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Outcomes of Living Kidney Donor Candidate Evaluations in the Living Donor Collective Pilot Registry

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Background. Gaps in our knowledge of long-term outcomes affect decision making for potential living kidney donors. **Methods.** The Scientific Registry of Transplant Recipients was asked to determine the feasibility of a candidate registry. **Results.** Ten living kidney donor programs evaluated 2107 consecutive kidney donor candidates; 2099 of 2107 (99.6%) completed evaluations, 1578 of 2099 (75.2%) had a decision, and 790 of 1578 (50.1%) were approved to donate as of March 12, 2020. By logistic regression, candidates most likely to be approved were married or had attended college or technical school; those least likely to be approved had ≥1 of the following characteristics: Black race, history of cigarette smoking, and higher blood pressure, higher triglycerides, or higher urine albumin-to-creatinine ratios. Reasons for 617 candidates not being approved included medical issues other than chronic kidney disease risk (25.3%), chronic kidney disease risk (18.5%), candidate withdrawal (15.2%), recipient reason (13.6%), anatomical risk to the recipient (10.3%), noneconomic psychosocial (10.3%), economic (0.5%), and other reasons (6.4%). **Conclusions.** These results suggest that a comprehensive living donor registry is both feasible and necessary to assess long-term outcomes that may inform decision making for future living donor candidates. There may be socioeconomic barriers to donation that require more granular identification so that active measures can address inequities. Some candidates who did not donate may be suitable controls for discerning the appropriateness of acceptance decisions and the long-term outcomes attributable to donation. We anticipate that these issues will be better identified with modifications to the data collection and expansion of the registry to all centers over the next several years.

(*Transplantation Direct* 2021;7: e689; doi: 10.1097/TXD.0000000000001143. Published online 22 April, 2021.)

Received 2 December 2020. Revision received 16 January 2021.

Accepted 1 February 2021.

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This work was conducted under the auspices of the Hennepin Healthcare Research Institute, contractor for the Scientific Registry of Transplant Recipients, as a deliverable under contract number HHSH250201500009C (US Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation).

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The authors declare no conflicts of interest.

These data were collected by the Scientific Registry of Transplantation (SRTR) under contract with the US Health Services and Research Administration under Public Health Authority. The SRTR is exempt from IRB review.

All authors contributed to the planning of the study, the collection of data, and the writing of the article and fulfill all 4 criteria of the ICMJE for authorship. Y.S.A. and D.M. analyzed the data.

Supplemental digital content (SDC) is available for this article. Direct URL citations appear in the printed text, and links to the digital files are provided in the HTML text of this article on the journal's Web site (www.transplantationdirect.com).

The Scientific Registry of Transplant Recipients and United States Renal Data System data are publicly available free of charge from the Scientific Registry of Transplant Recipients and the United States Renal Data System Coordinating Center, respectively.

**Living Donor Collective participants are listed in the appendix.*

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ISSN: 2373-8731

DOI: 10.1097/TXD.0000000000001143

INTRODUCTION

Although deceased and living kidney donations have increased in the United States, there remains a shortage of kidneys for transplant.[1] There is an ongoing need to understand barriers to living donation, especially in disadvantaged communities. One potential barrier to living donation is uncertainty over the long-term risk to donors, and potential living donors may decline or be turned down by transplant programs out of fear that the donation may cause long-term harm. The Kidney Disease Improving Global Outcomes clinical practice guideline recommends that each transplant program determine an acceptable end-stage kidney disease (ESKD) risk threshold for living donor candidates.[2,3] Unfortunately, there is little evidence available to estimate the long-term risk of ESKD attributable to donation,[4,5] and acceptance criteria may vary across programs.

Since 2000, at least 16 single-center, retrospective studies have reported the results of different processes for determining suitable living kidney donors (Table S1, SDC, http://links.lww.com/TXD/A319).[6-21] The proportion of accepted candidates was, on average, 36% (range, 8%–60%) across programs. The most common reason for declining donation was "medical risk," at 38% (range, 8%–90%). However, study quality and length of follow-up were often limited, and there was a large amount of heterogeneity in how programs determined unacceptable medical risk.

The Health Resources and Services Administration (HRSA) contracted with the Scientific Registry of Transplant Recipients (SRTR) to conduct a pilot program exploring the utility of establishing a comprehensive registry to examine decision processes and outcomes of living kidney and liver donation. Such a registry could allow programs to compare their rates of acceptance of candidates and their reasons for not accepting candidates with those of other programs. It could also allow donor candidates and intended recipients to compare programs based on characteristics of accepted donors and thereby help them select programs at which they may seek living donor transplant opportunities. In addition, it could allow long-term follow-up of candidates and donors by linking to other registries and using surveys to compare donors with approved donor candidates who did not donate. However, without first determining the feasibility of collecting such data from individual centers, it would be unreasonable to expect the transplant community to be willing to participate in any widespread deployment or national requirement to provide such data. Thus, to support the HRSA request that a detailed pilot investigation be mounted, the SRTR formed the Living Donor Collective.[22] In this report, we describe the results to date of our pilot registry, made up of 10 kidney transplant programs. Our objective is to inform the transplant community of this ongoing effort, which we anticipate will be expanded to register all living donor candidates in the United States. Our ultimate aim is to remove barriers to donation, including uncertainties over short- and long-term donor outcomes.

MATERIALS AND METHODS

Source of Data

We used existing and newly collected SRTR data. The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the United States submitted by the members of the Organ Procurement and Transplantation Network (OPTN) and has been described elsewhere.[23] HRSA, US Department of Health and Human Services, provides oversight for the activities of the OPTN and SRTR contractors. Ten living kidney donor transplant programs collected data, as previously described (Figure 1).[22]

Although programs began enrolling candidates at different times, the first program began enrolling in June 2018, and the last program began in February 2019. Three participating programs uploaded batched data electronically, and the rest entered data using a manual-entry web-based system. Candidates were followed through March 12, 2020, a date chosen to align with the declaration of the coronavirus disease 2019 (COVID-19) emergency in the United States on March 13, 2020.

Linking Candidates to Organ Procurement and Transplantation Network Data

To determine which candidates had donated a kidney by the end of our observation period, we linked our data to OPTN data collected for Living Donor Registration (LDR). Hospitals removing a kidney from a living donor for transplant ("recovery hospitals") are required to submit the LDR to the OPTN within 60 d postrecovery. From the LDR, we were able to ascertain whether the donation occurred with the same program as the one performing the evaluation. In each case, we protected the privacy of candidates so that programs could not know whether a candidate they evaluated was also evaluated by and, in some cases, donated at another program.

Statistical Analysis

We examined differences between candidates who were or were not approved for donation. Univariate analysis for these comparisons included chi-square tests for differences in categorical data, Fisher exact test for differences of small sample size categorical data when necessary, *t* tests for normally distributed continuous variables that were logarithmically transformed when necessary, and the Wilcoxon rank sum test for differences in medians of continuous variables, when necessary. In addition, we performed multiple logistic regression to determine which variables were significantly different between candidates who were approved versus not approved for donation. Specifically, we first examined by univariate logistic regression which variables were associated with being approved for donation at $P < 0.15$. We then included these variables in a multiple logistic regression model and conducted stepwise model selection using the Akaike information criterion to see which variables predicted approval for donation independent of other variables.

Data are mean ± SD or median (interquartile range [IQR]). All analyses were conducted using R V.3.6.0. (https://www.r-project.org/).

RESULTS

Evaluation Process

As of March 12, 2020, 2107 kidney donor candidates were registered, and 2099 of 2107 (99.6%) had completed registration (Figure 2). The candidate or program had made a decision regarding donation in 1578 of 2099 (75.2%), whereas decisions were still pending for 521 of 2099 (24.8%). Of

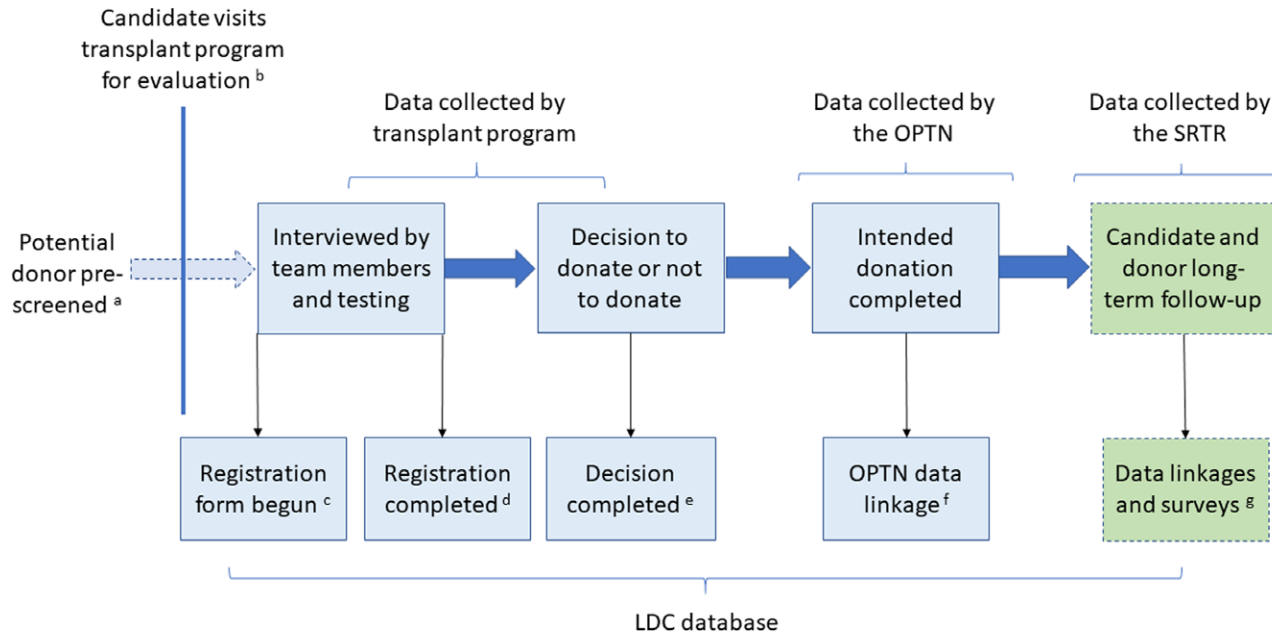

FIGURE 1. Living Donor Collective design and definitions. [a]Data on potential donors eliminated before being seen by the transplant team are not collected. [b]Potential donors selected to be evaluated are considered to be candidates. [c]Candidates are registered when a participating program enters data on the registration form. [d]Registration is complete when the form is completed and closed to further data entry. [e]Before a decision is made, the decision form remains open and pending. [f]SRTR linked candidate registration data to OPTN data to determine when a candidate donated. [g]SRTR will collect long-term follow-up data, which are not reported as part of this pilot project. LDC, Living Donor Collective; OPTN, Organ Procurement and Transplantation Network; SRTR, Scientific Registry of Transplant Recipients.

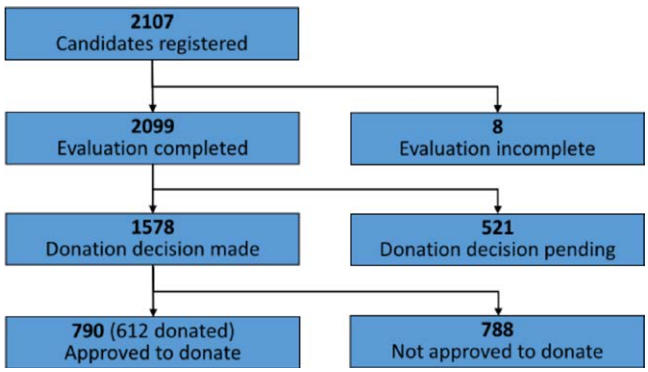

FIGURE 2. Number of candidates registered and having decided to donate or not as of March 12, 2020.

those with a decision, 790 of 1578 (50.1%) were approved to donate, whereas 788 of 1578 (49.9%) were not. The median time between candidate registration completion and the decision to donate or not was 89.5 d (IQR, 27–185.75; Figure 3).

Of the candidates approved for donation, 612 of 790 (77.5%) had donated, according to data from the OPTN, as of March 12, 2020. Of the 612 donated kidneys, all but 4 were recovered at the program at which the donor was evaluated. The time between registration completion and donation was 92 d (IQR, 58–148) for the 612 candidates who had donated (Figure 4).

Differences Between Candidates Accepted or Not Accepted for Donation

Slightly less than half of the candidates were biologically related to the intended recipient, and the proportions biologically related were not different between those accepted or not accepted (Table S2, SDC, http://links.lww.com/TXD/A319). More women were evaluated, and proportionally more were accepted for donation than men (Table 1). Age was not different for those accepted or not accepted for donation (Table 1); those approved for donation were (mean ± SD) 45.5 ± 13.6 y old, whereas those not approved were 45.9 ± 12.7 y ($P = 0.507$). Accepted donors were most likely to be married or have a life partner (Table 1), and White candidates were more likely to be accepted as donors than non-White candidates (Table 1). Those accepted as donors most often had more than a high school education and health insurance (Table 2); however, the proportions working for an income were not different. A history of cigarette smoking was less common among accepted donors than nonaccepted ones (Tables 3).

Concentrations of total and low-density lipoprotein cholesterol (LDL-C) were similar in accepted versus nonaccepted donors (Table 4). Total cholesterol was 187 ± 35.9 mg/dL in accepted donors, versus 186 ± 38.6 mg/dL in nonaccepted donors ($P = 0.366$), whereas LDL-C was 109 ± 28.9 mg/dL, versus 108 ± 31.0 mg/dL ($P = 0.594$), respectively. High-density lipoprotein cholesterol was higher in those accepted to donate than in those not accepted (69.5 ± 16.9 versus 56.3 ± 17.1 mg/dL) ($P < 0.001$) (Table 4). Triglycerides were lower in those accepted (median, 78 mg/dL; IQR, 60–111) than in those not accepted (median, 91 mg/dL; IQR, 64–131) ($P < 0.001$ by Wilcoxon rank-sum test). A history of hypertension was slightly less common and blood pressure was lower in accepted donors (Table 5). In those accepted versus not accepted, systolic blood pressure was a mean of 119 ± 13.8 mm Hg, versus 124 ± 15.8 mm Hg ($P < 0.001$), and diastolic blood pressure was 72.9 ± 9.0 mm Hg, versus 75.1 ± 10.2 mm Hg ($P < 0.001$).

Body mass index was not significantly different in those accepted to be donors compared with those not accepted (Table 6). Fasting glucose was slightly lower in those accepted

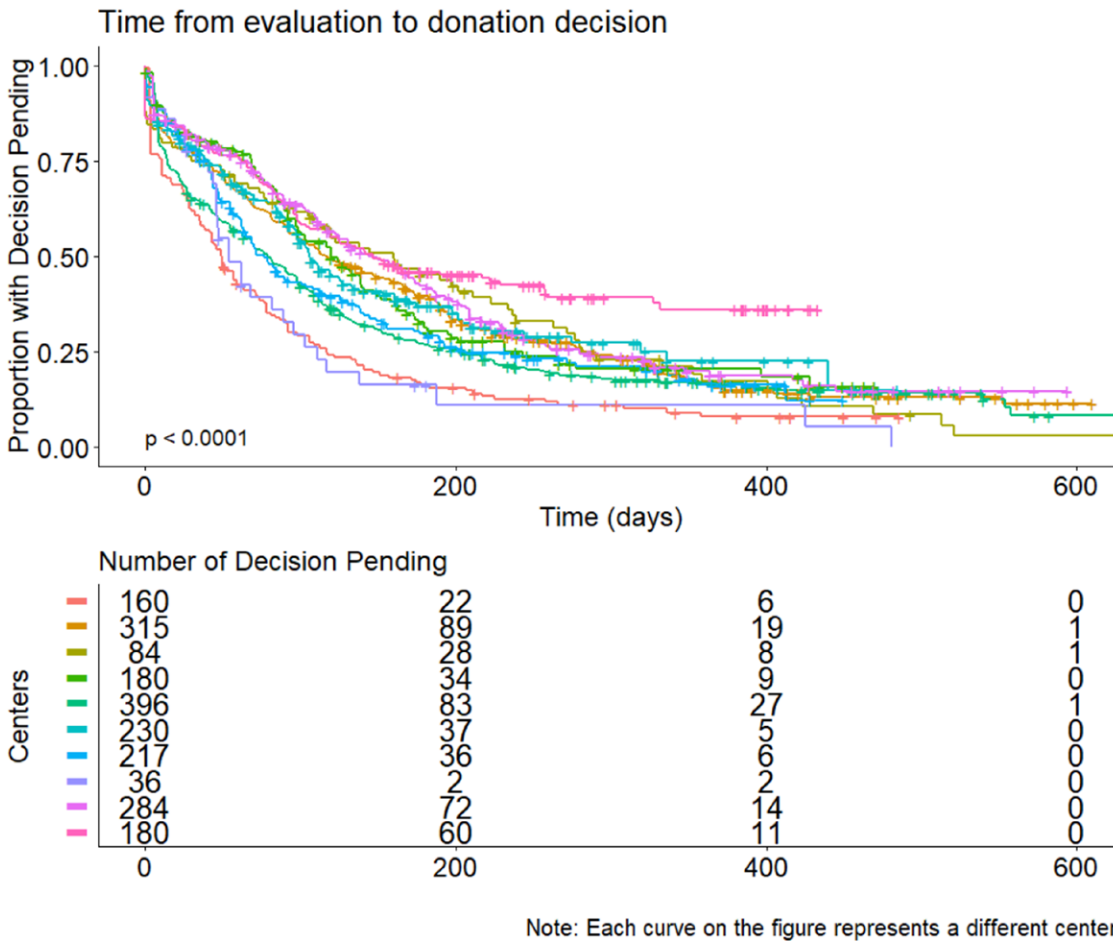

FIGURE 3. Time from registration of donor candidates to the donation decision as of March 12, 2020. Each curve represents a different transplant program.

versus not accepted (94.0 ± 14.2 versus 95.6 ± 15.9 mg/dL; $P = 0.030$). The estimated glomerular filtration rate (eGFR) from the Chronic Kidney Disease Epidemiology Consortium equation[24] was not different in those accepted or not accepted to donate (Table 6) (median, 94.0 ± 17.0 versus 95.5 ± 17.3 mL/min/1.73 m^2) ($P = 0.089$). Urine albumin-to-creatinine ratio, measured in about half of donor candidates, tended to be lower in those accepted than in those not accepted (Table 6) (median, 5.0; range, 3.0–9.0 versus median, 6.0; range, 3.6–10) ($P = 0.059$ by Wilcoxon rank sum test). There was no difference in history of kidney stones in those accepted or not accepted for donation (Table 7). Uric acid was lower in those accepted than in those not accepted (4.8 ± 1.2 versus 5.1 ± 1.3 mg/dL) ($P = 0.001$).

Although female sex and having health insurance were both associated with greater acceptance for donation, this was not the case in a multivariate logistic regression analysis adjusting for other candidate characteristics (Table 8) that demonstrated the following independent correlates of acceptance for donation: marital status, education level, race/ethnicity, smoking history, systolic blood pressure, fasting serum triglycerides, and urine albumin-to-creatinine ratio (Table 8).

Reasons for Not Donating

When the decision regarding suitability for donation was made, 788 candidates did not go on to donate, and 674 of 788 (85.5%) of them had completed their evaluation, 43 of 788 (5.5%) had completed the evaluation except for an imaging study, 23 of 788 (2.9%) lacked an imaging study and some other components of the evaluation, 13 of 788 (1.7%) lacked an imaging study and many other components of the evaluation, 4 of 788 (0.5%) were missing information on completeness of the evaluation, and data entry was still in process for 31 of 788 (3.9%).

Among the 788 candidates not approved for donation, 16 (2.0%) did not have an identifiable reason for not donating. For the remaining 772 candidates not approved, 594 of 772 (79.9%) had only 1 reason, 126 of 772 (16.3%) had 2 reasons, and 52 of 772 (6.7%) had >2 reasons (Table 9). Of the 594 with only 1 reason for not donating (Table 9), the reasons included medical issues (25.3%), chronic kidney disease risk (18.5%), candidate declined (15.2%), recipient reason (13.6%), anatomical risk to the recipient (eg, multiple renal arteries, small kidney size) (10.3%), and psychosocial (10.3%), economic (0.5%), or other reason (6.4%). Hypertension was the most common reason among those indicating only 1 reason (58 of 594 [9.8%]).

DISCUSSION

This pilot project was designed to assess the feasibility of a registry for living donor candidates to assess barriers to

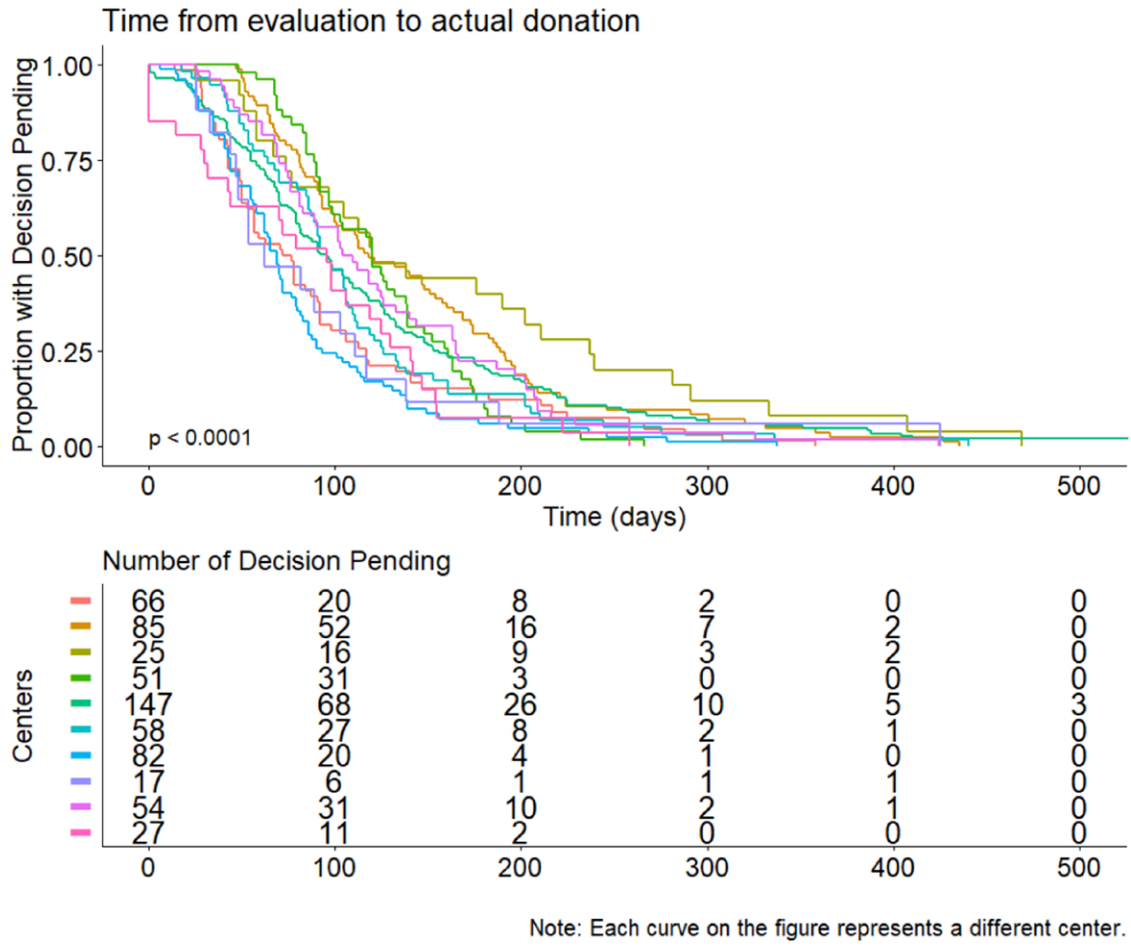

FIGURE 4. Time from registration of donor candidates to donation as of March 12, 2020, among the 612 who donated. Each curve represents a different transplant program.

donation and provide the foundation for determining long-term outcomes for donors and donor candidates who did not donate. Such pilot feasibility work is critical to ensuring that the transplant community understands what a future national registry would entail in terms of participation and data collection activities. We found that the initial 10 transplant programs could successfully register living kidney donor candidates, collect basic demographic and medical data required for donor evaluation, and determine whether the candidates were acceptable to donate or indicate why they were not. We found important differences between candidates accepted for donation and those not accepted. Specifically, those not accepted for donation were more likely to be of Black race, be less educated, be single, have smoked cigarettes, have higher blood pressure, higher triglycerides, or higher urine albumin-to-creatinine ratios, reflecting both psychosocial and medical differences and concerns.

Comparing accepted donor candidates with those not accepted may ultimately help define criteria for acceptance, reduce heterogeneity in these criteria between programs, and remove unnecessary barriers to living donation. Certainly, there will always be differences in the threshold of medical risk that programs are willing to accept. However, understanding the medical risks other programs are willing to accept may help programs refine and calibrate their own acceptable risk. In addition, better understanding nonmedical reasons for not donating may identify barriers to donation amenable to mitigation.

It is not surprising that there were differences in medical risk factors between those approved versus not approved for donation. Concerns that surgery and the effects of reduced kidney function could have adverse effects on donors are legitimate reasons for not accepting candidates for donation.[2,3] Theoretically, the risk of ESKD can be estimated, and if that risk is higher than the threshold risk that the program, the candidate, or the potential recipient will accept, donation may be declined. Unfortunately, there is a paucity of data on the long-term risk attributable to kidney donation, and a recent survey of US transplant programs indicated that few programs currently attempt to estimate this risk.[25] These data limitations may lead centers to accept donor candidates at higher risk and exclude donor candidates who are actually at low risk.

We found that Black candidates were half as likely to be approved for donation as non-Black candidates (Table 8). Others have reported that Black candidates are less likely to be accepted for donation.[10-13,15] This pilot study was too small to determine the extent to which differences in medical risk explain the lower acceptance of Black candidates and illustrates the need for a larger, more comprehensive registry to understand the role of risk variants such as APOL1 and how they affect the decision to donate.[26-28]

TABLE 1.

Demographics

Characteristic	Candidates evaluated (N = 2107), n (%)	Donation decision made		
		Not accepted (N = 788), n (%)	Accepted (N = 790), n (%)	*P* accepted vs not accepted
Sex (%)				0.001
Male	822 (39.0)	336 (42.6)	271 (34.3)	
Female	1282 (60.8)	452 (57.4)	519 (65.7)	
Unknown/missing	3 (0.1)	0 (0.0)	0 (0.0)	
Age (y)				0.578
18–34	495 (23.5)	195 (24.7)	174 (22.0)	
35–49	767 (36.4)	280 (35.5)	289 (36.6)	
50–64	671 (31.8)	245 (31.1)	262 (33.2)	
≥65	174 (8.3)	68 (8.6)	65 (8.2)	
Marital status (categories collapsed)				<0.001
Married, life partner	1314 (62.4)	449 (57.0)	540 (68.4)	
Single, divorced, separated, widowed	775 (36.8)	334 (42.4)	242 (30.6)	
Unknown/missing	18 (0.9)	5 (0.6)	8 (1.0)	
Race/ethnicity				0.001
White	1500 (71.2)	535 (67.9)	603 (76.3)	
Hispanic	14 (0.7)	5 (0.6)	6 (0.8)	
Black	257 (12.2)	120 (15.2)	63 (8.0)	
Asian	117 (5.6)	45 (5.7)	36 (4.6)	
Native American	6 (0.3)	2 (0.3)	4 (0.5)	
Pacific Islander	3 (0.1)	0 (0.0)	2 (0.3)	
Multiracial	203 (9.6)	78 (9.9)	73 (9.2)	
Unknown/missing	7 (0.3)	3 (0.4)	3 (0.4)	
Citizenship				0.150
US citizen	1802 (85.5)	660 (83.8)	651 (82.4)	
Non-US citizen/US resident	52 (2.5)	22 (2.8)	15 (1.9)	
Non-US citizen/non-US resident, traveled to United States for reason other than transplant	10 (0.5)	2 (0.3)	3 (0.4)	
Non-US citizen/non-US resident, traveled to United States for transplant	29 (1.4)	14 (1.8)	7 (0.9)	
Unknown/missing	214 (10.2)	90 (11.4)	114 (14.4)	

P values are from the χ^2 test.

TABLE 2.

Socioeconomics

Characteristic	Candidates evaluated (N = 2107), n (%)	Donation decision made		
		Not accepted (N = 788), n (%)	Accepted (N = 790), n (%)	*P* accepted vs not accepted
Highest education level achieved (categories collapsed)				0.001
High school or less	412 (19.6)	187 (23.7)	133 (16.8)	
Attended college or technical school	496 (23.5)	169 (21.4)	198 (25.1)	
Associate or bachelor's degree	726 (34.5)	268 (34.0)	259 (32.8)	
Postcollege graduate school	393 (18.7)	128 (16.2)	171 (21.6)	
Unknown/missing	80 (3.8)	36 (4.6)	29 (3.7)	
Health insurance coverage				0.032
Yes	1847 (87.7)	668 (84.8)	704 (89.1)	
No	194 (9.2)	91 (11.5)	62 (7.8)	
Unknown/missing	66 (3.1)	29 (3.7)	24 (3.0)	
Working for an income				0.290
Yes	1695 (80.4)	616 (78.2)	642 (81.3)	
No	350 (16.6)	145 (18.4)	127 (16.1)	
Unknown/missing	62 (2.9)	27 (3.4)	21 (2.7)	

P values are from the χ^2 test.

Education level was also strongly associated with candidate acceptance for donation (Table 8). Of course, education may be a surrogate for other socioeconomic factors (eg, disposable income) that could be major barriers to living donation.[29-33] Recent efforts to expand financial assistance to living donor candidates may help facilitate donations that would otherwise

TABLE 3.
Medical risk

Characteristic	Candidates evaluated (N = 2107), n (%)	Donation decision made		
		Not accepted (N = 788), n (%)	Accepted (N = 790), n (%)	*P* accepted vs not accepted
History of cigarette use				0.001
Yes	662 (31.4)	277 (35.2)	219 (27.7)	
No	1420 (67.4)	498 (63.2)	565 (71.5)	
Unknown/missing	25 (1.2)	13 (1.6)	6 (0.8)	
History of other tobacco use				0.297
Yes	107 (5.1)	38 (4.8)	44 (5.6)	
No	1946 (92.4)	725 (92.0)	730 (92.4)	
Unknown/missing	54 (2.6)	25 (3.2)	16 (2.0)	
History of marijuana use				0.003
Never	1264 (60.0)	454 (57.6)	508 (64.3)	
Other	460 (21.8)	196 (24.9)	143 (18.1)	
Declined, do not know, or missing	383 (18.2)	138 (17.5)	139 (17.6)	
History of cancer				0.052[a], 0.103[b]
Yes	49 (2.3)	10 (1.3)	20 (2.5)	
No	2038 (96.7)	768 (97.5)	766 (97.0)	
Unknown/missing	20 (0.9)	10 (1.3)	4 (0.5)	

P values are from the χ^2 test.
[a]With missing values.
[b]Without missing values.

TABLE 4.
Dyslipidemias

Characteristic	Candidates evaluated (N = 2107), n (%)	Donation decision made		
		Not accepted (N = 788), n (%)	Accepted (N = 790), n (%)	*P* accepted vs not accepted
Taking a cholesterol-lowering medication				0.959
Yes	88 (4.2)	34 (4.3)	36 (4.6)	
No	1827 (86.7)	678 (86.0)	676 (85.6)	
Unknown/missing	192 (9.1)	76 (9.6)	78 (9.9)	
Total cholesterol				0.034
<200 mg/dL (<51.8 mmol/L)	1351 (64.1)	525 (66.6)	506 (64.1)	
200–239 mg/dL (51.8–61.9 mmol/L)	570 (27.1)	184 (23.4)	227 (28.7)	
≥240 mg/dL (62.2 mmol/L)	165 (7.8)	70 (8.9)	52 (6.6)	
Unknown/missing	21 (1.0)	9 (1.1)	5 (0.6)	
High-density lipoprotein cholesterol				<0.001
<40 mg/dL (<10.4 mmol/L)	218 (10.3)	103 (13.1)	71 (9.0)	
40–49 mg/dL (10.4–12.7 mmol/L)	456 (21.6)	197 (25.0)	156 (19.7)	
≥50 mg/dL (13.0 mmol/L)	1412 (67.0)	478 (60.7)	559 (70.8)	
Unknown/missing	21 (1.0)	10 (1.3)	4 (0.5)	
Low-density lipoprotein cholesterol				0.018[a], 0.083[b]
<130 mg/dL (<33.7 mmol/L)	1521 (72.2)	573 (72.7)	577 (73.0)	
130–159 mg/dL (33.7–41.2 mmol/L)	379 (18.0)	125 (15.9)	154 (19.5)	
≥160 mg/dL (41.4 mmol/L)	123 (5.8)	52 (6.6)	38 (4.8)	
Unknown/missing	84 (4.0)	38 (4.8)	21 (2.7)	
Triglycerides				<0.001
<150 mg/dL (<1.7 mmol/L)	1786 (84.8)	634 (80.5)	699 (88.5)	
150–199 mg/dL (1.8–2.2 mmol/L)	167 (7.9)	69 (8.8)	52 (6.6)	
≥200 mg/dL (2.3 mmol/L)	132 (6.3)	74 (9.4)	34 (4.3)	
Unknown/missing	22 (1.0)	11 (1.4)	5 (0.6)	

P values are from the χ^2 test.
[a]With missing values.
[b]Without missing values.

represent a financial hardship.[34] Based on our pilot data, it is clear that collecting more granular information on potentially remediable barriers to donation must be a major focus of ongoing efforts.

Studies of long-term outcomes after living donation have had inherent flaws and produced conflicting results.[4,5,35-38] It has been most challenging to find suitable populations to compare outcomes with those of donors, given their verified

TABLE 5.

Blood pressure

Characteristic	Candidates evaluated (N = 2107), n (%)	Donation decision made		
		Not accepted (N = 788), n (%)	Accepted (N = 790), n (%)	*P* accepted vs not accepted
Hypertension				0.610
Yes	145 (6.9)	61 (7.7)	54 (6.8)	
No	1782 (84.6)	660 (83.8)	660 (83.5)	
Unknown/missing	180 (8.5)	67 (8.5)	76 (9.6)	
Systolic blood pressure (mm Hg)				<0.001
<120	988 (46.9)	315 (40.0)	425 (53.8)	
120–129	556 (26.4)	209 (26.5)	202 (25.6)	
≥130	551 (26.2)	260 (33.0)	160 (20.3)	
Unknown/missing	12 (0.6)	4 (0.5)	3 (0.4)	
Diastolic blood pressure (mm Hg)				<0.001
<80	1467 (69.6)	508 (64.5)	599 (75.8)	
80–89	527 (25.0)	228 (28.9)	165 (20.9)	
≥90	102 (4.8)	49 (6.2)	23 (2.9)	
Unknown/missing	11 (0.5)	3 (0.4)	3 (0.4)	
Mean arterial pressure (mm Hg)				<0.001
<93	1331 (63.2)	440 (55.8)	560 (70.9)	
93–97	203 (9.6)	84 (10.7)	72 (9.1)	
≥97	561 (26.6)	260 (33.0)	155 (19.6)	
Unknown/missing	12 (0.6)	4 (0.5)	3 (0.4)	

P values are from the χ^2 test.

TABLE 6.

Risk of diabetes and kidney disease

Characteristic	Candidates evaluated (N = 2107), n (%)	Donation decision made		
		Not accepted (N = 788), n (%)	Accepted to donate (N = 790), n (%)	*P* accepted vs not accepted
Body mass index (kg/m^2)				0.151
<20	77 (3.7)	32 (4.1)	31 (3.9)	
20–<25	557 (26.4)	201 (25.5)	205 (25.9)	
25–<30	830 (39.4)	291 (36.9)	320 (40.5)	
30–<35	438 (20.8)	172 (21.8)	151 (19.1)	
≥35	88 (4.2)	39 (4.9)	22 (2.8)	
Unknown/missing	117 (5.6)	53 (6.7)	61 (7.7)	
Fasting blood glucose				<0.001
<100 mg/dL (<5.6 mmol/L)	1537 (72.9)	527 (66.9)	608 (77.0)	
100–125 mg/dL (5.6–6.9 mmol/L)	480 (22.8)	221 (28.0)	153 (19.4)	
≥126 mg/dL (7 mmol/L)	59 (2.8)	26 (3.3)	23 (2.9)	
Unknown/missing	31 (1.5)	14 (1.8)	6 (0.8)	
Diabetes				0.064[a]
Yes	2 (0.1)	1 (0.1)	0 (0.0)	
No	2083 (98.9)	778 (98.7)	787 (99.6)	
Unknown/missing	22 (1.0)	9 (1.1)	3 (0.4)	
Family history of diabetes				0.212
Yes	592 (28.1)	223 (28.3)	217 (27.5)	
No	1451 (68.9)	537 (68.1)	556 (70.4)	
Unknown/missing	64 (3.0)	28 (3.6)	17 (2.2)	
Urine albumin-creatinine ratio (mg/g)				0.125
<30	1061 (50.4)	383 (48.6)	381 (48.2)	
30–299	61 (2.9)	30 (3.8)	16 (2.0)	
≥300	1 (0.0)	1 (0.1)	0 (0.0)	
Unknown/missing	984 (46.7)	374 (47.5)	393 (49.7)	
CKD-EPI eGFR (mL/min/1.73 m^2)				0.130
<60	28 (1.3)	12 (1.5)	12 (1.5)	
60–89	789 (37.4)	291 (36.9)	315 (39.9)	
≥90	1270 (60.3)	476 (60.4)	461 (58.4)	
Unknown/missing	20 (0.9)	9 (1.1)	2 (0.3)	

P values are from the χ^2 test.
[a]*P* value from the Fisher exact test.
CKD-EPI eGFR, Chronic Kidney Disease Epidemiology Consortium estimated glomerular filtration rate (in mL/min/1.73 m^2).[24]

TABLE 7.

Serum uric acid and kidney stones

Characteristic	Candidates evaluated (N = 2107), n (%)	Donation decision made		
		Not accepted (N = 788), n (%)	Accepted (N = 790), n (%)	*P* accepted vs not accepted
Serum uric acid (mg/dL)				0.074[a], 0.033[b]
<7	1549 (73.5)	557 (70.7)	572 (72.4)	
≥7	118 (5.6)	51 (6.5)	31 (3.9)	
Unknown/missing	440 (20.9)	180 (22.8)	187 (23.7)	
History of gout				0.967
Yes	20 (0.9)	9 (1.1)	9 (1.1)	
No	1864 (88.5)	691 (87.7)	696 (88.1)	
Unknown/missing	223 (10.6)	88 (11.2)	85 (10.8)	
History of kidney stones				0.045[a], 0.066[b]
Yes	71 (3.4)	34 (4.3)	20 (2.5)	
No	2010 (95.4)	743 (94.3)	765 (96.8)	
Unknown/missing	26 (1.2)	11 (1.4)	5 (0.6)	

P values are from the χ^2 test.
[a]With missing values.
[b]Without missing values.

health after a rigorous screening and selection process.[39,40] Also problematic is the fact that outcomes that matter most to patients, such as ESKD, are rare—even with long-term follow-up.[39]

Because we cannot conduct a randomized controlled trial to determine the effects of living kidney donation on these important outcomes, the best alternative is to conduct a prospective observational study of adequate sample size and follow-up to measure differences in infrequent but critical events between donors and comparable controls. The best controls might be candidates approved for donation but not donating for reasons unrelated to the potential outcomes of interest. We found that the only reason for 13.9% of candidates not donating was attributable to the recipient and not the donor (Table 9), making these candidates potentially suitable controls for matching to donors. This is comparable with 16% of candidates evaluated in the published literature who did not donate because it became unnecessary (Table S1, SDC, http://links.lww.com/TXD/A319).

Another potential approach is to include all candidates evaluated for donation but adjust the analysis using a stratified propensity score for donor acceptance. The detailed data on risk factors uniformly collected for controls and donors could enable us to assess the risk of important outcomes attributable to donation. Of course, long-term follow-up would still be needed, but including the whole cohort of candidates could greatly enhance statistical power.

Events that matter to candidates, donors, families, transplant programs, and the general public will need to be further refined over time and, ideally, collected for the lifetime of participants. Deaths and their causes can be obtained with some reliability from the Centers for Disease Control and Prevention, the National Center for Health Statistics, and the National Death Index (https://www.cdc.gov/nchs/ndi/index.htm). Dialysis for ESKD can be ascertained for most patients from the United States Renal Data System. Data on kidney transplant can be obtained from the United States Renal Data System and the OPTN, and other long-term follow-up

TABLE 8.

Correlates (odds ratios) of being approved for donation[a]

Variable	Unadjusted odds (95% CI)	*P*	Adjusted odds (95% CI)	*P*
Married or life partner (reference: other)	1.62 (1.32-2.00)	<0.0001	1.54 (1.23-1.93)	0.0001
Education (reference: high school or less)				
Attended college or technical school	1.34 (1.01-1.78)	0.0397	1.56 (1.13-2.14)	0.0062
Associate or bachelor's degree	1.86 (1.35-2.56)	0.0001	1.09 (0.81-1.47)	0.5625
Postcollege graduate degree	1.35 (0.77-2.56)	0.2943	1.49 (1.06-2.10)	0.0225
Unknown	1.62 (1.32-2.00)	<0.0001	1.18 (0.66-2.13)	0.5795
Race/ethnicity (reference: Hispanic, White, or Asian)				
Black	0.48 (0.35-0.66)	<0.0001	0.47 (0.33-0.67)	<0.0001
Other	0.91 (0.66-1.27)	0.5931	1.02 (0.72-1.44)	0.9347
History of cigarette use (reference: none or missing)	0.71 (0.57-0.88)	0.0018	0.73 (0.58-0.92)	0.0067
Log (triglycerides mg/dL)	0.60 (0.49-0.73)	<0.0001	0.60 (0.49-0.75)	<0.0001
Systolic blood pressure (mm Hg)	0.98 (0.97-0.98)	<0.0001	0.98 (0.97-0.99)	<0.0001
Log (urine albumin-creatinine ratio)	0.87 (0.77-0.97)	0.0123	0.86 (0.76-0.97)	0.0144
Intercept	–	–	144 (39.4-527)	0.0452

[a]Results of logistic regression.
CI, confidence interval.

TABLE 9.

Reasons for not donating[a]

	The only reason, n (%)[b]	One of 2 reasons, n (%)[c]	One of ≥1 reason(s), n (%)[d]
Medical risk too high	150 (25.3)	113 (44.8)	333 (32.8)
Hypertension	58 (9.8)	49 (19.4)	126 (12.4)
Obesity	22 (3.7)	23 (9.1)	53 (5.2)
Cardiovascular disease	20 (3.4)	8 (3.2)	31 (3.1)
Another living donor candidate was a better choice for medical reasons	12 (2.0)	1 (0.4)	13 (1.3)
Concern for risk of diabetes	9 (1.5)	12 (4.8)	32 (3.2)
Newly detected mass or malignancy	9 (1.5)	2 (0.8)	13 (1.3)
Recent/current malignancy	9 (1.5)	1 (0.4)	12 (1.2)
Diabetes	3 (0.5)	2 (0.8)	7 (0.7)
Risk of transmitting an infection to the intended recipient	3 (0.5)	1 (0.)	7 (0.7)
High cholesterol or high triglycerides	2 (0.3)	2 (0.8)	15 (1.5)
Liver disease	2 (0.3)	3 (1.2)	7 (0.7)
Concern for future pregnancy and childbirth	1 (0.2)	1 (0.)	3 (0.3)
Tobacco use	0 (0.0)	7 (2.8)	11 (1.1)
Age (too old)	0 (0.0)	1 (0.4)	3 (0.3)
Risk for chronic kidney disease too high	110 (18.5)	33 (13.1)	170 (16.7)
Low kidney function	44 (7.4)	9 (3.6)	56 (5.5)
Kidney stones	42 (7.1)	13 (5.2)	68 (6.7)
Proteinuria	9 (1.5)	5 (2.0)	17 (1.7)
Hematuria	4 (0.7)	3 (1.3)	12 (1.2)
Risk of hereditary kidney disease	6 (1.0)	2 (0.8)	9 (0.9)
Other disease involving the renal arteries	3 (0.5)	1 (0.4)	5 (0.5)
Renal artery fibromuscular dysplasia	2 (0.3)	0 (0.0)	3 (0.3)
Psychosocial issues	61 (10.3)	44 (17.5)	146 (14.4)
Multiple psychosocial stressors	25 (4.2)	15 (6.0)	50 (4.9)
Psychiatric illness	9 (1.5)	9 (3.6)	28 (2.8)
Another living donor candidate was a better choice for other reasons	9 (1,5)	2 (0.8)	11 (1.1)
Substance use disorder	7 (1.2)	7 (2.8)	24 (2.4)
Donor conflicted or felt coerced	7 (1.2)	7 (2.8)	19 (1.9)
Limited psychosocial support	3 (0.5)	2 (0.8)	10 (1.0)
Another living donor candidate was a better choice for psychosocial reasons	1 (0.2)	0 (0.0)	1 (0.1)
Age (too young)	0 (0.0)	2 (0.8)	3 (0.3)
Unable to provide informed consent because of cognitive impairment or a developmental disability	0 (0.)	0 (0.0)	0 (0.0)
Candidate declined	90 (15.2)	24 (9.5)	116 (11.4)
Decided against donation for undisclosed reason(s)	44 (7.4)	11 (4.4)	55 (5.4)
Missed appointments or became unavailable	35 (5.9)	7 (2.8)	43 (4.2)
Candidate declined after deciding risk was too high	7 (1.2)	4 (1.6)	11 (1.1)
Member(s) of family against the candidate donating	4 (0.)	2 (0.8)	7 (0.7)
Anatomical reasons that donation increases risk to recipient	61 (10.3)	21 (8.3)	100 (9.9)
Other unfavorable anatomical abnormality	28 (4.7)	10 (4.0)	47 (4.6)
Kidney cysts	13 (2.2)	6 (2.4)	23 (2.3)
Multiple renal arteries or veins	13 (2.2)	3 (1.2)	20 (2.0)
Kidney(s) too small	4 (0.7)	2 (0.8)	7 (0.7)
Recipient HLA antibodies to the donor candidate	3 (0.5)	0 (0.0)	3 (0.3)
Recipient reason	81 (13.6)	9 (3.6)	90 (8.9)
Intended recipient underwent deceased donor transplant	40 (6.7)	1 (0.4)	41 (4.0)
Intended recipient died	12 (2.0)	0 (0.0)	12 (1.2)
Intended recipient became too ill for transplant	9 (1.5)	2 (0.8)	11 (1.1)
Intended recipient kidney function improved	8 (1.3)	0 (0.0)	8 (0.8)
Intended recipient decided not to undergo transplant	4 (0.7)	0 (0.0)	4 (0.4)
Intended recipient did not use this candidate for other reasons	3 (0.5)	0 (0.0)	3 (0.3)
Another living donor candidate was a better HLA match	2 (0.3)	1 (0.4)	3 (0.3)
Intended recipient decided not to have this candidate donate	2 (0.3)	1 (0.4)	3 (0.3)
Incompatible blood group	1 (0.2)	3 (1.2)	4 (0.4)
Unwilling to discontinue medications potentially toxic to the kidney	0 (0.0)	1 (0.4)	1 (0.1)
Economic barriers	3 (0.5)	0 (0.0)	11 (1.1)
Limitations on taking time off work	2 (0.3)	0 (0.0)	4 (0.4)
Economic burden of donation	1 (0.2)	0 (0.0)	6 (0.6)
Lack of health insurance coverage	0 (0.0)	0 (0.0)	1 (0.1)
Other	38 (6.4)	8 (3.2)	49 (4.8)

[a]Sixteen of 788 (2.0%) candidates were not approved to donate, but no reason was indicated. Of those not approved who indicated a reason for not donating, 594 of 772 (79.9%) indicated only 1 reason, 126 of 772 (16.3%) indicated 2 reasons, and 52 of 772 (6.7%) indicated >2 reasons.
[b]Number and percent of each reason indicated for those indicating only 1 reason.
[c]Number and percent of each reason indicated for those indicating 2 reasons.
[d]Number and percent of each reason indicated for those indicating any number of reasons.

information can be obtained by directed surveys. Indeed, a model cohort study that assessed the effects of smoking on long-term health outcomes demonstrated the feasibility of (1) defining a large prospective cohort, (2) conducting periodic surveys for follow-up information, (3) linking to registries for vital status, and (4) continuing follow-up for >50 y.[41]

A comprehensive registry with long-term follow-up of candidates and donors is needed to understand the long-term health effects of living donation on donors. Events such as ESKD that are important to donors are uncommon, may take years to occur, and cannot be attributed to donation without appropriate controls. Further, the proposed registry of living donor candidates will provide ideal controls to compare with donors, examining outcomes over many years using linkages to other data sources and surveys. Information from this registry, with its long-term follow-up, will help inform future candidates for living donation and their healthcare providers of the risks of donation. In addition, understanding these risks will be an important first step in future efforts to mitigate them.

There are some important limitations to the current report on the Living Donor Collective pilot. First, the sample size of the pilot is too small to examine important subgroups. It will be important, for example, to examine differences according to race/ethnicity for the evaluation process (Figure 2), risk factors (Tables 2–8), or reasons for not donating (Table 9). The need for larger numbers of candidates is itself a cogent argument to go forward with the registry. Second, the reasons selected for not donating may not reflect true reasons for not donating. The list of reasons for not donating was selected during an initial in-person meeting of representatives from the 10 pilot sites (April 2017) and then refined in a second in-person follow-up meeting of the same group (July 2019) after a collective experience using the first list. A coordinator can always select "other specify," and the list may be modified as needed over time. Finally, there are as yet no long-term follow-up data to report. If we are successful, the registry will provide unique and valuable information on outcomes important to patients over many years.

The Living Donor Collective pilot has demonstrated the feasibility of collecting comprehensive information on candidates for living kidney donation at 10 participating transplant programs and activating processes to continue following them to monitor their ESKD risk. Understandably, medical risk factors differed in candidates approved or not approved for donation. The threshold for approval varied by the center, and more granular analysis will provide pathways to greater standardization of these decisions. However, socioeconomic differences also suggest that there remain potentially surmountable social barriers to living donation. Reasons for not donating can identify candidates who can be compared with donors to ascertain the long-term risks attributable to donation. Further development of this registry is both clinically and scientifically critical to ensure the safety of living donors. To this end, HRSA has contracted with the SRTR to expand the Living Donor Collective over the next 5 y to include all living donor programs in the United States.

To meet this obligation, the SRTR will gradually expand the number of participating programs while continuing to refine data collection tools suitable for as many different programs as possible. Going forward, there will be an ongoing effort to update data collection items and processes based on input from multiple stakeholders that includes short- and long-term follow-up data using electronic tools. In addition, we will coordinate data collection with data already required and collected by the OPTN to minimize unnecessary duplication. With the support and commitment of HRSA and the transplant community, we are optimistic that the registry we now call "The Living Donor Collective" (https://livingdonorcollective.org/) will enhance living donation in the United States for years to come.

ACKNOWLEDGMENTS

The authors thank SRTR colleague Mary Van Beusekom, MS, ELS, MWC, for article editing.

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APPENDIX

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