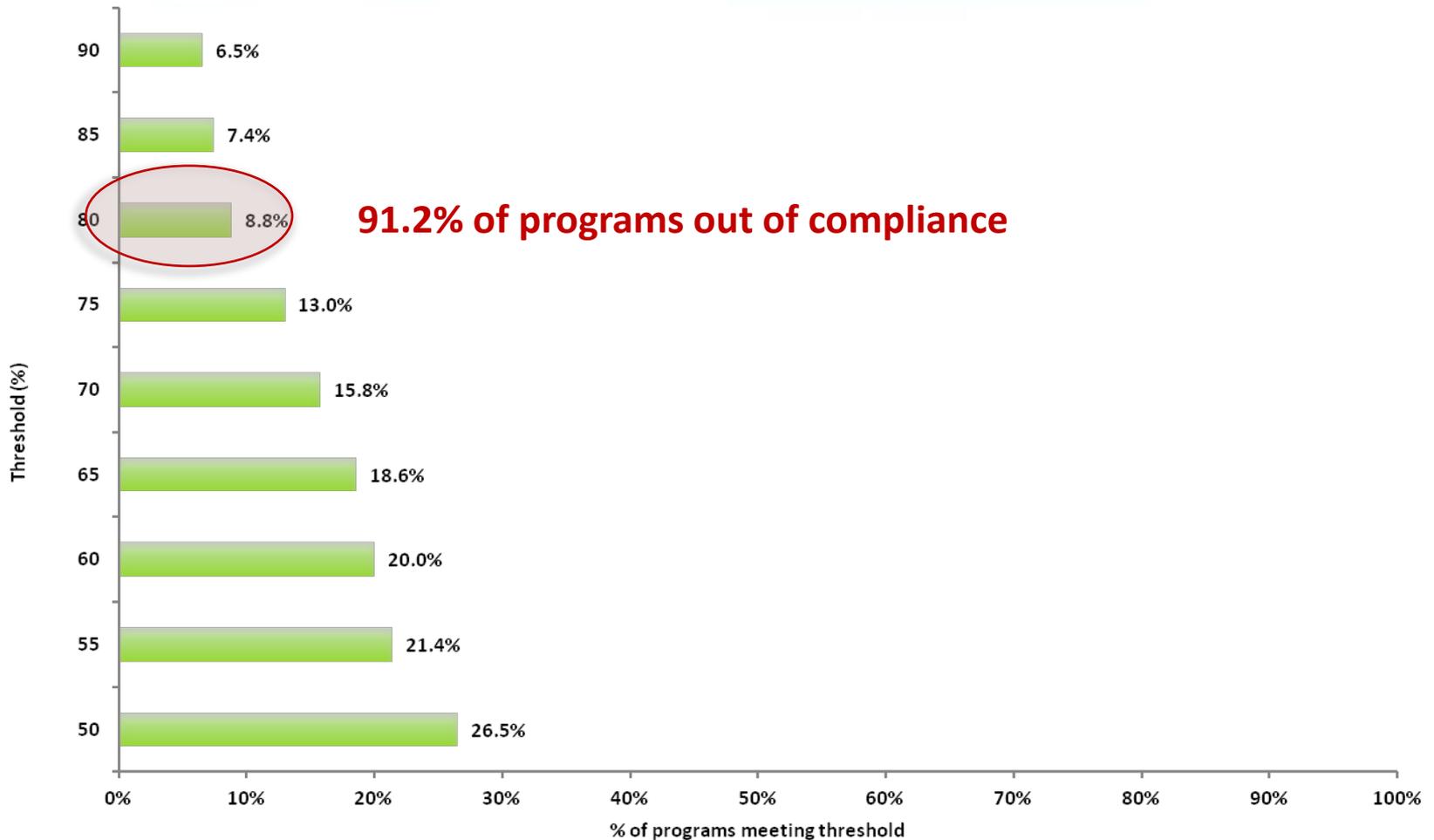
*Note: Each bar represents 1 program (N=215). Includes living kidney donors who donated between 1/1/10 and 12/31/10. 45 programs (blank area on right side of graph) reported status and clinical data for 0% of their donors.*

# Percent of Living Kidney Donors with a 1 Year LDF Form with Clinical Data and a Known Patient Status Dated within 2 Months of the Donation Anniversary by Program Volume *(Living kidney donors who donated in 2010)*

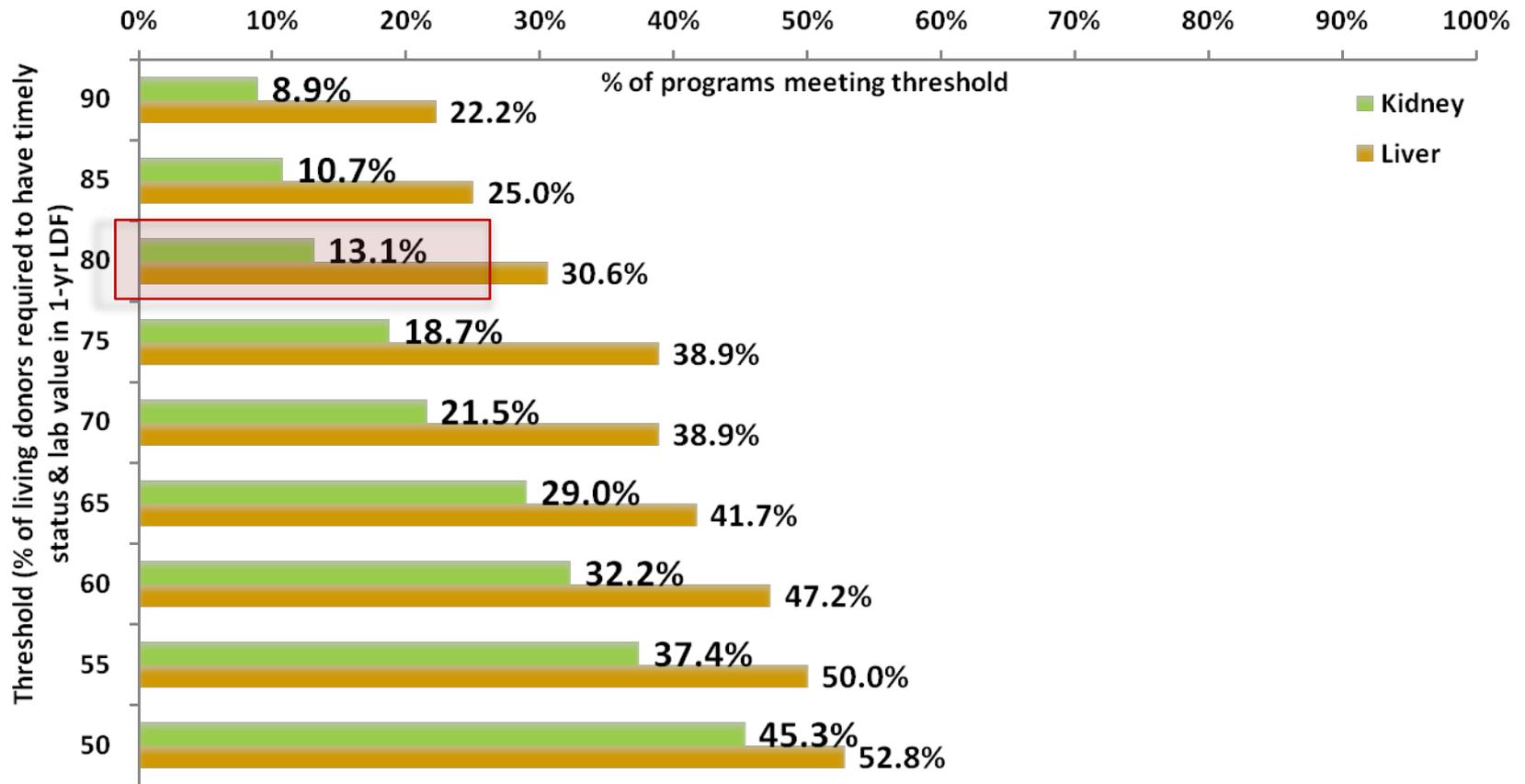


**How would programs fare if the committee's proposed follow-up policy went into effect for living kidney donors today?**

# Percent of Living Donor **Kidney** Programs that meet Various Thresholds for Timely Status & Clinical Data on **1 Year LDF** *(includes living donors between 1/1/10 and 12/31/10)*



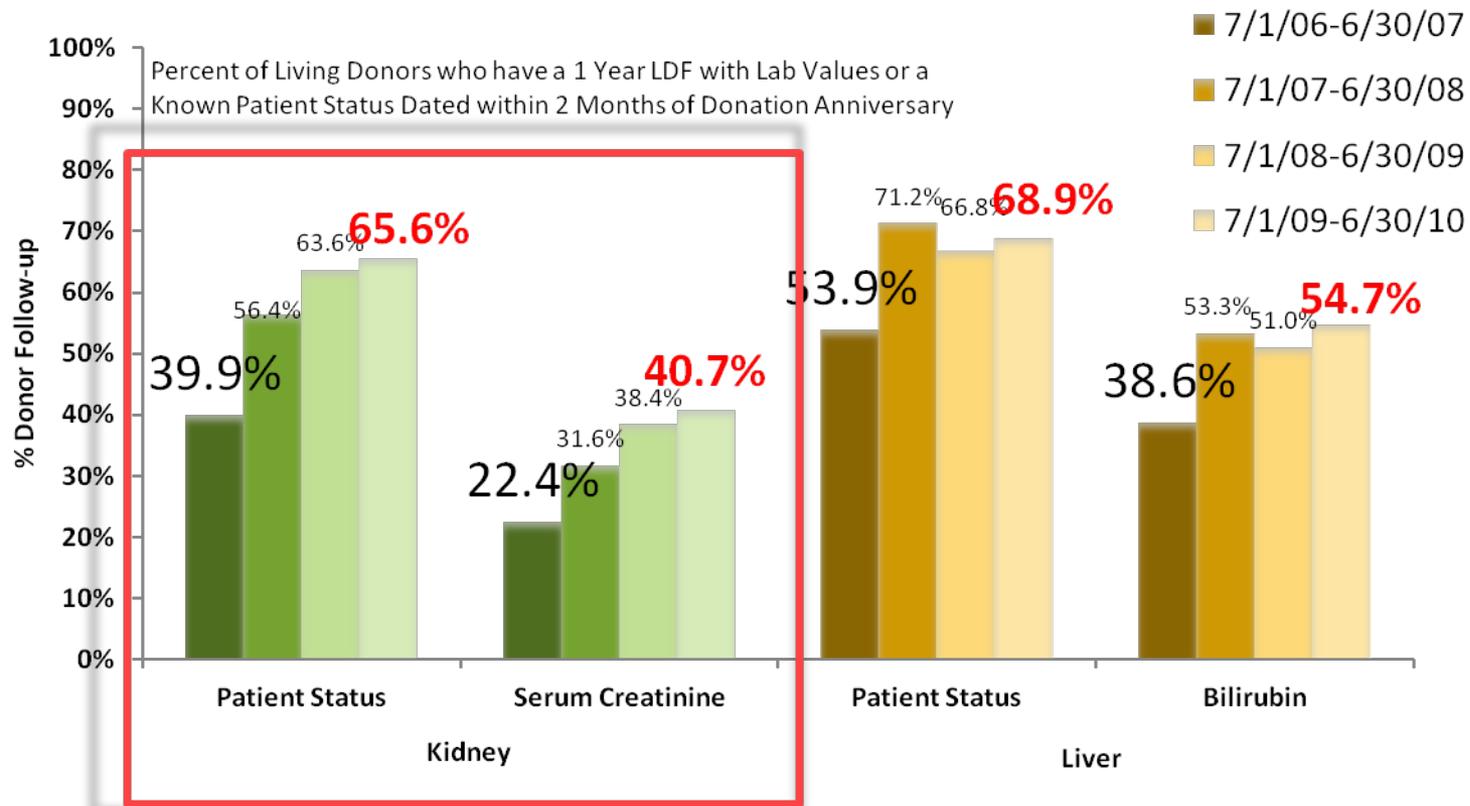
## Percent of Living Donor Liver and Kidney Programs in Compliance (*timely status & lab value*) at Various Thresholds (includes living donors between 7/1/09 and 6/30/10)



# Improvement with Time:

## Still a long way to go

Percent of Living **Kidney and Liver** Donors who have a **1-Year** LDF Form with Lab Values or a Known Patient Status



# How is follow-up with funded coordinators?

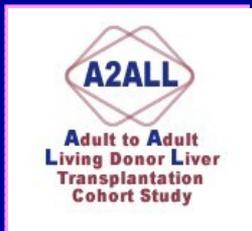
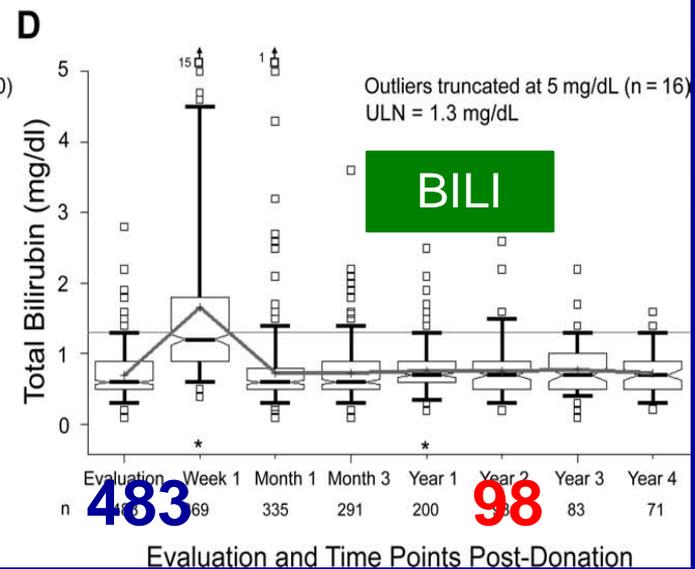
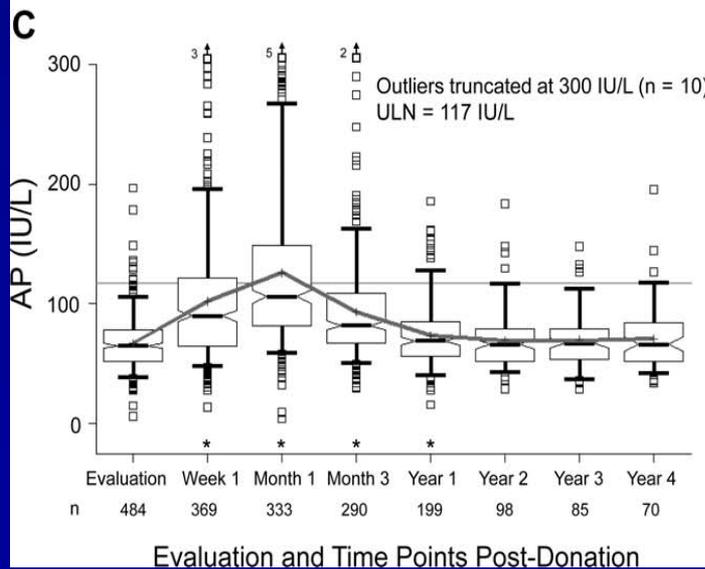
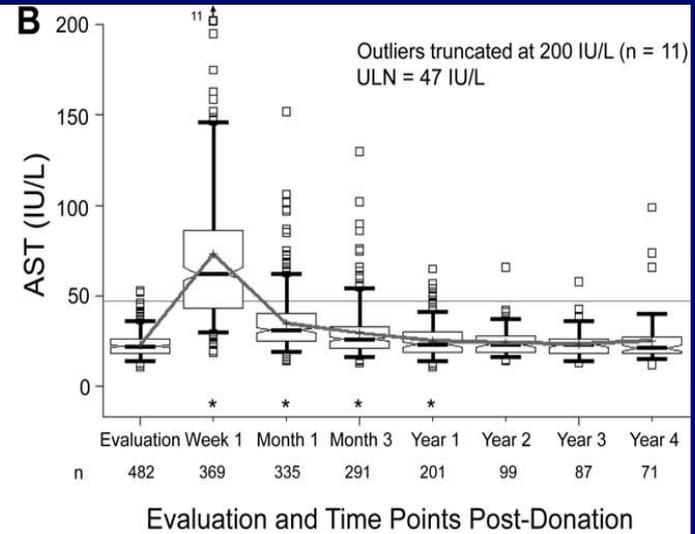
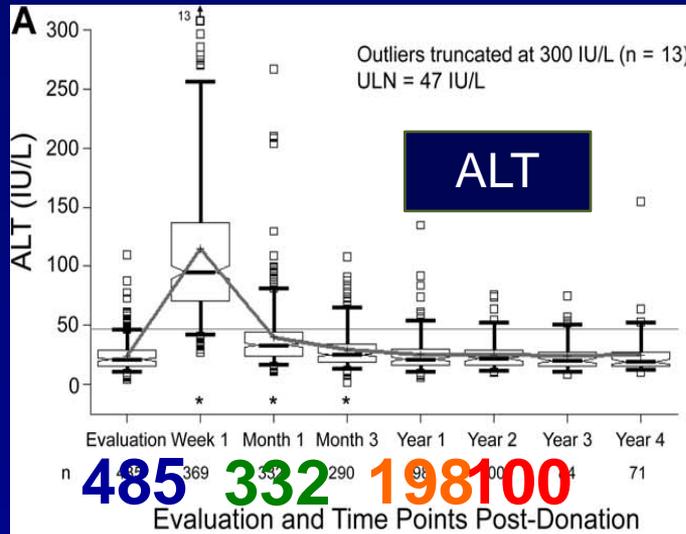


- A2ALL –
  - Adult to Adult Living Donor Liver Transplant Consortium
- 9 centers following LDs over 10 years
- Each center has a full-time funded study coordinator
- Extensive data collected
- Donors sign consent that they will be followed for 10 years



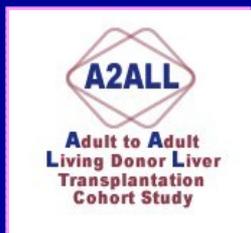
# Donor laboratory follow-up:

*Trotter et al Liver Transpl 2011*



# **A2ALL1 Prospective Cohort Only Laboratory Follow-up**

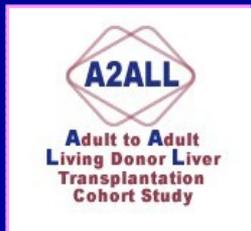
- **173 donors with expected follow-up 2 years post-donation**
  - Defined as having consented before end of 2 year followup window and remaining in the study at the end
- **Only 69 (40%) had at least ONE 2 year labs**
- **Only 33 (19%) had all 2 year labs**



# A2ALL1:

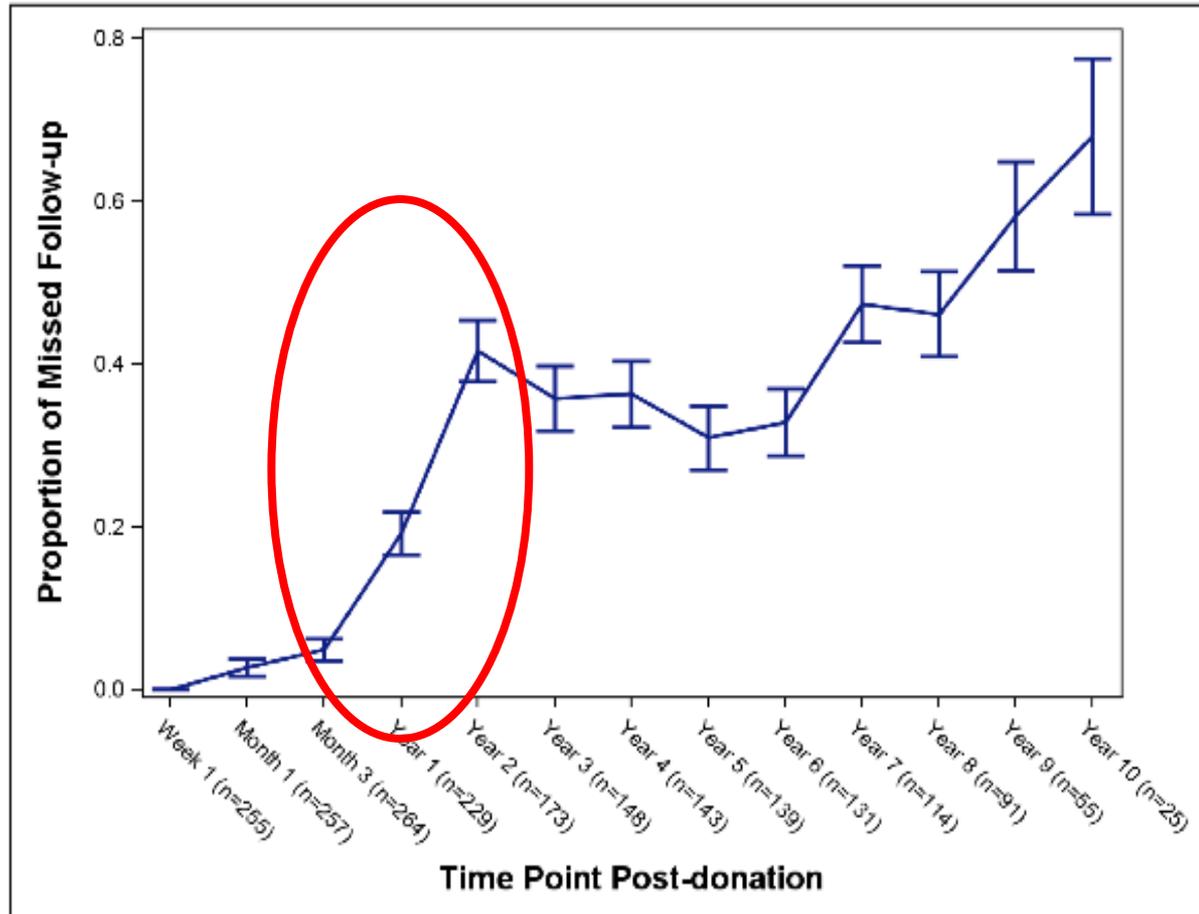
## Reasons for lack of donor follow-up

- 455 LD recruited between 1998-2010
- Missed follow-up defined as no physical, phone, or lab contact with donor *despite center efforts*
- Missed clinic visit defined as no physical contact with donor *at the transplant center*
- Subanalysis to predict probability of missed annual follow-up using 2 QOL measures
  - SF-36 PCS and MCS



# A2ALL: Proportion of missed donor follow-up

Proportion of Missed Follow-up by Time Point



Adult to Adult  
Living Donor Liver  
Transplantation  
Cohort Study

R. Brown et al, Abstract and poster, ATC 2012. Manuscript in progress

# Overall Summary of Current Data

- Centers submit forms, but a significant amount of forms are lacking data
- There are significant issues with data collection from a small proportion of specific centers, whereas other centers demonstrate excellent follow-up
- There is evidence that there are donor issues that are outside of the center's control that prevent them from obtaining labs at required times, despite donor education and significant center efforts
- Donor follow-up decreases the further out from donation

# Concern about monitoring, evaluation, and corrective action

- During onsite reviews, DEQ site surveyors review a sample of a center's follow-up forms for 6 months, 1 year and 2 years. Site surveyors verify information submitted on the form with medical record documentation.
- The DEQ will request a corrective action if the transplant center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee
- ***What will be the MPSC response to the many centers that do not meet the threshold for donor clinical status or lab data?***



# JSWG Impression

- Wholeheartedly agrees that significant improvement in LD follow-up is absolutely necessary, and ideally should occur with 100% of donors. The current situation is unacceptable and needs to be corrected.
- It must be recognized that there will be donor drop-out over time due to issues outside of center control
  - Donor expense, time, interest
  - Clinical data and labs obtained outside determined window
  - Respecting donor autonomy



# JSWG Impression

- It also must be recognized that improved follow-up will take significant resources at transplant centers and may take significant time to find financial resources and put processes in place
- It is not known how many centers will be “out of compliance,” nor is it known what the consequences of this will be with regard to center closure, decreased transplants, media response, etc



# JSWG Recommendations

- Recommend clarification on what “required follow-up data for donor status and clinical information” means.
  - Could this be done with mailed surveys, phone calls, etc, rather than a clinic visit?
  - An option of “patient refused” or “patient opt-out” must be included.
- Recommend a lower threshold for lab collection due to lack of evidence regarding association of “kidney laboratory tests” and long-term outcome. Potential risk that such testing could lead to unanticipated medical complications or insurability problems.

# JSWG Recommendations

- Recommend a longer “ramp-up” period so that centers have time to implement processes and obtain resources from their centers; from three to five years.
- Recommend decreasing requirements with time out from donation, with higher threshold at 6 months but significantly lower at 2 years.
- Develop “best practices” by learning from centers that have been successful, and identify their successful strategies and how to implement them.



# THANK YOU

- QUESTIONS?

