ORIGINAL ARTICLE



Outcomes of living liver donor candidate evaluations in the **Living Donor Collective pilot registry**

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Abstract

Background: To gather information on long-term outcomes after living donation, the Scientific Registry of Transplant Recipients (SRTR) conducted a pilot on the feasibility of establishing a comprehensive donor candidate registry.

Methods: A convenience sample of 6 US living liver donor programs evaluated 398 consecutive donor candidates in 2018, ending with the March 12, 2020, COVID-19 emergency.

Results: For 333/398 (83.7%), the donor or program decided whether to donate; 166/333 (49.8%) were approved, and 167/333 (50.2%) were not or opted out. Approval rates varied by program, from 27.0% to 63.3% (median, 46%; intraquartile range, 37.3-51.1%). Of those approved, 90.4% were white, 57.2% were women, 83.1% were < 50 years, and 85.5% had more than a high school education. Of 167 candidates, 131 (78.4%) were not approved or opted out because of: medical risk (10.7%); chronic liver disease risk (11.5%); psychosocial reasons (5.3%); candidate declined (6.1%); anatomical reasons increasing recipient risk (26.0%); recipient-related reasons (33.6%); finances (1.5%); or other (5.3%).

Conclusions: A comprehensive national registry is feasible and necessary to better understand candidate selection and long-term outcomes. As a result, the US Health Resources and Services Administration asked SRTR to expand the pilot to include all US living donor programs.

KEYWORDS

decision making, liver failure, liver transplantation, risk assessment, scientific registry of transplant recipients

1 | INTRODUCTION

Living donor liver transplants have helped ease the shortage of livers from deceased donors. Between 1998 and 2001, the annual number of living liver donations in the United States increased from

92 to 524 (https://optn.transplant.hrsa.gov/data/view-data-reports/ national-data/). The number of living donor liver transplants declined over the next several years, to 219 in 2009. Subsequently, the number of living donor transplants increased to 524 in 2019. Nevertheless, a number of factors, including uncertainty over the

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long-term risk to donors, remain potential barriers to living liver donation.

The Organ Procurement and Transplantation Network (OPTN) registers all living donors at the time of donation, but does not collect data on candidates for living donation who do not donate, or long-term donor follow-up. A number of studies have suggested that two-thirds of candidates evaluated for living donation do not donate. However, potential barriers to living donation remain unclear. Therefore, the Health Resources and Services Administration (HRSA) asked the Scientific Registry of Transplant Recipients (SRTR) to conduct a pilot program to explore the feasibility of establishing a comprehensive registry to monitor processes and outcomes of living kidney and liver donation.

SRTR formed the Living Donor Collective to pilot for a comprehensive registry to monitor processes and outcomes of living donation. ¹⁴ The purpose of this pilot was to establish methods and demonstrate the value and feasibility of a registry. A national registry could allow programs to compare their rates of donor candidate acceptance and their reasons for not accepting donor 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 select programs that may provide living donor transplant opportunities. In addition, it could allow long-term follow-up of candidates and donors, both by linking to other registries and by surveys, comparing donors with healthy donor candidates who do not donate. In the present report, we describe the results of living liver donor candidate evaluations at six liver transplant programs.

2 | METHODS

2.1 | Source of data

This study used existing and newly collected SRTR data. The SRTR data system includes data on all donors, waitlisted transplant candidates, and transplant recipients in the United States submitted by the members of OPTN and has been described elsewhere. No organs from executed prisoners have been used in the United States. All protocols and procedures conformed to the ethical guidelines of the 1975 Declaration of Helsinki. HRSA, US Department of Health and Human Services, provides oversight of the activities of the OPTN and SRTR contractors under public health authority not otherwise requiring institutional review.

Six living donor liver transplant programs participated, as previously described. 14 Only potential donors who came to the transplant program for evaluation were considered to be living donor candidates. Potential donors who opted not to donate or were excluded from consideration before being seen by members of the transplant team were not included in our cohort of potential donors. Data were collected at the time of evaluation. In addition, the decision to accept or reject donation was recorded, and the reasons for not donating were noted for those who were not approved to donate.

Candidates were followed through March 12, 2020. This date was chosen to align with the declaration of the coronavirus disease 2019

(COVID-19) emergency in the United States on March 13, 2020, so the data would reflect the activity of the participating programs under "normal" circumstances. Nevertheless, we repeated key elements of the analysis using follow-up through June 30, 2020, and found that none of the major findings changed substantively (data not shown).

2.2 Data collected

The data collected at the time of registration and at the time the decision of whether or not to donate was made by the candidate or the program have been described in detail. These data include basic demographic information, medical history, and key laboratory values. For donor candidates who were not approved or who decided not to donate, one or more reasons were selected by programs from a list or provided as free text when a reason was not included among those that could be selected. We estimated glomerular filtration rate (eGFR) from serum creatinine using the Chronic Kidney Disease Epidemiology Consortium equation. We are the time of registration and at the time the decision of whether or not to donate, and the constraint of the const

2.3 | Linking to organ procurement and transplantation network data

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

2.4 Statistical analysis

We examined differences between candidates who were and were not approved for donation. Univariate analysis for these comparisons included chi-square tests for differences in categorical data, Fisher's 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 Wilcoxon Rank Sum test for differences in medians of continuous variables, when necessary. All analyses were conducted using R v.3.6.0. (https://www.r-project.org/).

3 | RESULTS

3.1 | The evaluation process

As of March 12, 2020, 398 donor candidates had registered at the six programs. All had completed their evaluations; 333/398 (83.7%) had a

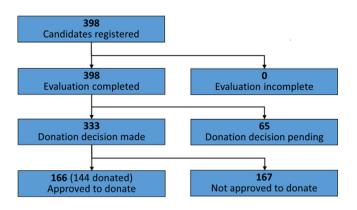


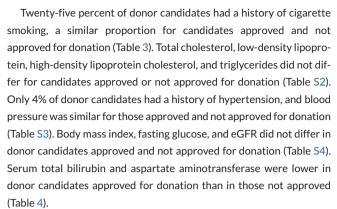
FIGURE 1 Number of candidates registered who decided to donate or not as of March 12. 2020

"decision," that is , had been approved or not approved or had decided not to donate, and decisions were still pending for 65/398 (16.3%) (Figure 1). Of those with a donation decision, 166/333 (49.8%) elected to donate and were approved by the program, and 167/333 (50.2%) opted not to donate and/or were not approved by the program. There was substantial heterogeneity in the approval rates from program to program, ranging from 27.0% to 63.%; median and intra-quartile range (IQR) was 46.0% (37.3–51.1%).

The median (IQR) time between candidate registration and the decision to donate or not was 44 days (14–78 days). The time between evaluation and approval or non-approval for donation varied by program (Figure 2). Of the candidates approved for donation, 144/166 (86.7%) actually donated, according to OPTN data. All donations occurred at the participating program where the evaluations occurred. The median time between evaluation and actual donation, 62.5 days (43-85) for the 144 candidates who had donated as of March 12, 2020, was similar across programs (Figure 3).

3.2 Differences between candidates who were or were not accepted for donation

Half of donor candidates were biologically related to the intended recipient, a number that did not differ between those approved and not approved for donation (Table S1). More candidates approved for donation were women than men (Table 1). Age did not differ between those approved or not approved for donation (Table 1); mean \pm SD ages were, respectively, 39.2 ± 9.7 years and 40.0 ± 10.6 years (P=.414). Approved donors were most likely to be married or have a life partner (Table 1). Ninety percent of candidates were white, and the proportions approved or not approved for donation were similar (Table 1). Candidates were generally well-educated; only 13% had less than a high school education (Table 2). Education did not differ between those approved or not approved for donation. Approximately 95% had health insurance, and this number did not differ between those approved or not approved for donation; likewise, approximately 85% in both groups were working for an income (Table 2).



3.3 Reasons for not donating

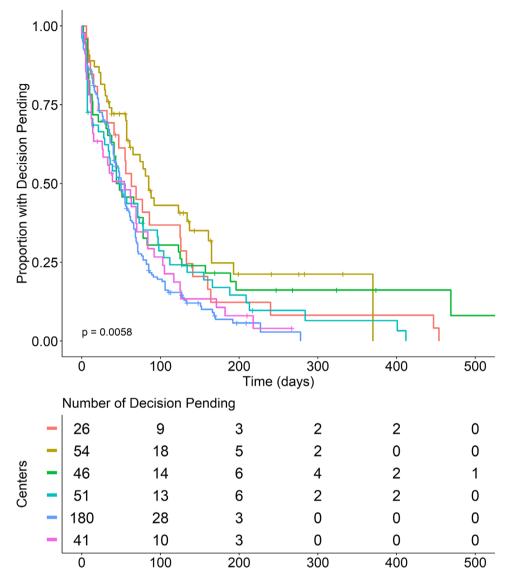
At the time of decision by the program or the candidate that 167 candidates would not donate, 149 (89.2%) had completed the evaluation, 12 (7.2%) lacked a few components of the evaluation, three (1.8%) lacked many components of the evaluation, and for three (1.8%), information regarding completeness of the evaluation was missing.

Among the 167 donor candidates not approved for donation, the reason was not available for 2/167 (1.2%). Of the 165 who indicated a reason or reasons, 131/165 (79.4%) indicated only one reason, 24/165 (14.5%) indicated two reasons, and 10/165 (6.1%) indicated more than two reasons (Table 5). Of the 131/165 (79.4%) with only one reason, reasons were medical risk, 17 (13.0%); psycho-social reasons, 19 (14.5%); candidate declined, 8 (6.1%), anatomical reasons that donation would have increased the risk to the recipient, 34 (26.0%); recipient-related reasons, 44 (33.6%); economic burden, two (1.5%); other reason, 7 (5.3%) (Table 5).

The numbers are too small to compare the six programs for each individual reason for not donating. However, we looked at differences between the six programs in seven categories of reasons for not donating. Results showed that there were significant differences between programs (Table 6).

4 | DISCUSSION

The primary purpose of this pilot program was to develop methods for establishing a comprehensive registry of living liver donor candidates. The purpose was not to answer specific research questions, but to conduct a pilot that would justify establishing a permanent national registry for living liver donors that would someday have adequate numbers of candidates, donors, and duration of follow-up to answer important questions about access and outcomes that can only be answered by a national, prospective registry. Thus, the data reported from this pilot effort are so far largely confirmatory of other previously published studies, and follow-up data are not yet available. We registered candidates for living liver donation at six programs, and collected data on their evaluation findings, whether they were approved for donation or not, and if not why not.



Note: Each curve on the figure represents a different center.

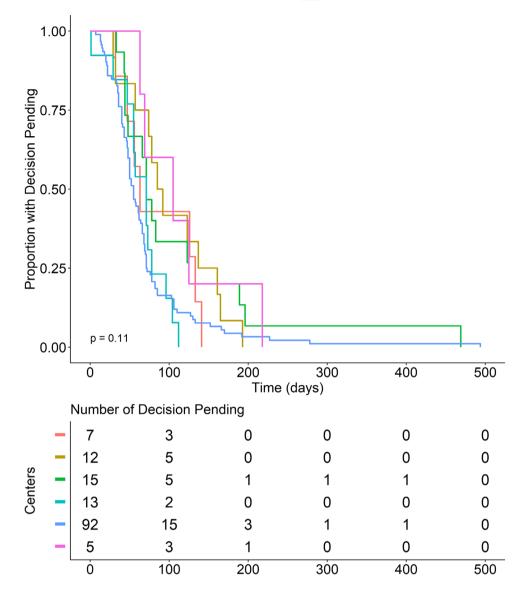
FIGURE 2 Time from registration of donor candidates to the time of the donation decision as of March 12, 2020. Each curve represents a different transplant program

Among the 166 candidates approved for liver donation in this pilot program, 90.4% were white, 2.4% were Black, none were Hispanic, 1.8% were Asian, and 4.8% multi-racial (Table 1). In comparison, among all 524 living liver donors in the United States in 2019, 80.5% were white, 3.4% were Black, 9.5% were Hispanic, and 2.9% were Asian. The ethnic categories chosen were mutually exclusive (e.g., whites were non-Hispanic whites). The incidence of end-stage liver disease is difficult to ascertain, but in 2019, 12 941 transplant candidates were added to the OPTN deceased donor waiting list, 69.1% white, 7.5% Black, 17.4% Hispanic, and 4.2% Asian. Thus, the ethnic makeup of donor candidates in the Living Donor Collective, approved or unapproved for donation, appeared to be similar to the ethnic makeup of all living liver donors in the United States. However, there were fewer Black and notably fewer Hispanic living donor candidates than transplant can-

didates with end-stage liver disease, as reflected by additions to the OPTN waiting list.

Among candidates for living liver donation, 53.5% were women, slightly fewer of whom were not approved for donation than were (Table 1). Among all living liver donors in the United States in 2019, 52.7% were women. However, among transplant candidates added to the OPTN deceased donor waiting list in 2019, only 38.3% were women. This remarkable disparity in the sex of donors and recipients warrants further attention, and the Living Donor Collective could provide a means to study reasons for these differences.

In the current pilot, 166 (49.8%) of 333 candidates who completed an evaluation were approved for donation, and 144 (86.7%) of those approved actually donated. Thus, of the candidates who completed an evaluation, 43.2% donated. These results are similar to results



Note: Each curve on the figure represents a different center.

FIGURE 3 Time from evaluation of donor candidates to the time of actual donation as of March 12, 2020, among the 144 candidates who donated. Each curve represents a different transplant program

reported by others. Across 13 studies evaluating 4137 donor candidates, 1430 (34.6%) were approved for donation (Table S5). However, study-to-study variability was high, and reported rates of approval were as low as 16.9% and as high as 60.4%. In the largest study, the retrospective Adult-to-Adult Living Donor Liver Transplantation Cohort Study (A2ALL), 405 (40%) of 1011 donor candidates were approved. Of these 405 approved donor candidates, 392 donated, 12 attempted surgeries were aborted, and in one the liver lobe was resected but not transplanted.

We found few differences between donor candidates approved and unapproved for donation. Demographics and indicators of socioeconomic status were similar in the two groups. Most clinical parameters were also similar. The only differences were that serum total bilirubin and alanine aminotransferase were more likely to be higher in candi-

dates who were not approved to be donors (Table 4). In the A2ALL study, characteristics associated with approval for donation included younger age, lower body mass index, and biological or spousal relationship to the recipient. Why these results differ from the current results is unclear, but times may have changed, with more liberal acceptance criteria being applied more recently.

Among studies reporting reasons that candidates were not approved for donation, the reasons were variable (Table S5). This is due, at least in part, to how the different studies defined reasons for not donating. Most studies acknowledged that for 20.0% of candidates, the reason for not donating was that the donation was no longer necessary because the intended recipient underwent deceased donor transplant or became too sick to undergo transplant. In our study, 33.6% did not donate because the donation was no longer needed, most commonly

TABLE 1 Demographic characteristics

		Donation decision made			
Characteristic	Candidates evaluated n = 398 (%)	Not approved n = 167 (%)	Approved n = 166 (%)	P, approved versument approved	
Sex, female (%)	213 (53.5)	83 (49.7)	95 (57.2)	.205	
Age (years)				.903	
18-34	138 (34.7)	55 (32.9)	54 (32.5)		
35-49	184 (46.2)	78 (46.7)	84 (50.6)		
50-64	74 (18.6)	33 (19.8)	27 (16.3)		
≥ 65	2 (.5)	1 (.6)	1 (.6)		
Marital status (categories collapsed)				.812	
Married, life partner	228 (57.3)	99 (59.3)	93 (56.0)		
Single, divorced, separated, widowed	158 (39.7)	64 (38.3)	68 (41.0)		
Unknown/missing	12 (3.0)	4 (2.4)	5 (3.0)		
Ethnicity				.696	
White	356 (89.4)	147 (88.0)	150 (90.4)		
Hispanic	0 (.0)	0 (.0)	0 (.0)		
American Indian	0 (.0)	0 (.0)	0 (.0)		
Pacific Islander	0 (.0)	0 (.0)	0 (.0)		
Black	9 (2.3)	4 (2.4)	4 (2.4)		
Asian	7 (1.8)	3 (1.8)	3 (1.8)		
Multi-race	25 (6.3)	13 (7.8)	8 (4.8)		
Unknown/missing	1 (.3)	0 (.0)	1 (.6)		
Citizenship				.715	
US citizen	364 (91.5)	148 (88.6)	153 (92.2)		
Non-US citizen/US resident	4 (1.0)	2 (1.2)	1 (.6)		
Non-US citizen/non-US resident, traveled to US for reason other than transplant	1 (.3)	1 (.6)	0 (.0)		
Non-US citizen/non-US resident, traveled to US for transplant	9 (2.3)	5 (3.0)	3 (1.8)		
Unknown/missing	20 (5.0)	11 (6.6)	9 (5.4)		

because the intended recipient underwent deceased donor transplant (Table 5). Since most of these candidates had completed the evaluation, they would be ideal controls for comparing long-term outcomes with outcomes of those who did donate. Similarly, those who did not donate because of normal anatomical reasons (e.g., liver volume too small for the intended recipient) could also be suitable controls.

It is noteworthy that there were differences between the six programs in the reasons indicated for not donating. In Table 6, we compared reasons for not donating between the different programs, using all reasons when there were multiple reasons, and comparing the numbers of reasons (N=212) not the numbers of candidates (N=165) not donating. Although the distribution in the reasons was significantly different between the programs, this result should be interpreted with caution. The numbers in this pilot are small and comparisons will be more valid when there are greater numbers of candidates and programs. In addition, there may have been artifactual differences in how coordinators at the different programs selected reasons for

not donating, rather than actual differences in the candidates and donors. This will be an important area to explore in the future, and could provide information that will allow programs to compare "best practices".

Several studies have examined donor outcomes more than a year after donation. $^{17-21}$ However, follow-up in these studies has been relatively short compared with the expected life time of healthy donors. Also problematic is the selection of controls to compare long-term outcomes with donors, given that donors are screened and selected to be healthy. The Living Donor Collective, thus, provides an opportunity to follow donors for a long term, using as controls candidates who were similarly healthy but did not donate.

In conclusion, the Living Donor Collective pilot has demonstrated the feasibility of collecting comprehensive information on candidates for living liver donation at six participating transplant programs. Interestingly, demographics, socioeconomic characteristics, and medical risk factors were similar in candidates approved and not approved for

TABLE 2 Socioeconomic characteristics

		Donation decision made			
Characteristic	Candidates evaluated $n = 398$ (%)	Not approved n = 167 (%)	• • • • • • • • • • • • • • • • • • • •		
Highest education level achieved (categories colla	psed)			.427	
High school or less	52 (13.1)	18 (10.8)	24 (14.5)		
Attended college or technical school	103 (25.9)	37 (22.2)	47 (28.3)		
Associate or bachelor degree	164 (41.2)	78 (46.7)	65 (39.2)		
Post-college graduate school	71 (17.8)	32 (19.2)	27 (16.3)		
Unknown/missing	8 (2.0)	2 (1.2)	3 (1.8)		
Health insurance coverage				.627	
Yes	376 (94.5)	159 (95.2)	155 (93.4)		
No	22 (5.5)	8 (4.8)	11 (6.6)		
Unknown/missing	0 (.0)	0 (.0)	0 (.0)		
Working for an income				.939	
Yes	338 (84.9)	142 (85.0)	143 (86.1)		
No	41 (10.3)	17 (10.2)	15 (9.0)		
Unknown/missing	19 (4.8)	8 (4.8)	8 (4.8)		

TABLE 3 Medical risk

		Donation decision m	nade	
Characteristic	Candidates evaluated $n = 398$ (%)	Not approved n = 167 (%)	Approved n = 166 (%)	P approved versus not approved
History of cigarette use				.376
Yes	99 (24.9)	38 (22.8)	46 (27.7)	
No	295 (74.1)	126 (75.4)	119 (71.7)	
Unknown/missing	4 (1.0)	3 (1.8)	1 (.6)	
Other tobacco use				.222
Yes	22 (5.5)	8 (4.8)	8 (4.8)	
No	373 (93.7)	156 (93.4)	158 (95.2)	
Unknown/missing	3 (.8)	3 (1.8)	0 (.0)	
Marijuana use				.025
Never	232 (58.3)	91 (54.5)	105 (63.3)	
Other	121 (30.4)	48 (28.7)	49 (29.5)	
Declined, unknown, missing	45 (11.3)	28 (16.8)	12 (7.2)	
History of cancer				.134
Yes	3 (.8)	3 (1.8)	0 (.0)	
No	394 (99.0)	163 (97.6)	166 (100.0)	
Unknown/missing	1 (.3)	1 (.6)	0 (.0)	

donation, the exception being higher total bilirubin or aspartate aminotransferase concentrations in some candidates not approved for donation. Reasons for not donating can also be determined to identify donor candidates who can be compared with donors in order to ascertain the long-term risks attributable to donation. The United States Health Resources and Services Administration has asked the Scientific Reg-

istry of Transplantation to expand the pilot program to include all living donor programs in the United States. The Living Donor Collective will ultimately provide information on access and long-term outcomes of living liver donation. This information will be useful to all living donor programs, as well as to potential living donors, their intended recipients and families.

 TABLE 4
 Risk for surgery and liver disease

Characteristic		Donation decision made			
	Candidates Evaluated n = 398 (%)	Not approved n = 167 (%)	Approved n = 166 (%)	P approved versus	
International normalized ratio (%)				.975	
≤ 1.1	368 (92.5)	153 (91.6)	153 (2.2)		
> 1.1	21 (5.3)	10 (6.0)	9 (5.4)		
Missing	9 (2.3)	4 (2.4)	4 (2.4)		
Platelet count (%)				.549	
150-450 mcl	391 (98.2)	163 (97.6)	164 (8.8)		
> 450 mcl	1 (.3)	1 (.6)	0 (.0)		
Missing	6 (1.5)	3 (1.8)	2 (1.2)		
Total bilirubin (%)				.046	
≤ 1.0 mg/dl	360 (90.5)	143 (85.6)	154 (3.4)		
> 1.0 mg/dl	36 (9.0)	22 (13.2)	11 (6.6)		
Missing	2 (.5)	2 (1.2)	0 (.0)		
SGOT/AST (%)				.014	
≤ 40 U/L	383 (96.2)	155 (92.8)	164 (98.8)		
> 40 U/L	13 (3.3)	11 (6.6)	1 (.6)		
Missing	2 (.5)	1 (.6)	1 (.6)		
SGPT/ALT (%)	2 (.5)	1 (.0)	1 (.0)	.114	
≤ 56 U/L	385 (96.7)	157 (94.0)	163 (98.2)	.11.	
155 56 U/L	7 (1.8)	6 (3.6)	1 (.6)		
Missing	6 (1.5)	4 (2.4)	2 (1.2)		
Serum albumin (%)	0 (1.5)	7 (2.7)	2 (1.2)	.202	
< 3.5 g/dl	4 (1.0)	3 (1.8)	1 (.6)	.202	
3.5-5.0 g/dl	373 (93.7)	159 (95.2)	155 (93.4)		
> 5.0 g/dl	19 (4.8)	4 (2.4)	10 (6.0)		
> 5.0 g/di Liver biopsy (%)	17 (4.0)	4 (2.4)	10 (6.0)	.208	
	2/5\	2 (4 2)	0 (0)	.206	
Yes	2 (.5)	2 (1.2)	0 (.0)		
No	370 (93.0)	156 (93.4)	152 (91.6)		
Missing	26 (6.5)	9 (5.4)	14 (8.4)	(04	
Hepatitis, jaundice, or abnormal liver test		0.40	4.60	.604	
Yes	1 (.3)	0 (.0)	1 (.6)		
No	391 (98.2)	164 (98.2)	162 (97.6)		
Unknown/missing	6 (1.5)	3 (1.8)	3 (1.8)	44-	
Alcohol, days per week (%)	0.47 (07.0)	444/07.00	445/055	.415	
0–2 days per week	347 (87.2)	144 (86.2)	145 (87.3)		
3–5 days per week	35 (8.8)	16 (9.6)	15 (9.0)		
6-7 days per week	13 (3.3)	7 (4.2)	4 (2.4)		
Declined/Missing	3 (.8)	0 (.0)	2 (1.2)		
Alcohol, drinks per week (%)				.032	
0-6 drinks	360 (90.5)	158 (94.6)	149 (89.8)		
7–11 drinks	5 (1.3)	4 (2.4)	1 (.6)		
More than 11 drinks	16 (4.0)	1 (.6)	8 (4.8)		
Declined/missing	17 (4.3)	4 (2.4)	8 (4.8)		

Abbreviations: AST, aspartate aminotransferase; ALT, alanine aminotransferase; SGOT, serum glutamic-oxaloacetic transaminase; SGPT, serum glutamic-pyruvic transaminase.

TABLE 5 Reasons for not donating^a

	The only reason n (%) ^b	One of two reasons n (%)°	One of ≥ 1 reason(s n (%) ^d
Medical risk too high	17 (13.0%)	14 (29.1%)	51 (24.1%)
Liver disease	3 (2.3%)	2 (4.2%)	10 (4.7%)
Obesity	5 (3.8%)	1 (2.1%)	9 (4.2%)
Donor liver steatosis on imaging or biopsy	3 (2.3%)	2 (4.2%)	7 (3.3%)
Diabetes	1 (.8%)	5 (10.4%)	6 (2.8%)
Recent/current malignancy	0 (.0%)	2 (4.2%)	5 (2.4%)
Concern for risk of diabetes	0 (.0%)	2 (4.2%)	4 (1.9%)
High cholesterol and/or high triglycerides	1 (.8%)	0 (.0%)	3 (1.4%)
Hypertension	0 (.0%)	0 (.0%)	2 (.9%)
Another living donor candidate was a better choice for medical reasons	2 (1.5%)	0 (.0%)	2 (.9%)
Age (too old)	0 (.0%)	0 (.0%)	1 (.5%)
Newly detected mass or malignancy	1 (.8%)	0 (.0%)	1 (.5%)
Risk of transmitting an infection to the intended recipient	1 (.8%)	0 (.0%)	1 (.5%)
Concern for future pregnancy and childbirth	0 (.0%)	0 (.0%)	0 (.0%)
Cardiovascular disease	0 (.0%)	0 (.0%)	0 (.0%)
Tobacco use	0 (.0%)	0 (.0%)	0 (.0%)
Hypercoagulable state	0 (.0%)	0 (.0%)	0 (.0%)
Psycho-social issues	19 (14.5%)	11 (22.8%)	38 (17.9%)
Another living donor candidate was a better choice for other reasons	8 (6.1%)	4 (8.3%)	14 (6.6%)
Donor conflicted or felt coerced	4 (3.1%)	2 (4.2%)	10 (4.7%)
Multiple psychosocial stressors	3 (2.3%)	1 (2.1%)	5 (2.4%)
Psychiatric illness	2 (1.5%)	1 (2.1%)	4 (1.9%)
Another living donor candidate was a better choice for psychosocial reasons	0 (.0%)	3 (6.3%)	3 (1.4%)
Substance use disorder	1 (.8%)	0 (.0%)	1 (.5%)
Limited psychosocial support	1 (.8%)	0 (.0%)	1 (.5%)
Age (too young)	0 (.0%)	0 (.0%)	0 (.0%)
Unable to provide informed consent due to cognitive impairment or a developmental disability	0 (.0%)	0 (.0%)	0 (.0%)
Candidate Declined	8 (6.1%)	3 (6.3%)	13 (6.1%)
Decided against donation for undisclosed reason(s)	5 (3.8%)	3 (6.3%)	9 (4.2%)
Candidate declined after deciding risk was too high	2 (1.5%)	0 (.0%)	3 (1.4%)
Missed appointments or became unavailable	1 (.8%)	0 (.0%)	1 (.5%)
Member(s) of family against the candidate donating	0 (.0%)	0 (.0%)	0 (.0%)
Anatomical reasons that donation increases risk to recipient	34 (26.0%)	15 (31.3%)	52 (24.5%)
Inadequate liver volumes on imaging	14 (10.7%)	4 (8.3%)	20 (9.4%)
Other unfavorable anatomical abnormalities on imaging	8 (6.1%)	7 (14.6%)	15 (7.1%)
Vascular or biliary anatomic abnormalities on imaging	9 (6.9%)	4 (8.3%)	13 (6.1%)
Other biopsy abnormalities	3 (2.3%)	0 (.0%)	4 (1.9%)
Recipient HLA antibodies to the donor candidate	0 (.0%)	0 (.0%)	0 (.0%)
Recipient reason	44 (33.6%)	4 (8.3%)	48 (22.6%)
Intended recipient underwent deceased donor transplant	29 (22.1%)	0 (.0%)	29 (13.7%)
Intended recipient became too ill for transplant	4 (3.1%)	1 (2.1%)	5 (2.4%)
Intended recipient died	4 (3.1%)	0 (.0%)	4 (1.9%)

(Continues)

TABLE 5 (Continued)

	The only reason n (%) ^b	One of two reasons n (%) ^c	One of ≥ 1 reason(s) n (%) ^d
Intended recipient did not use this candidate for other reasons	1 (.8%)	3 (6.3%)	4 (1.9%)
Intended recipient decided not to have this candidate donate	3 (2.3%)	0 (.0%)	3 (1.4%)
Intended recipient liver function improved	2 (1.5%)	0 (.0%)	2 (.9%)
Intended recipient decided not to undergo transplant	1 (.8%)	0 (.0%)	1 (.5%)
Incompatible blood group	0 (.0%)	0 (.0%)	0 (.0%)
Another living donor candidate was a better HLA match	0 (.0%)	0 (.0%)	0 (.0%)
Economic barriers	2 (1.5%)	0 (.0%)	2 (.9%)
Limitations on taking time off work	2 (1.5%)	0 (.0%)	2 (.9%)
Economic burden of donation	0 (.0%)	0 (.0%)	0 (.0%)
Lack of health insurance coverage	0 (.0%)	0 (.0%)	0 (.0%)
Other	7 (5.3%)	1 (2.1%)	8 (3.8%)

^aThere were 2/167 (1.2%) candidates who were not approved to donate but no reason was indicated. Of those not approved who indicated a reason for not donating, 131/165 (79.4%) indicated only one reason, 24/165 (14.5%) indicated two reasons, and 10/165 (6.1%) indicated more than two reasons.

TABLE 6 Comparison of programs' reasons for not donating^a

Reason	Programs N (%)						
	A	В	С	D	E	F	
Medical risk too high	1 (5%)	12 (34%)	12 (34%)	6 (15%)	12 (19%)	8 (40%)	
Psycho-social issues	0 (0%)	5 (14%)	3 (9%)	7 (18%)	19 (30%)	4 (20%)	
Candidate Declined	4 (20%)	3 (9%)	1 (3%)	3 (8%)	2 (3%)	0 (0%)	
Anatomical reasons that donation increases risk to recipient	9 (45%)	11 (31%)	9 (26%)	17 (44%)	2 (3%)	4 (20%)	
Recipient reason	5 (25%)	4 (11%)	10 (29%)	6 (15%)	21 (33%)	2 (10%)	
Economic barriers	1 (5%)	0 (0%)	0 (0%)	0 (0%)	1 (2%)	0 (0%)	
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	6 (10%)	2 (10%)	
Total (N $=$ 212 for all programs)	20 (100%)	35 (100%)	35 (100%)	39 (100%)	63 (100%)	20 (100%)	

^aShown are the numbers of each reason for not donating in each program, including all reasons shown in the fourth column of Table 5; Some candidates had multiple reasons each of which are included here.

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^bNumber and percent of each reason indicated for those indicating only one reason.

^cNumber and percent of each reason indicated for those indicating two reasons.

^dNumber and percent of each reason indicated for those indicating any number of reasons.

^bP = .0005 by Chi-square for overall differences between programs in the distribution of reasons for not donating. Percentages are column percentages.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest to disclose as described by *Clinical Transplantation*.

DATA AVAILABILITY STATEMENT

The Scientific Registry of Transplant Recipients and the 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.

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REFERENCES

- Marcos A, Fisher RA, Ham JM, et al. Selection and outcome of living donors for adult to adult right lobe transplantation. *Transplantation*. 2000;69(11):2410-2415.
- Pomfret EA. Live donor adult liver transplantation using right lobe grafts: donor evaluation and surgical outcome. Arch Surg. 2001;136(4):425-433.
- Kamel IR, Kruskal JB, Pomfret EA, et al. Impact of multidetector CT on donor selection and surgical planning before living adult right lobe liver transplantation. Am J Roentgenol. 2001;176(1):193-200.
- Pascher A. Donor evaluation, donor risks, donor outcome, and donor quality of life in adult-to-adult living donor liver transplantation. *Liver Transpl.* 2002;8(9):829-837.

- Valentín-Gamazo C, Malagó M, Karliova M, et al. Experience after the evaluation of 700 potential donors for living donor liver transplantation in a single center. *Liver Transpl.* 2004;10(9):1087-1096.
- Trotter JF, Wisniewski KA, Terrault NA, et al. Outcomes of donor evaluation in adult-to-adult living donor liver transplantation. *Hepatology*. 2007;46(5):1476-1484.
- Pacheco-Moreira LF, Enne M, Balbi E, et al. Selection of donors for living donor liver transplantation in a single center of a developing country: lessons learned from the first 100 cases. *Pediatr Transplant*. 2006;10(3):311-315.
- Tsang LL-C, Chen C-L, Huang T-L, et al. Preoperative imaging evaluation of potential living liver donors: reasons for exclusion from donation in adult living donor liver transplantation. *Transplant Proc.* 2008:40(8):2460-2462.
- Salama IA, Dessouky BA, Korayem EM, Aal SA. Impact of multislice spiral computed tomography on donor selection and surgical planning in living-related liver transplant. Exp Clin Transplant. 2010;8(2):111-124.
- Sharma A, Ashworth A, Behnke M, Cotterell A, Posner M, Fisher RA. Donor selection for adult-to-adult living donor liver transplantation: well begun is half done. *Transplantation*. 2013;95(3):501-506.
- Hahn LD, Emre SH, Israel GM. Radiographic features of potential donor livers that precluded donation. AJR Am J Roentgenol. 2014;202(4):W343-8.
- 12. Nugroho A, Kim O-K, Lee K-W, et al. Evaluation of donor workups and exclusions in a single-center experience of living donor liver transplantation. *Liver Transpl.* 2017;23(5):614-624.
- Weng L-C, Huang H-L, Lee W-C, et al. Psychological profiles of excluded living liver donor candidates: an observational study. *Medicine (Baltimore)*. 2018;97(52):e13898.
- Kasiske BL, Asrani SK, Dew MA, et al. The living donor collective: a Scientific Registry for living donors. Am J Transplant. 2017;17(12):3040-3048.
- 15. Leppke S, Leighton T, Zaun D, et al. Scientific Registry of Transplant Recipients: collecting, analyzing, and reporting data on transplantation in the United States. *Transplant Rev (Orlando)*. 2013;27(2):50-56.
- Levey AS, Stevens LA, Schmid CH, et al. A new equation to estimate glomerular filtration rate. Ann Intern Med. 2009;150(9):604-612.
- Adcock L, Macleod C, Dubay D, et al. Adult living liver donors have excellent long-term medical outcomes: the University of Toronto liver transplant experience. Am J Transplant. 2010;10(2):364-371.
- Muzaale AD, Dagher NN, Montgomery RA, et al. Estimates of early death, acute liver failure, and long-term mortality among live liver donors. Gastroenterology. 2012;142(2):273-280.
- Abecassis MM, Fisher RA, Olthoff KM, et al. Complications of living donor hepatic lobectomy-a comprehensive report. Am J Transplant. 2012;12(5):1208-1217.
- Butt Z, Dimartini AF, Liu Q, et al. Fatigue, pain, and other physical symptoms of living liver donors in the adult-to-adult living donor liver transplantation cohort study. *Liver Transpl.* 2018;24(9):1221-1232.
- Lin S-Y, Lin C-L, Hsu W-H, et al. Risk of biliary tract disease in living liver donors: a population-based cohort study. *PLoS One*. 2020;15(3):e0230840.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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