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Rates of Living Kidney Donor Follow-up: Findings from the KDOC Study

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Implemented in 2013, Organ Procurement and Transplant Network (OPTN) Policy 18 requires transplant programs to submit complete, accurate and timely clinical (patient status, working status, insurance status, readmission, kidney complications, dialysis status, hypertension requiring medication, diabetes, and cause of death, if applicable) and laboratory (serum creatinine, urine protein) data within 60 days of the 6-, 12-, and 24-month anniversary of living kidney donor (LKD) nephrectomy.¹ A program is noncompliant if any required element is missing or if elements were not collected ± 60 days of the anniversary date for each of the follow-up time points.

The Kidney Donor Outcomes Cohort (or KDOC) Study ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01427452) Identifier: NCT01427452) is an NIDDK-funded multi-center, prospective, observational cohort study that examined surgical, medical, functional, psychosocial, and cost outcomes of 193 LKDs. Study procedures and characteristics of the LKD cohort (n=193) are described elsewhere.² LKDs agreed to follow-up questionnaire assessments and laboratory testing at the transplant center, primary care physician's (PCP) office, or local laboratory at pre-donation and at 1, 6,

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Disclosure

The authors declare no conflicts of interest.

12, and 24 months post-donation. While our *a priori* objective was to collect the data ± 60 days of the assessment time point (ie, same as OPTN policy requirement), we accepted data outside of this time window. We examined rates of clinical and laboratory data capture for this cohort and identified associations between LKD characteristics and missing/incomplete data.

Of the 6,369 possible clinical and laboratory data points targeted for collection (11 clinical and laboratory elements $\times$ 193 LKDs $\times$ 3 follow-up assessments), we successfully captured 64% ($n=4,734$) within the targeted ± 60 day data collection window (79% for clinical information and 54% for laboratory data). An additional 772 data points were collected beyond the ± 60 day target, resulting in a final data collection proportion of 86% overall ($n=5,506$; 91% for clinical information and 68% for laboratory data).

The percent of LKDs for whom we had complete, partial, or no information for clinical and laboratory elements at the follow-up time points is summarized in Figure 1a and 1b, respectively. All clinical information elements were gathered within the ± 60 day window for 56%, 48%, and 43% of LKDs at 6, 12, and 24 months post-donation, respectively. However, substantially more LKDs had complete data if we included data collected outside the ± 60 day window: 75% at 6 months, 75% at 12 months, and 75% at 24 months. Both laboratory elements (serum creatinine and urine protein) were collected within the ± 60 day window for 44%, 45%, and 36% of LKDs at 6, 12, and 24 months post-donation, respectively. However, moderately more LKDs had both serum creatinine and urine protein results if we extend the data collection window beyond ± 60 days: 53% at 6 months, 55% at 12 months, and 43% at 24 months. In almost all instances of only partial laboratory data, serum creatinine was collected but not urine protein.

In the logistic regression model, none of the LKD baseline characteristics were significantly associated with missing or incomplete data at any of the three follow-up assessments. LKDs with missing/incomplete clinical and laboratory data at the 6-month time point were more likely to have missing data at the subsequent 12-month (aOR vs complete data at 6-month time point = 4.73; 95% CI = 2.49, 9.27) and 24-month (aOR vs. complete data at 6-month time point = 5.72; 95% CI = 2.92, 11.65) follow-up assessments.

OPTN Policy 18 requires both complete and timely collection of clinical information and laboratory data for 80% and 70% of LKDs, respectively. Despite the NIH-funded resources available to us, the *a priori* strategies we implemented to maximize data collection, and the eventual high proportion of data elements captured for most LKDs enrolled in the study, as a consortium we would not have fared well in meeting these policy requirements. While we had clinical and laboratory data on the majority of LKDs, respectively, we did not have complete data on the required proportion of donors (80% and 70%, respectively). Also, a moderately high proportion of clinical and laboratory data were not captured within the targeted ± 60 days of the follow-up time point.

Although we were collecting data for research purposes and our study was conducted prior to full policy implementation, our inability to meet policy requirements is generally consistent with what others have found and reported nationally.^{3,4} More than half of all

kidney transplant programs in the United States are noncompliant with Policy 18 for at least one of the required follow-up thresholds (i.e., 6, 12, or 24 months).⁵ Barrier to collecting LKD follow-up data include donor inconvenience, cost, competing programmatic priorities, and insufficient staffing levels.^{6,7}

Novel strategies are needed to increase data collection within the required time window. Maximizing data collection at the 6-month assessment should be a focus since the odds of missing or incomplete data are 4.7 and 5.7 times greater at the 12- and 24-month assessments for LKDs with missing data at this earlier time period. Research is needed to develop and evaluate such strategies; especially as the transplant community moves toward more routine longer-term follow-up of LKDs.⁸ In addition to recommendations that can be acted upon at the program level, LKDs would best be served by a coordinated national initiative to increase the collective rate of LKD follow-up in the United States. This might include the development of mobile data collection platforms, the use of in-home sample collection and testing kits, formal OPTN partnerships with national corporations with community-based health or laboratory clinics, and changes to Medicare to provide coverage for routine donor follow-up surveillance. Finally, considering the resource-intensive nature of follow-up data collection, the transplant community should consider re-evaluating Policy 18 definitions and requirements, particularly the definition of “complete and timely” data collection as it pertains to program compliance. While not the focus of the KDOC study, we can infer from our findings that expanding the data collection window (particularly for the annual assessments) and distinguishing programs with partially complete or complete data from those with no follow-up data is likely to increase Policy 18 compliance overall.

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Figure 1. Percent of living kidney donors in the KDOC study with no, partial, or complete clinical information collected within (a) or without consideration of (b) the targeted ± 60 days of the 6-, 12-, and 24-month follow-up.