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Patient-Reported Outcomes Following Living Kidney Donation: A Single Center Experience

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Abstract This article describes the development and implementation of an initiative at one transplant center to annually assess psychosocial outcomes of living kidney donors. The current analysis focuses on a cohort of adults (n = 208) who donated a kidney at BIDMC between September 2005 and August 2012, in which two post-donation annual assessments could be examined. One and two year post-donation surveys were returned by 59 % (n = 123) and 47 % (n = 98) of LKDs, respectively. Those who did not complete any survey were more likely to be younger ($p = 0.001$), minority race/ethnicity ($p < 0.001$), and uninsured at the time of donation ($p = 0.01$) compared to those who returned at least one of the two annual surveys. The majority of donors reported no adverse physical or psychosocial consequences of donation, high satisfaction with the donation experience, and no donation decision regret. However, a sizable minority of donors felt more pain intensity than expected and recovery time was much slower than expected, and experienced a clinically significant decline in vitality. We describe how these outcomes are used to inform clinical practice at our transplant center as well as highlight challenges in donor surveillance over time.

Keywords Living donation · Kidney donation · Psychosocial · Outcomes

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Abbreviations

BIDMC	Beth Israel Deaconess Medical Center
BMI	Body mass index
LKD	Living kidney donor
NLDAC	National Living Donor Assistance Center
OPTN	Organ Procurement and Transplantation Network
QAPI	Quality Assessment and Performance Improvement
RCI	Reliable Change Index
UNOS	United Network for Organ Sharing

Introduction

Living kidney donors (LKDs) account for one-third of all kidney transplants performed in the United States in the last three decades (Organ Procurement and Transplantation Network, OPTN, 2014). Despite the relative importance of LKDs to the transplant patient (better outcomes), transplant program (higher transplant volume), and society at large (healthcare cost savings), their health and well-being beyond the initial post-operative recovery are not routinely monitored. Favorable long-term donation outcomes, lack of insurance coverage, and perceived inconvenience to the donor are only a few of the many barriers to long-term follow-up assessment of LKDs (Leichtman et al., 2011; Mandelbrot et al., 2009; Waterman et al., 2013).

Beginning in 1999, the United Network for Organ Sharing (UNOS) required transplant programs to report clinical information (e.g., death, hospital readmissions, onset of hypertension or kidney disease) and laboratory data (e.g., serum creatinine, urine protein or protein-creatinine ratio) about LKDs at post-operative discharge and

again at 6 and 12 months post-donation. The regulation was amended in 2007 to include an additional data reporting requirement at 24 months post-donation. Since transplant programs were allowed to report that LKDs were "lost to follow-up" and still be in compliance with the regulation, there was little incentive to systematically track the health and well-being of LKDs. Consequently, in 2011 the transplant community issued a strong consensus recommendation to develop better follow-up care processes for LKDs (Leichtman et al., 2011). This was followed in 2013 by a modification to UNOS regulations making the collection and reporting of follow-up data mandatory for the majority of LKDs. These events are likely to propel the implementation of more comprehensive follow-up practices by transplant programs.

The psychosocial health of LKDs increasingly has been the focus of the transplant community (Clemens et al., 2006). In the last 50 years, research has progressed from a narrow focus on identification of psychopathology in LKDs (1960s–1980s) to retrospective and cross-sectional studies of quality of life, emotional distress, and relationship issues (1980s–2000s) to more sophisticated multi-center prospective studies of psychosocial outcomes (2000s to present). Currently, the conceptualization of optimal psychosocial health in LKDs includes perceived benefits of donation, decision stability, healthy donor-recipient relationship, and limited financial impact (Dew & Jacobs, 2012). Collectively, study findings and broader conceptualization of donor outcomes have led to improvements in informed consent (Parekh et al., 2008; Thiessen, Kim, Formica, Bia, & Kulkarni, 2013) and psychosocial evaluation (Dew et al., 2007; Schroder, McDonald, Etringer, & Snyders, 2008) processes for potential LKDs, as well as the inclusion of two psychosocial outcomes (donor work status, loss of insurance due to donation) as part of the UNOS-mandated LKD follow-up requirements.

Despite the increased attention on psychosocial health following living donation, it is not entirely clear how individual transplant programs are monitoring such outcomes for their donors. It is important for transplant programs to track LKD psychosocial outcomes for several reasons. First, while LKD psychosocial outcomes are generally very favorable, a minority of donors do report psychological distress, problems in the relationship with the recipient, and financial consequences as a result of donation (Clarke et al., 2006; Dew & Jacobs, 2012; Papachristou, Walter, Schmid, Frommer, & Klapp, 2009). By assessing psychosocial outcomes, transplant programs can identify and respond to any problems as they develop for individual LKDs. Dissatisfaction or adverse donation outcomes, if unaddressed, may lead to significant distress for the donor and violate the "do no harm" principle. Second, existing knowledge pertaining to the long-term psychosocial outcomes of LKDs is based largely on donors who were young, biologically related to the recipient, and without pre-existing medical or psychological comorbidities. In more recent years, transplant programs have expanded eligibility criteria to include LKDs with isolated medical (e.g., hypertension, obesity) and psychological (e.g., history of depression or substance abuse/dependence) complexities, those without health insurance, and those who are more biologically and emotionally distant from the recipient (Mandelbrot et al., 2007; Rodrigue et al., 2007). These factors may increase risk for a poor psychosocial outcome following donation. Third, increased understanding of psychosocial outcomes—both favorable and unfavorable—can be integrated into the evaluation consent process for prospective donors and also be disseminated to transplant candidates who are considering talking to others about living donation.

In this paper, we report the development and implementation of an initiative at Beth Israel Deaconess Medical Center (BIDMC, Boston, Massachusetts) to assess LKD psychosocial outcomes annually. We provide data on these outcomes and describe how they are used to inform clinical practice and quality assessment and performance improvement (QAPI) activities at our transplant center.

Methods

In October 2005, the Transplant Institute at BIDMC hired a full-time clinical health psychologist (JRR) to expand behavioral health services for solid organ transplant patients and living donors. In this context, one initiative focused on developing and implementing a process for routine assessment of psychosocial outcomes following living kidney donation. Between March 2006 and July 2006, an iterative process was used to identify psychosocial outcomes that were clinically relevant and important to LKDs and to develop a process for assessing them. We reviewed relevant literature on living kidney donation, met with several transplant professionals (nephrologists, surgeons, nurse coordinators, social workers and psychologists) experienced in the care of LKDs, and conducted individual interviews (face-to-face or by phone) with eight LKDs. The primary focus was to characterize the range of psychosocial outcomes, identify which outcomes were most important for both transplant professionals and donors, and determine the optimal strategy and timing for assessing outcomes.

On the basis of these activities, we generated more than two dozen survey questions that could be used to prospectively assess psychosocial outcomes for all future living donors at BIDMC. The questions were reviewed by the transplant team and several LKDs, which led to wording modifications for clarity, elimination of redundant

questions, and further item reduction to ensure brevity. In the end, we constructed one 20-item survey that would be mailed on the first donation anniversary (Survey 1) and a much shorter 10-item survey that would be mailed annually thereafter (Survey 2 on second donation anniversary and so on). Questions about how well informed donors felt, surgical recovery, and return to work appear only in Survey 1, while questions about outcomes, satisfaction with the donation process, and decision stability are included in all annual surveys. These two surveys were approved by members of the kidney transplant program.

Additionally, since most potential living donors at BIDMC complete the SF-36 Health Survey (Ware, Kosinski, & Dewey, 2000) as part of their pre-donation psychosocial evaluation, this measure is integrated into the annual follow-up assessments. The SF-36 is a generic measure of health-related quality of life that includes 8 domains: (1) physical functioning (the extent that health limits physical activities such as self-care, walking, climbing stairs, bending, lifting, and moderate to vigorous activities), (2) role functioning—physical (the extent to which physical health interferes with work or other daily activities, such as accomplishing less than desired or limitations in type of activities), (3) bodily pain (the intensity of pain and the effect of pain on activities), (4) general health (personal evaluation of health, health outlook, and perceived resiliency to illness), (5) vitality (the extent of feelings of energy versus feelings of fatigue), (6) social functioning (the extent to which physical health or emotional problems interfere with normal social activities), (7) role functioning—emotional (the extent to which emotional problems interfere with work or other daily activities, including decreased productivity or quality of time spent on activities), and (8) mental health (general mental health, including depression, anxiety, behavioral-emotional control, and positive affect). There are also two component scores: Physical Component Summary (PCS) and Mental Component Summary (MCS). Higher scores are indicative of better quality of life.

In September 2006, we started mailing each LKD a survey packet at the time of their 1 year donation anniversary and then annually thereafter. The packet includes a cover letter describing the rationale and importance of the information being collected and notes that the information collected would be reviewed by their donor team and entered into their medical record. A postage-paid return envelope is included to facilitate survey return. If a survey is not returned within 1 month of its initial mailing, a replacement survey is mailed to the donor. If a donor attends an annual clinic appointment and we have not received the annual survey, then a transplant staff member provides a new copy to the donor while in the waiting room. The donor has the option to complete it in the clinic or to take it home and mail it back to us in a postage-paid envelope.

Our approach for this article is to provide descriptive information about the LKD cohort, survey responses, and the relationship between survey responses and LKD characteristics using *t* tests, Chi square or Fisher's tests, or Pearson correlation coefficients. Additionally, we gathered information from the donor's medical record to examine adherence to the donation follow-up schedule as well as changes in any variables for which we also had pre-donation data (e.g., weight, body mass index, quality of life).

Results

LKD Cohort

The current analysis focuses on a cohort of adults who donated a kidney at BIDMC between September 2005 and August 2012, in which the first two post-donation annual assessments (i.e., Survey 1 and 2) could be examined. During this time period, there were 208 LKDs at BIDMC and all were mailed follow-up surveys annually. We report on only the first 2 years post-donation because this timeframe corresponds to the Organ Procurement and Transplantation Network (OPTN) follow-up reporting requirements (OPTN, 2013). Characteristics of this cohort are summarized in Table 1. Mean age was 44.1 (±11.2) and the majority were women, white, college graduates, employed, had health insurance at the time of donation, and were biologically related to the recipient. The BIDMC cohort was generally representative of the U.S. LKD population during this time period (N = 42,504) (OPTN, 2014), although our cohort, as a percentage, had comparatively fewer minorities ($p < 0.001$) and more highly educated donors ($p = 0.003$).

All LKDs underwent laparoscopic nephrectomy. Mean body mass index (BMI) at time of donation was 27.3 (±4.1). Approximately one-quarter of the cohort (24 %, n = 49) was obese (BMI ≥ 30.0) or a smoker (24 %, n = 49) and 11 % (n = 22) had well-controlled hypertension at time of donation.

Survey Respondents

Survey 1 and 2 were returned by 59 % (n = 123) and 47 % (n = 98) of LKDs, respectively. Only 37 % (n = 77) returned both surveys, while 31 % (n = 64) did not return either survey. Those who did not complete any survey were more likely to be younger (40.1 ± 9.9 vs. 45.8 ± 11.4, $t = 3.3$, $p = 0.001$), minority race/ethnicity (58 vs 25 %, $p < 0.001$), and uninsured at time of donation (54 vs. 28 %, $p = 0.01$) compared to those who returned at least one survey.

Table 1 Characteristics of BIDMC living kidney donor (LKD) cohort and LKDs in the United States

Variable	BIDMC LKD Cohort (N = 208)	United States LKDs (N = 42,504)[a]
Age (years)		
18–34	47 (23 %)	12,907 (30 %)
35–49	87 (42 %)	18,407 (43 %)
50–64	70 (34 %)	10,499 (25 %)
≥65	4 (2 %)	688 (2 %)
Sex, female	118 (57 %)	25,788 (61 %)
Race		
White, non-Hispanic	174 (84 %)	29,685 (70 %)
Hispanic	11 (5 %)	5827 (14 %)
Black	14 (7 %)	5028 (12 %)
Other	9 (4 %)	1964 (5 %)
Education, college degree	113 (54 %)	15,811 (37 %)
Employment status, working	184 (89 %)	33,918 (80 %)
Health insurance, insured	182 (88 %)	35,426 (83 %)
Relationship to recipient		
Parent	6 (3 %)	3836 (9 %)
Child	35 (17 %)	7014 (17 %)
Sibling	71 (34 %)	9851 (23 %)
Other relative	18 (9 %)	3185 (7 %)
Spouse	31 (15 %)	5506 (13 %)
Friend/acquaintance	34 (16 %)	9273 (22 %)
Non-directed stranger	13 (6 %)	929 (2 %)

[a] Living kidney donors in the United States, September 2005 and August 2012. Data obtained from http://optn.transplant.hrsa.gov. Empty cells reflect data that is not available for the population of United States donors

Perceptions of the Pre-donation Process

Looking back at the pre-donation process, the majority of Survey 1 respondents felt fully informed about the risks/benefits of donation (n = 108/123, 88 %). Those who reported physical health problems associated with donation were less likely to feel informed about donation risks than those without donation-related health concerns (63 vs. 16 %, $p < 0.001$). Only two donors reported having fear or anxiety about the surgery that they did not feel comfortable discussing with members of the transplant or donation team. No LKDs reported feeling pressured by the transplant recipient or transplant program; 1 donor reported feeling pressured by someone other than the recipient or transplant program to go through with surgery. Finally, most LKDs (n = 102/123, 83 %) felt well informed during the evaluation process about likely out-of-pocket expenses.

Recovery and Return to Work

On Survey 1, 46 % (n = 53/116) reported more post-surgery pain than expected (Fig. 1a), 8 % (n = 9/116) stated that the scarring was worse than expected (Fig. 1b), and 30 % (n = 35/116) described the recovery time as slower than expected (Fig. 1c). Compared to non-obese LKDs, obese donors were more likely to feel that surgical scarring was worse than expected (5 vs. 21 %, $p = 0.03$) and that the recovery took longer than expected (26 vs. 47 %, $p = 0.02$).

Employed LKDs who returned Survey 1 (n = 109) reported being out of work an average of 5.3 (±3.1) weeks (median = 5.0, range = 1–12). A total of 9 donors (6 donors on Survey 1, 3 donors on Survey 2) reported difficulty finding work, lost job opportunities, or an unexpected change in job plans due to donation.

Perceived Health Problems Associated with Donation and Weight Changes

Twenty-two LKDs (18 %) attributed physical health problems to donation in the first post-donation year (Survey 1) and 5 different donors reported new-onset health problems in the second year after donation (Survey 2). These health problems included persistent fatigue (n = 12), chronic pain or discomfort (n = 6), infertility (n = 1), muscle weakness due to positional injury (n = 3), and new-onset hypertension requiring medication (n = 8). Of those with new-onset hypertension, 6 LKDs gained weight

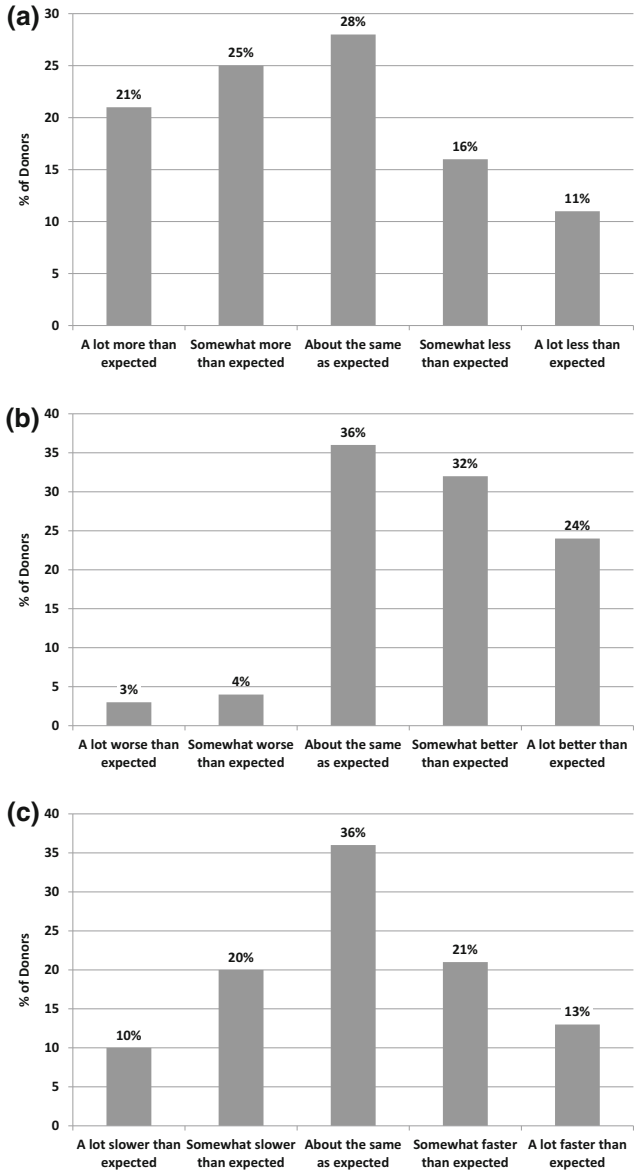

Fig. 1 (**a**) Perception of pain intensity following donation (n = 116). (**b**) Perception of surgical scarring following donation (n = 116). (**c**) Perception of recovery time following donation (n = 116)

and 2 did not (mean weight change = +4.3 lbs). Donation-related health problems were not associated with any sociodemographic characteristics.

Of the 166 LKDs for whom weights were obtained both before and 1 year after donation, 51 (31 %) experienced weight gain >5.0 lbs (median = 10.3 lbs, mean = 2.2 ± 13.1, range = 6–93 lbs). Of the 33 obese donors at the time of surgery for whom weights were available 1 year after donation, 14 (42 %) gained >5.0 lbs during the year (median = 17.3 lbs, mean = 8.3 ± 21.1, range = 9–93 lbs). Six (18 %) donors who were obese at time of donation lost >5.0 lbs in the first post-donation year.

Insurance and Financial Impact of Donation

A total of 16 (8 %) LKDs in the cohort had health insurance at the time of donation but reported being uninsured at some point during the 2 years after donation. Two donors (one on Survey 1, one on Survey 2) reported being declined health insurance after donation. In both instances, the donor had health insurance at the time of donation and changed jobs following donation. Six donors (5 on Survey 1, one on Survey 2) reported problems getting life insurance after donation.

The majority (70 %) of LKDs reported out-of-pocket expenses directly related to donation. The most common expense was for travel (55 %), medications related to donation (30 %), meals during required transplant center appointments (27 %), and lodging (10 %). Also, 20 % (n = 22/109) did not have sufficient paid medical leave or vacation to cover the entire time away from work and consequently lost wages/income. One (Survey 1) and two (Survey 2) years following donation, 8 % (n = 10/123) and 7 % (n = 7/98) of LKDs, respectively, reported financial hardship due to the costs associated with donation.

Quality of Life

All SF-36 (subscale and composite) mean scores fell within the average range (50 ± 10) prior to donation and at one (Survey 1) and two (Survey 2) years post-donation (mean range = 53.8–59.7). However, as part of our clinical care process, we examine individual change in quality of life scores from pre-donation to post-donation. This is done by calculating a Reliable Change Index (RCI), which shows how much and in what direction a donor has changed and whether that change is both reliable and clinically meaningful (Bauer, Lambert, & Nielsen, 2004; Jacobson & Truax, 1991). While group means can provide information about change over time at the group or cohort level, calculating the RCI allows for change to be assessed at the individual level. As noted in Table 2, the vast majority of LKDs experienced no change or favorable changes in all quality of life domains from pre-donation to 1 and 2 years post-donation. However, 28 % of LKDs reported a clinically meaningful decline in vitality at both follow-up time points, relative to pre-donation levels, which indicates a decline in energy and an increase in fatigue.

Adherence to Post-donation Surveillance

During the donation era of this cohort, our center's practice was to conduct post-surgical follow-up of the donor in clinic at 1 and 6 weeks post-donation, and medical follow-up in the transplant center or by their primary care

Table 2 Number (%) of living kidney donors with clinically significant decline, increase, or no change in SF-36 quality of life domains from pre-donation to 1 and 2 years post-donation based on the calculated Reliable Change Index

	Quality of life domains							
	Physical function n (%)	Role physical n (%)	Bodily pain n (%)	General health n (%)	Vitality n (%)	Social function n (%)	Role emotional n (%)	Mental health n (%)
Pre-donation to 1 year (n = 83)								
Decline	10 (12)	17 (21)	14 (17)	15 (18)	23 (28)	14 (17)	11 (13)	15 (18)
Increase	4 (5)	1 (1)	8 (10)	3 (4)	7 (8)	4 (5)	7 (8)	5 (6)
No change	69 (83)	65 (78)	61 (73)	65 (78)	53 (64)	65 (78)	65 (78)	63 (76)
Pre-donation to 2 years (n = 61)								
Decline	7 (11)	8 (13)	10 (16)	11 (18)	17 (28)	7 (11)	7 (11)	9 (15)
Increase	3 (5)	1 (2)	5 (8)	2 (3)	5 (8)	2 (3)	4 (7)	7 (11)
No change	51 (84)	52 (85)	46 (75)	48 (79)	39 (64)	52 (85)	50 (82)	45 (74)

physician annually post-donation. These surveillance visits are designed to gather regulatory status (e.g., alive or dead) and clinical information (e.g., new-onset hypertension, diabetes, or kidney disease) and laboratory data (e.g., serum creatinine) about the donor. Follow-up status and clinical information was obtained for the majority of LKDs in this cohort (96 % at 1 week, 89 % at 6 weeks, 76 % at 1 year, and 70 % at 2 years); however, follow-up laboratory data were obtained for only 66 and 57 % at 1 and 2 years, respectively. At 1 and 2 years post-donation, follow-up clinical and/or laboratory information was more likely to be obtained from LKDs with health insurance than those who were uninsured (80 vs. 50 %, $p = 0.001$ and 87 vs. 62 %, $p = 0.05$, respectively). Also, at 1 year post-donation, we were more likely to obtain follow-up information from those who resided closer to the transplant center at the time of surgery than those who traveled greater distances ($t = 3.8$, $p < 0.001$).

Overall Satisfaction and Decision Stability

A total of 8 donors across both surveys (6 %) reported that donation caused problems in their relationship with the recipient. However, the majority of LKDs reported being "quite a bit" or "extremely" satisfied with the donation experience overall on both Survey 1 (94 %, n = 116/123) and Survey 2 (97 %, n = 95/98). Also, most LKDs on both Survey 1 (94 %, n = 116/123) and Survey 2 (99 %, n = 97/98) reported that they would make the same decision to be a donor if they had to do it all over again. Two donors who stated they would not make the same decision 1 year after donation (Survey 1) reported that they would make the same donation decision 2 years post-donation (Survey 2).

Discussion

Living donors are responsible for one-third of all kidney transplants performed annually in the United States (OPTN, 2014). To facilitate informed consent for prospective donors, it is important to ensure that they are provided with short-term and long-term surgical, medical, and psychosocial outcomes of living donation. Comparatively less is known about psychosocial outcomes of LKDs than both surgical and medical outcomes. To both enhance our informed consent process and to identify and respond to emerging psychosocial concerns of donors, we have established a brief annual survey that is administered to donors as part of our clinical care and donor surveillance processes. Our analysis of survey data in the two years following donation yielded four primary findings: (1) The majority of LKDs reported having a positive experience with donation. Most felt fully informed about the risks and benefits of living donation, and most reported no occupational problems related to donation, no major health problems, no difficulties with health or life insurance, no negative changes in their quality of life, high levels of satisfaction with donation, and no regret about their donation decision; (2) A sizable minority of LKDs felt more pain than expected and recovery time was much slower than expected, gained an unhealthy amount of weight, and experienced a clinically significant decline in vitality; (3) Non-reimbursed out-of-pocket expenses were very common for LKDs; and (4) Donor adherence to follow-up surveillance during the required 2 years after donation is challenging, especially for certain subgroups (e.g., younger, minority, or uninsured LKDs).

Consistent with several cross-sectional studies (Clemens et al., 2006; Gross et al., 2013; Jowsey et al., 2014; Messersmith et al., 2014), we found that the majority of

LKDs experienced no adverse life impact from donation, report high overall satisfaction with donation, and have no decision regret. These LKDs had excellent health-related quality of life prior to donation and, for the most part, there was no adverse impact on quality of life after donation. While these data are comforting, there are clearly some LKDs whose 1 and/or 2 year outcomes are not entirely optimal, ranging from unhealthy weight gain and new-onset hypertension to persistent fatigue and loss of health insurance that could adversely impact post-donation surveillance. Several LKDs identified physical health problems that they attributed to donation. Importantly, while these symptoms (e.g., chronic pain, hypertension, fatigue) can be associated with donor nephrectomy, we did not confirm their etiology. As part of our clinical and quality process, all returned surveys are reviewed by a member of the transplant behavioral health team. Any clinical or psychosocial concerns are identified, discussed with relevant donor team members (e.g., nephrologist, surgeon), and an action plan is developed and implemented if needed. Typically, this might include a phone call to the donor to gather more detailed information about the noted changes in behavioral, physical, or psychosocial health. Based on this discussion, we might schedule the donor for further evaluation and management in our transplant center, coordinate care and communication with the donor's primary care physician, or facilitate a mental health referral in their local community.

Aggregate data from these donor surveys are integrated into our center's annual review of the living donation program, quality assessment and performance improvement (QAPI) Committee activities, and quarterly meetings of our Living Donor Advisory Group (i.e., 8 living donors who meet quarterly and advise the Transplant Institute on how to improve the living donation process). This enables us to establish target metrics and to identify areas for future programmatic focus and associated implementation strategies. For instance, on the basis of data reported herein and consultation with the QAPI Committee and Living Donor Advisory Group, we could modify our approach to post-operative pain education and management with implementation of an Enhanced Recovery Program (Waits, Hilliard, Sheetz, Sung, & Englesbe, 2015), something that is currently under consideration. Also, findings of excessive weight gain and new-onset hypertension after donation have led us to refer more donor candidates to our transplant nutritionist for consultation and to consider developing a post-donation lifestyle curriculum focused on healthy nutrition, weight management, physical activity, and regular blood pressure monitoring. Such a curriculum could be delivered electronically (using mobile health technology) to LKDs at designated intervals post-donation (Hebden et al., 2013).

Most LKDs in our cohort reported incurring some out-of-pocket expenses associated with donation, which is similar to what has been reported by others (Clarke et al., 2006; Klarenbach et al., 2014). There is clearly a need for research to better identify the sources of financial impact for donors as well as the impact of both direct and indirect expenses on LKDs and their families. Historically, we have not required donor candidates to meet with the transplant financial coordinator, although we are considering this on the basis of our survey findings. All transplant programs are required by UNOS to inform potential donors about the possible financial consequences of donation. However, a meeting with the financial coordinator may elevate the importance of financial considerations for donor candidates and facilitate the provision of information summarizing likely out-of-pocket costs, possible lost wages, state-specific Family Medical Leave Act (FMLA) options, and expense reimbursement programs (e.g., National Living Donor Assistance Center). Also, we are now attempting to minimize donation-related costs by paying for required follow-up laboratory tests, parking at the transplant center, and other incidental expenses, which we hope will reduce financial disincentives to participate in follow-up appointments.

Our data further support the need for more prospective cohort studies to better characterize donation outcomes over time and factors that may contribute to favorable or unfavorable outcomes. We present one example of how outcomes data can be acquired at the level of an individual transplant program; however, in addition to programmatic efforts, we also strongly support establishing a national registry of patient-reported outcomes following living kidney donation (Davis, 2012; Leichtman et al., 2011; Ommen, LaPointe Rudow, Medapalli, Schröppel, & Murphy, 2011). Data collected by individual transplant programs, through prospective cohort studies, and via a national registry have the potential to influence clinical practice, informed decision-making, and policy development for the benefit of past and future LKDs.

While the response rate to the first annual survey was acceptable (59 %), there was considerable attrition by the second year, as only one-third of LKDs completed both surveys. Moreover, while we obtained clinical information on most LKDs in the cohort (most of it from primary care physicians), it was far more difficult to obtain laboratory data through 2 years after donation. In a national survey of kidney transplant programs, Waterman et al. (2013) found that nearly half of all programs lost contact with more than 75 % of their LKDs within 2 years after donation. While our follow-up rates compare favorably to this national survey, our level of attrition for survey and laboratory data is inconsistent with maintaining a robust follow-up program that meets the new OPTN policy requiring clinical

and laboratory data on 80 and 70 % of LKDs, respectively, through the 2 year time point. Moreover, like others (Schold et al., 2015; Weng et al., 2012), we found that minorities were less likely to participate in follow-up care after donation, which is concerning in light of recent data on the increased risk of adverse long-term outcomes among some minority donors (Mjøen et al., 2014; Muzaale et al., 2014). We have engaged our Living Donor Advisory Group to help develop a strategy for improving outcomes assessment, and we are developing an electronic system for capturing survey outcomes, clinical information, and laboratory data. More focused attention on how best to gather follow-up data from donors at higher risk of being lost to follow-up (e.g., uninsured, younger, minorities) is urgently needed in this climate of increased regulatory oversight (Schold et al., 2015). These strategies might include more frequent contact with LKDs, telephone-based and electronic surveys, and small incentives for survey completion.

Our findings should be evaluated in their appropriate context. First, we report on an initiative to improve outcomes surveillance, which was not intended to serve as a research study. We designed a survey that included several outcomes that were considered relevant and important to LKDs and to the kidney transplant program to augment donor surveillance activities. Consequently, we are not able to provide more detailed information about these outcomes. Second, while LKDs are encouraged to complete the annual surveys as part of our follow-up process, some choose not to do so for reasons that are not known to us. It is possible that those who return the surveys differ systematically from non-responders in ways that we did not assess (e.g., more committed to their health status, better health, more financial resources, and geographic proximity). Third, fewer minority LKDs returned the annual surveys, thus our knowledge and understanding of their experiences is much more limited and warrants further study. Finally, it is difficult to interpret some aspect of the data (e.g., changes in vitality scores, etc.) without an appropriate comparison group of non-donors. These limitations notwithstanding, we believe that annual assessment of outcomes that extend beyond the two UNOS-required psychosocial elements (i.e., employment status, loss of insurance) can enhance the informed consent process for potential donors, facilitate post-donation care, and inform quality improvement processes for transplant programs.

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Conflict of Interest The authors declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation of the Beth Israel Deaconess Medical Center whose Institutional Review Board approved the protocol for data collection and use as "Exempt," and so ruled that informed consent was not required. Additionally, all procedures followed were in accordance with the Helsinki Declaration of 1975, as revised in 2000.

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