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

James R. Rodrigue, PhD,[1,2] Aaron Fleishman, MPH,[1] Claire M. Sokas, MD,[1,2] Jesse D. Schold, PhD,[3] Paul Morrissey, MD,[4] James Whiting, MD,[5] John Vella, MD,[5] Liise K. Kayler, MD,[6] Daniel Katz, MD,[7] Jody Jones, PhD,[7] Bruce Kaplan, MD,[8] Martha Pavlakis, MD,[1,2] and Didier A. Mandelbrot, MD[9]

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 Identifier: NCT01427452) is a National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK)-funded multicenter, 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 office, or local laboratory at predonation and at 1, 6, 12, and 24 months postdonation. 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 6369 possible clinical and laboratory data points targeted for collection (11 clinical and laboratory elements × 193 LKDs × 3 follow-up assessments), we successfully captured 64% (n = 4734) 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 = 5506; 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 B, 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 postdonation, 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 postdonation, 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 3 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 (adjusted odds ratio [aOR] versus complete data at 6-month time point = 4.73; 95% confidence interval, 2.49-9.27) and 24-month (aOR versus complete data at 6-month time point = 5.72; 95% confidence interval, 2.92-11.65) follow-up assessments.

Received 27 February 2019.

Accepted 3 March 2019.

[1] *Department of Surgery, Beth Israel Deaconess Medical Center, Boston, MA.*

[2] *Departments of Surgery and Medicine, Harvard Medical School, Boston, MA.*

[3] *Department of Quantitative Health Sciences, Cleveland Clinic, Cleveland, OH.*

[4] *Transplant Center, Rhode Island Hospital, Providence, RI.*

[5] *Maine Transplant Center, Maine Medical Center, Portland, ME.*

[6] *Department of Surgery, Regional Center of Excellence for Transplantation & Kidney Care, Erie County Medical Center, University of Buffalo, Buffalo, NY.*

[7] *Department of Surgery, Organ Transplantation Program, University of Iowa Hospitals and Clinics, Iowa City, IA.*

[8] *Transplant Services, Baylor Scott and White Health, Temple, TX.*

[9] *Department of Medicine, University of Wisconsin, Madison, WI.*

The authors declare no conflicts of interest.

The preparation of this manuscript was supported by Award No. R01DK085185 from the National Institute of Diabetes and Digestive and Kidney Diseases. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Diabetes and Digestive and Kidney Diseases or the National Institutes of Health.

Correspondence: James R. Rodrigue, PhD, Department of Surgery, Beth Israel Deaconess Medical Center, 110 Francis St, 7th Floor, Boston, MA 02215. (jrrodrig@bidmc.harvard.edu).

ISSN: 0041-1337/19/10307-e209

DOI: 10.1097/TP.0000000000002721

<zdoi;10.1097/TP.0000000000002721>

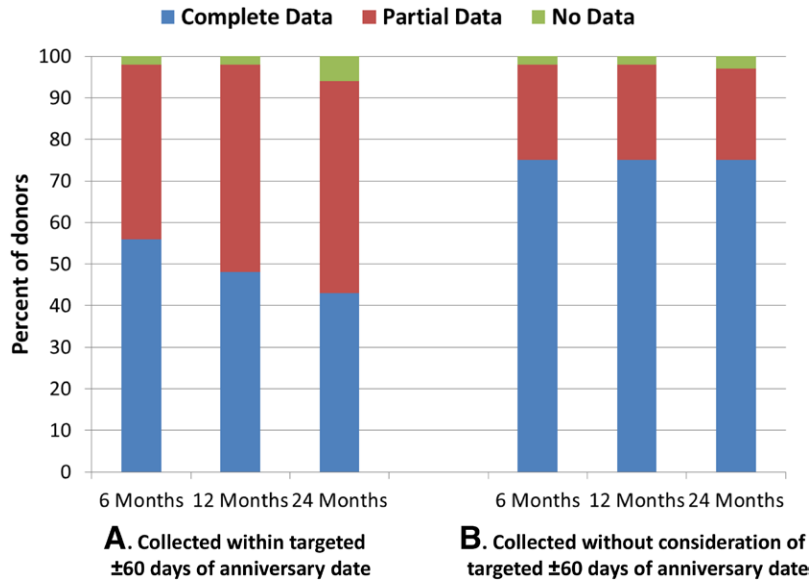

FIGURE 1. Percent of living kidney donors in the KDOC study with no, partial, or complete clinical information collected within (A) or without consideration of (B) the targeted ±60 days of the 6-, 12-, and 24-mo follow-up. KDOC, Kidney Donor Outcomes Cohort.

OPTN Policy 18 requires both complete and timely collection of clinical information and laboratory data for 80% and 70% of LKDs, respectively. Despite the National Institutes of Health (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 before 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 1 of the required follow-up thresholds (ie, 6, 12, or 24 mo).[5] Barriers to collecting LKD follow-up data includes 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 because 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 reevaluating 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 are likely to increase Policy 18 compliance overall.

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